

DELCATH SYSTEMS INC  
Form 10-Q  
August 04, 2011

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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 June 30, 2011.

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-16133

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or  
organization)

06-1245881  
(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 ☒ No ☐

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

Yes ☐ No ☐

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

Large accelerated filer ☐

Accelerated filer ☒

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

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

As of August 1, 2011, 47,993,732 shares of the Company's common stock, \$0.01 par value were outstanding.

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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

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Consolidated Condensed Balance Sheets  
(Unaudited)

	June 30, 2011	December 31, 2010
Assets:		
Current assets		
Cash and cash equivalents	\$31,051,572	\$45,621,453
Investments – Certificates of deposit	-	1,492,000
Prepaid expenses and other assets	1,473,546	1,784,276
Total current assets	32,525,118	48,897,729
Property, plant and equipment		
Land	154,144	-
Furniture and fixtures	1,863,718	669,296
Computers and equipment	986,955	548,586
Leasehold improvements	1,031,277	939,518
	4,036,094	2,157,400
Less: accumulated depreciation	(933,632 )	(477,420 )
Property, plant and equipment, net	3,102,462	1,679,980
Total assets	\$35,627,580	\$50,577,709
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	\$770,844	\$610,457
Accrued expenses	3,237,184	2,581,853
Warrant liability	7,012,723	18,005,014
Total current liabilities	11,020,751	21,197,324
Deferred revenue	300,000	300,000
Commitments and contingencies	-	-
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, \$.01 par value; 70,000,000 shares authorized; 43,204,164 and 43,028,146 shares issued and 42,993,732 and 42,932,460 outstanding at June 30, 2011 and December 31, 2010, respectively	432,042	430,281
Additional paid-in capital	147,325,740	144,782,807
Deficit accumulated during the development stage	(123,362,650)	(116,055,400)
Treasury stock, at cost; 28,100 shares at June 30, 2011 and December 31, 2010	(51,103 )	(51,103 )
Accumulated other comprehensive loss	(37,200 )	(26,200 )
Total stockholders' equity	24,306,829	29,080,385
Total liabilities and stockholders' equity	\$35,627,580	\$50,577,709

See accompanying notes to consolidated condensed financial statements.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Consolidated Condensed Statements of Operations and Comprehensive Income  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Cumulative from Inception (Aug 5, 1988) to June 30, 2011
	2011	2010	2011	2010	2011
Costs and expenses:					
General and administrative expenses	\$5,238,072	\$3,702,123	\$9,404,086	\$6,248,295	\$49,269,168
Research and development costs	5,247,896	4,603,110	8,896,120	7,544,219	65,486,284
Total costs and expenses	10,485,968	8,305,233	18,300,206	13,792,514	114,755,452
Operating loss	(10,485,968)	(8,305,233)	(18,300,206)	(13,792,514)	(114,755,452)
Change in fair value of warrant liability, net	5,026,634	(634,694)	10,992,291	(8,053,023)	(9,706,311)
Interest income	106	2,610	665	3,875	2,871,944
Other income	-	-	-	-	(102,753)
Interest expense	-	-	-	-	(171,473)
Net loss	(5,459,228)	(7,667,929)	(7,307,250)	(21,841,662)	(121,864,045)
Other comprehensive income (loss)	(3,000)	(9,000)	(11,000)	(1,000)	(37,200)
Total comprehensive loss	\$(5,462,228)	\$(7,676,929)	\$(7,318,250)	\$(21,842,662)	\$(121,901,245)
Common share data:					
Basic and diluted loss per share	\$(0.13)	\$(0.21)	\$(0.17)	\$(0.60)	
Weighted average number of shares of common stock outstanding, basic and diluted	42,988,240	37,090,559	42,971,148	36,676,944	

See accompanying notes to consolidated condensed financial statements.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Consolidated Condensed Statements of Cash Flows  
(Unaudited)

	Six Months Ended June 30,		Cumulative from inception (Aug. 5, 1988) to June 30, 2011
	2011	2010	
Cash flows from operating activities:			
Net loss	\$ (7,307,250 )	\$ (21,841,662 )	\$ (121,864,045 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	2,208,347	1,542,685	12,986,606
Restricted stock and warrant compensation expense	253,180	1,020,198	3,809,127
Depreciation expense	456,212	175,056	988,246
Amortization of organization costs	-	-	42,165
Loss on disposal of furniture and fixtures	-	6,730	10,172
Warrant liability fair value adjustment	(10,992,291 )	8,053,023	9,706,311
Non-cash interest income	-	(3,051 )	(11,735 )
Changes in assets and liabilities:			
Decrease (increase) in prepaid expenses and other assets	299,730	(163,647 )	(1,460,715 )
Increase (decrease) in accounts payable and accrued expenses	815,718	(19,120 )	4,008,028
Deferred revenue	-	300,000	300,000
Net cash used in operating activities	(14,266,354 )	(10,891,548 )	(91,485,840 )
Cash flows from investing activities:			
Purchase of property, plant and equipment	(1,878,694 )	(964,276 )	(4,101,081 )
Proceeds from sale of equipment	-	-	200
Purchase of short-term investments	-	(3,235,000 )	(44,646,452 )
Purchase of marketable equity securities	-	-	(46,200 )
Proceeds from maturities of short-term investments	1,492,000	-	44,654,356
Organization costs	-	-	(42,165 )
Net cash used in investing activities	(386,694 )	(4,199,276 )	(4,181,342 )
Cash flows from financing activities:			
Net proceeds from sale of stock and exercise of stock options and warrants	83,167	3,458,627	125,564,428
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	83,167	3,458,627	126,718,754
(Decrease) increase in cash and cash equivalents	(14,569,881 )	(11,632,197 )	31,051,572
Cash and cash equivalents at beginning of period	45,621,453	35,486,319	-
Cash and cash equivalents at end of period	\$ 31,051,572	\$ 23,854,122	\$ 31,051,572
Supplemental cash flow information:			
Cash paid for interest	\$ -	\$ -	\$ 171,473



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Supplemental non-cash activities:

Cashless exercise of stock options and shares withheld upon restricted stock vesting	\$ 61,031	\$ 424,332	\$ 1,305,625
Fair value of warrants issued	\$ -	\$ -	\$ 6,459,979
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	\$ -	\$ 8,541,937	\$ 9,153,567

See accompanying notes to consolidated condensed financial statements.

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Notes to Consolidated 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 obtained authorization to affix a CE Mark for the Hepatic CHEMOSAT delivery system in April 2011. The Company has not yet received FDA approval for commercial sale of its system in the United States

Note 2: Consolidated Financial Statements

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

Note 3: Basis of Financial Statement Presentation

The accompanying consolidated 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 consolidated 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 June 30, 2011 and 2010, and cumulative from inception (August 5, 1988) to June 30, 2011.

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

Research and Development Costs

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

General and Administrative Costs

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

Investments

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

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## Deferred Revenue Recognition

Deferred revenue on the accompanying balance sheets includes payment received upon execution of a research and distribution agreement with Chi-Fu Trading Co, Ltd. This agreement is discussed further in Note 7 to the Company's unaudited interim condensed financial statements contained in this Quarterly Report on Form 10-Q.

## Note 4: Recent Accounting Pronouncements

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

## Note 5: 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 six month period ended June 30, 2011 is as follows:

		The Plans		
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2010	3,760,650	\$ 1.23 – \$15.54	\$ 4.88	6.65
Granted	490,706	5.09 – 9.18	6.49	
Forfeited	(12,900 )	7.15 – 7.58	7.26	
Exercised	(45,327 )	2.44 – 3.28	3.18	
Outstanding at June 30, 2011	4,193,129	\$ 1.23 – \$15.54	\$ 5.08	6.62



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For the three and six months ended June 30, 2011, the Company recognized stock option compensation expense of \$716,047 and \$1,807,185 respectively, relating to options granted in previous years and \$305,007 and \$401,162 respectively, relating to options granted during 2011, for a total of \$1,021,054 and \$2,208,347, respectively.

For the three and six months ended June 30, 2010, the Company recognized stock option compensation expense of \$909,550 and \$1,542,685 respectively.

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

The Company accounts for stock-based compensation expense for non-employees using the fair-value method which requires the award to be re-measured at each reporting date until the award is vested. The Company estimates the fair value using an option pricing model. The Company has expensed its share-based compensation for non-employees under the ratable method.

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

	Six Months Ended June 30,	
	2011	2010
Dividend yield	None	None
Expected volatility	73.90% – 79.11%	72.16% – 75.04%
Weighted average volatility	74.40%	73.04%
Risk-free interest rates	1.9% – 2.54%	2.16% – 3.11%
Expected life (in years)	5.0 – 6.0	5.5 – 6.0

For the three and six months ended June 30, 2011, the Company recognized compensation expense of \$35,813 and \$113,170 respectively, relating to restricted stock granted in previous years. For the three and six months ended June 30, 2011, the Company recognized \$112,807 and \$140,010 respectively, relating to restricted stock granted during 2011, for a total of \$148,620 and \$253,180, respectively.

For the three and six months ended June 30, 2010, the Company recognized restricted stock compensation expense of \$679,016 and \$1,020,498, respectively.

#### Note 6: Assets and Liabilities Measured at Fair Value

##### Derivative warrant liability

The Company allocated part of the proceeds of a private placement and a public offering of the Company's common stock to warrants issued in connection with such transactions. The Company determined that these warrants should be classified as liabilities rather than equity. The valuation of the warrants is determined using an option pricing model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the model against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in FASB ASC 820-10-35. There are six inputs: the closing price of the Company's common stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath's stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of the

warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on 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.

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In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the “2007 Warrants” and together with the 2009 Warrants, the “Warrants”) in a private placement to institutional and accredited investors. The Company received net proceeds of \$13.3 million in this transaction. The Company allocated \$4.3 million of the total proceeds to 2007 Warrants (see below). The 2007 Warrants were initially exercisable at \$4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company’s June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at \$3.44 per share with 1,469,456 warrants outstanding at June 30, 2011. The shares were issued pursuant to an effective registration statement on Form S-3.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the “2009 Warrants”) pursuant to a subscription agreement with a single investor. The Company received gross proceeds of \$3.0 million, with net cash proceeds after related expenses from this transaction of approximately \$2.67 million. Of those proceeds, the Company allocated an estimated fair value of \$2.2 million to the 2009 Warrants (see below), resulting in net proceeds of \$476,255. The 2009 Warrants are currently exercisable at \$3.60 per share with 1,043,478 warrants outstanding at June 30, 2011 and have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

The \$2.2 million in proceeds allocated to the 2009 Warrants and the \$4.3 million in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the six month period ended June 30, 2011, the Company recorded pre-tax derivative instrument income of \$11.0 million. The resulting derivative instrument liabilities totaled \$7.0 million at June 30, 2011. The fair value of the Warrants at June 30, 2011 was determined by using the Black-Scholes model assuming a risk free interest rate of 0.80% for the 2009 Warrants and 0.25% for the 2007 Warrants, volatility of 81.46% for the 2009 Warrants and 84.27% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

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

Money Market Funds

Cash and cash equivalents includes a money market account valued at \$31.0 million.



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The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of June 30, 2011, aggregated by the level in the fair value hierarchy within which those measurements fall:

## Assets and Liabilities Measured at Fair Value on a Recurring Basis at June 30, 2011

	Level 1	Level 2	Level 3	Balance at June 30, 2011
<b>Assets</b>				
Marketable equity securities	\$9,000	\$-	\$-	\$9,000
Money market funds	30,985,111	-	-	30,985,111
<b>Total Assets</b>	<b>\$30,994,111</b>	<b>\$-</b>	<b>\$-</b>	<b>\$30,994,111</b>
<b>Liabilities</b>				
Warrant liability	\$-	\$-	\$7,012,723	\$7,012,723
<b>Total Liabilities</b>	<b>\$-</b>	<b>\$-</b>	<b>\$7,012,723</b>	<b>\$7,012,723</b>

## Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant Liability
Beginning balance	\$ 18,005,014
Total decrease in the liability included in earnings	(10,992,291)
Ending balance	\$ 7,012,723

## Note 7: Research and Distribution Agreement

On February 9, 2010, the Company entered into an initial five (5) year 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, including satisfying minimum purchase commitments.

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, of which \$300,000 was paid upon execution of the Research and Distribution Agreement. The timing of the remaining payments will be subject to a modification currently being discussed. The modified timing reflects the Company's decision to focus its resources on melphalan in its initial clinical studies of primary liver cancer instead of doxorubicin as was envisioned by the parties in the original agreement.

## Note 8: 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 June 30, 2011 and 2010 upon exercise or conversion that were not included in the computation of net loss per share

totaled 6,706,063 and 6,189,913 shares, respectively.

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Note 9: Taxes

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

The Company is subject to U.S. federal income tax as well as income tax of certain state jurisdictions. The Company has not been audited by the United States Internal Revenue Service (the "IRS") or any states in connection with income taxes. The periods from December 31, 2004 to December 31, 2010 remain open to examination by the IRS and state authorities. Also note that for federal and state purposes, the tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

For the six months ended June 30, 2011, the Company recorded a state capital tax benefit of \$125,000. This benefit is a result of State of New York legislation, which allows companies to obtain cash refunds from the State of New York at a rate of 100% of their annual research and development expense credits, limited to \$250,000 per year. Since this is not an income tax benefit, it is reflected as a component of general and administrative expenses.

Note 10: Subsequent Events

On July 20, 2011, the Company completed the sale of 5,000,000 shares of its common stock pursuant to an underwriting agreement with Jeffries & Co., Inc. The Company received net cash proceeds after related expenses from this transaction of approximately \$23.5 million. The shares were issued pursuant to an effective registration statement on Form S-3 (333-165677).

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

2.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited interim consolidated condensed financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto as of and for the year ended December 31, 2010 included in our Annual Report on Form 10-K for the year ended December 31, 2010 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 chemosaturation system; and
- our ability to successfully negotiate and enter into agreements with strategic and corporate partners.

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

#### Overview

The following section should be read in conjunction with Part I, Item 1: Consolidated 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.

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

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

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### European Economic Area

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

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

### United States

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

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

Based on the Phase III results, we submitted our Section 505(b)(2) NDA, to the FDA in December 2010, seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. In February 2011, we received a Refusal to File RTF letter, or RTF, from the FDA for the NDA. The FDA will issue an RTF if it determines upon an initial review that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a

determination of the ultimate approvability of the drug product at issue. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. At this time, the FDA has not requested additional studies to be conducted. We have had subsequent communications with the FDA, including a meeting in early April 2011 to discuss the issues raised and to confirm our understanding of the additional information required by the FDA in order to permit a substantive review of the application upon resubmission, which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA. Based on management's current understanding of the issues raised in the RTF and our subsequent communications with the FDA, we currently intend to resubmit an NDA by December 31, 2011.

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Since our inception we have raised approximately \$148.6 million (net of fundraising expenses), which includes approximately \$23.5 million raised in our July 2011 offering. 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. Although we expect that the amount of capital required for operations including preparation of the Company's submission to the FDA, operations at the manufacturing facility in upstate New York, and efforts to commercialize the Delcath chemosaturation system in Europe will continue to increase over the coming months, we believe that we have sufficient capital for operations through 2011.

## Regulatory Environment

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

## EEA and Other International Regulation

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

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

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



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

A manufacturer without a registered place of business in a Member State of the European Union which places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer's behalf with regard to the manufacturer's obligations under the EU Medical Devices Directive. We have appointed such a representative, although we are in the process of establishing our infrastructure in the EEA and expect that we will not need a third party representative in the future.

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

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

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



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

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

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

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

## United States Regulation

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

- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;

a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review; satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

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

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

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

**Phase I Clinical Trials.** Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.

**Phase II Clinical Trials.** Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials.

**Phase III Clinical Trials.** These are commonly referred to as pivotal studies. When Phase II evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.

**Phase IV Clinical Trials.** The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase IV clinical trials.

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

**New Drug Applications.** The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which is may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from

submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. The FDA may deny approval of an NDA by issuing a Complete Response Letter if the applicable regulatory criteria are not satisfied. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

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In December 2010, we submitted our NDA for the Delcath chemosaturation system under Section 505(b)(2) of the FDCA seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA's findings of safety and effectiveness for previously approved products, such as melphalan. Melphalan, the drug we are initially seeking to have approved for use with the Delcath chemosaturation system, is a widely used chemotherapy agent that has already been approved by the FDA for use at a lower dose than we used in our Phase III clinical trial. The approved labeling for melphalan includes indications for use, method of action, dosing, side effects and contraindications. Because the Delcath chemosaturation system delivers the drug through a different mode of administration and at a dose strength that is substantially higher than that which is currently approved, we will be seeking a revised label of melphalan for use with the Delcath chemosaturation system through its Section 505(b)(2) NDA. The clinical trials were designed to provide the necessary clinical data to support this required labeling change.

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

Upon resubmission of our application, the FDA will again perform an initial review to assess whether the NDA is sufficiently complete to warrant a substantive review. If the FDA agrees to formally file the application, it will issue a Prescription Drug User Fee Act, or PDUFA, action date. If the drug is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrates the potential to address unmet medical needs for the condition, the sponsor may be subject to a Fast Track designation. The Fast Track program is a process designed to facilitate the development and expedite the review of drugs to treat serious diseases and fill an unmet medical need. Under the program, the sponsor of a new drug may request that the FDA designate the drug for a specific indication as a fast track product concurrent with or after the IND is filed for the product candidate, and the FDA must determine if the product qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. The Delcath chemosaturation system has received a Fast Track designation. A drug that receives Fast Track designation may be eligible for more frequent meetings with FDA to discuss the drug's development; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials; eligibility for accelerated approval, i.e., approval of an effect on a surrogate, or substitute endpoint; and rolling review, meaning the sponsor may submit its NDA in sections rather than wait until the entire NDA is complete, among others. Most drugs with Fast Track designation are likely to be considered appropriate to receive a Priority Review. In 1992, under PDUFA, the FDA created a two-tiered system of review times – Standard Review and Priority Review. Standard

Review is applied to a drug that offers at most, only minor improvement over existing marketed therapies with a goal of completing the FDA review of the NDA within a ten-month time frame. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes FDA to review a new drug application is reduced. The goal for completing a Priority Review is six months. We intend to request a Priority Review in our resubmitted NDA to the FDA. We cannot guarantee that our application for approval of the Delcath chemosaturation system will receive a Priority Review, or that if Priority Review is received, that the review or approval will be faster than conventional FDA procedures or that FDA will ultimately grant approval.



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

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

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

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

## Results of Operations

### Three Months Ended June 30, 2011 and June 30, 2010

Delcath has operated at a loss for our entire history. The Company had a net loss for the three months ended June 30, 2011, of \$5.5 million, which is a \$2.2 million decrease in the net loss for the same period in 2010. The decrease in net loss is due to a \$4.4 million change in the fair value of the warrant liability, which was offset by an increase of \$2.2 million in operating costs.

The Company's operating loss for the three months ended June 30, 2011 was \$10.5 million, of which approximately \$1.2 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 Financial Statement Footnote 4 of this filing. This compares to an operating loss for the three months ended June 30, 2010 of \$8.3 million, of which approximately \$1.6 million was non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans.

At the end of the second quarter of 2011 the Company had 51 full-time employees compared to 32 at the end of the second quarter of 2010. 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. Additionally, the Company's continued expansion of research and development activities as well as preparations for commercialization in Europe and regulatory expenses related to our submission to the FDA has contributed to the rise in our total costs and expenses. We anticipate continued increases in our total costs and expenses throughout 2011.

General and administrative expenses increased to \$5.2 million for the three months ended June 30, 2011, from \$3.7 million for the three months ended June 30, 2010. The Company is continuing its progress in transitioning from a development stage company to a commercial enterprise with staff dedicated to commercializing the Delcath chemosaturation system. The increase in the Company's general and administrative expenses is commensurate with our increase in staffing, as well as our European commercialization efforts.

Research and development expenses increased to \$5.2 million for the three months ended June 30, 2011, from \$4.6 million during the three months ended June 30, 2010. During the second quarter of 2010, the Company was incurring expenses related to completing its Phase III clinical trial. The reduction in trial related expenses during the second quarter of 2011 was more than offset by an increase in expenses related to expanded research and development

activities and regulatory expenses related to our submission to the FDA.

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Interest income is from our money market account and certificates of deposit. During the three months ended June 30, 2011, the Company had interest income of \$106, as compared to \$2,610 for the same period in 2010. For the three months ended June 30, 2010, the Company earned interest from certificates of deposit. Those certificates of deposit matured throughout 2010 and the first quarter of 2011, yielding lower interest income for the three months ended June 30, 2011.

### Six Months Ended June 30, 2011 and June 30, 2010

The Company had a net loss for the six months ended June 30, 2011, of \$7.3 million, which is a \$14.5 million decrease in the net loss for the same period in 2010. The decrease in net loss is primarily due to a \$19 million change in the fair value of the warrant liability, which was offset by an increase of approximately \$4.5 million in total costs.

Our operating loss for the six months ended June 30, 2011 was \$18.3 million, of which approximately \$2.5 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 six months ended June 30, 2010 of \$13.8 million, of which approximately \$2.6 million was non-cash expense related to stock option and restricted stock grants made under our 2004 and 2009 Stock Option Plans.

General and administrative expenses increased to \$9.4 million for the six months ended June 30, 2011 from \$6.2 million for the six months ended June 30, 2010. The Company is continuing its progress in transitioning from a development stage company to a commercial enterprise with staff dedicated to commercializing the Delcath chemosaturation system. The increase in the Company's general and administrative expenses is commensurate with our increase in staffing, as well as our European commercialization efforts.

Research and development expenses increased to \$8.9 million for the six months ended June 30, 2011, from \$7.5 million during the first six months of 2010. Our continued hiring has also contributed to an increase in research and development expenses. During the second quarter of 2010, the Company was incurring expenses related to wrapping up its Phase III clinical trial. The reduction in trial related expenses during the second quarter of 2011 was more than offset by an increase in expenses related to expanded research and development activities and regulatory expenses related to our submission to the FDA.

Interest income is from our money market account and certificates of deposit. During the six months ended June 30, 2011, the Company had interest income of \$665, as compared to \$3,875 for the same period in 2010. For the six months ended June 30, 2010, the Company earned interest from certificates of deposit. Those certificates of deposit matured throughout 2010 and the first quarter of 2011, yielding lower interest income for the six months ended June 30, 2011.

### Liquidity and Capital Resources

Our future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and anticipates that losses will continue over the coming 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. The Company continues to move forward aggressively. As Delcath commences commercial sales and marketing activity in Europe and seeks FDA approval of the Delcath chemosaturation system in the U.S. we expect that both our expenses and capital expenditures will increase.

At June 30, 2011, we had cash and cash equivalents of \$31.1 million, as compared to \$23.9 million at June 30, 2010. During the six months ended June 30, 2011, we used \$14.3 million of cash in our operating activities, which compares to \$10.9 million used in our operating activities during the comparable six month period in 2010. The increase of \$3.5 million, or 31.6%, is primarily due to our preparations to commercialize the Delcath chemosaturation system, as well as an increase in compensation related expenses as the Company grew from 32 employees at June 30, 2010 to 51 employees at June 30, 2011. The Company expects that our cash allocated to operating activities will continue to increase as we aggressively move forward with our commercialization plans for Europe and incur regulatory expenses related to our submission to the FDA. The Company believes it has sufficient capital to fund our operating activities through 2011.

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At June 30, 2011, the Company's accumulated deficit was approximately \$123.4 million. Because our business does not generate positive cash flow from operating activities, the Company may need to raise additional capital in order to fully commercialize our product or to fund development efforts relating to additional indications. Delcath believes that we will be able to raise additional capital in the event that we find it in our best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from our actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of our clinical trials and costs related to commercializing our product.

In March 2010, the Company filed a registration statement on Form S-3 with the SEC, which allows the Company to offer and sell, from time to time in one or more offerings up to \$100,000,000 of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The registration statement became effective on April 13, 2010 (333-165677). The Company used this registration statement for its August 2010 public offering detailed in Note 3 to the Company's audited financial statements contained in the 2010 Annual Report on Form 10-K. In July 2011, the Company completed the sale of 5,000,000 shares of its common stock pursuant to an underwriting agreement with Jefferies & Company, Inc., raising approximately \$23.5 million after expenses. Because the maximum aggregate offering price of all securities registered is \$100,000,000, the Company's issuance of any securities will reduce the amount of other securities that it can issue pursuant to the registration statement on Form S-3.

The Company has funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000, 2003, 2009, 2010, and 2011 along with our registered direct offerings in 2007 and 2009. As of July 31, 2011, Delcath had approximately \$41,250,000 aggregate amount of common stock, preferred stock, stock purchase contracts, warrants and debt securities (or a combination of these securities) available to be issued under our effective registration statement on Form S-3. The Company intends to use the net proceeds from any future offerings for general corporate purposes, including, but not limited to, obtaining regulatory approvals, commercialization of our products, funding of our clinical trials, capital expenditures and working capital. For a detailed discussion of our various sales of securities see Note 3 to the Company's audited financial statements contained in the 2010 Annual Report on Form 10-K.

### Critical Accounting Estimates

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

Additionally, the Company devotes substantial resources to obtaining regulatory approvals for the Delcath chemosaturation system as well as its research and development activities, the cost of which is required to be charged to expense as incurred. This further limits our choice of accounting policies and methods. Similarly, management believes there are very limited circumstances in which the Company's financial statement estimates are significant or critical.

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

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

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

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

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

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

### Item 3. Quantitative and Qualitative Disclosure about Market Risk

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

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



In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the “2009 Warrants”) in a subscription agreement with a single investor. The Company received gross proceeds of \$3.0 million, with net cash proceeds after related expenses from this transaction of approximately \$2.67 million. Of those proceeds, the Company allocated an estimated fair value of \$2.2 million to the 2009 Warrants, resulting in net proceeds of \$467,559. The 2009 Warrants are currently exercisable at \$3.60 per share with 1,043,478 shares outstanding at June 30, 2011 and have a five-year term.

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In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the “2007 Warrants”) in a private placement to institutional and accredited investors. The Company received net proceeds of \$13.3 million in this transaction. The Company allocated \$4.3 million of the total proceeds to the 2007 Warrants. The 2007 Warrants were initially exercisable at \$4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company’s June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at \$3.44 per share with 1,469,456 warrants outstanding at June 30, 2011.

The \$2.2 million in proceeds allocated to the 2009 Warrants and the \$4.3 million in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the 2007 Warrants and the 2009 Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the six month period ended June 30, 2011, the Company recorded the change in fair value of the warrant liability as pre-tax derivative instrument income of \$11.0 million. The resulting derivative instrument liabilities totaled \$7.0 million at June 30, 2011. The fair value of the Warrants at June 30, 2011 was determined by using an option pricing model assuming a risk free interest rate of 0.80% for the 2009 Warrants and 0.25% for the 2007 Warrants, volatility of 81.46% for the 2009 Warrants and 84.27% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

ItemControls and Procedures

4.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of June 30, 2011 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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PART II:  
OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

You should carefully consider the risks described below together with the other information in the Quarterly Report on Form 10-Q and our Annual Report on Form 10-K. Our business, financial condition, liquidity and results of operations could be adversely affected by any of these risks. If any of these risks occur, the value of our common stock could decline.

Risks Related to Our Business and Financial Condition

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

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

Continuing losses may exhaust our capital resources.

As of June 30, 2011, we had \$31.1 million in cash, cash equivalents and certificates of deposit. We have had no revenue to date, a substantial accumulated deficit, recurring operating losses and negative cash flow. We expect to continue to incur losses while generating minimal revenues over the next year. From our inception on August 5, 1988 through June 30, 2011, we have incurred cumulative net losses of approximately \$121.9 million. For the six months ended June 30, 2011 and years ended December 31, 2010, 2009 and 2008, we incurred net losses of approximately \$7.3 million, \$46.7 million, \$22.1 million and \$6.9 million, respectively, with these amounts being effected by derivative accounting related to warrants as described in our Annual Reports on Form 10-K for the years ended December 31, 2010, 2009 and 2008. To date, we have funded our operations through a combination of private placements and public offerings of our securities. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to complete our clinical trials, product development, regulatory approval process and commercialization of the Delcath chemosaturation system with melphalan or any other versions of the system.

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

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

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

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

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

## Risks Related to FDA and Foreign Regulatory Approval

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

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

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

We are not permitted to market the Delcath chemosaturation system in the United States unless and until we obtain regulatory approval from the FDA. To market the product in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing and controls, or CMC, to demonstrate the safety and effectiveness of the applicable product candidate. Regulatory approval of an NDA is not guaranteed. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target and the regulations applicable to any particular product

candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

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

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

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

adversely affect the commercialization of the current Delcath chemosaturation system or any products that we develop in the future;

impose additional costs on us;  
diminish any competitive advantages that may be attained; and  
adversely affect our ability to generate revenues.

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

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

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







in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or other chemotherapeutic agent used in our system. We are seeking approval of the Delcath chemosaturation system for a substantially higher dose of melphalan than prior approved doses of melphalan and such other drugs. We must obtain separate regulatory approvals for the Delcath chemosaturation system with melphalan and every other chemotherapeutic agent or other compound used with our system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA's satisfaction the product's safety, efficacy, potency and purity for each intended use. The pre-clinical testing and clinical trials of the Delcath chemosaturation system with melphalan or any other chemotherapeutic agent or compound we use in our system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete our clinical trials. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for our system and our use of melphalan or other chemotherapeutic agents, the value of our company and our results of operations will be harmed.

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

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

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

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



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

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

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

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

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

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

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

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



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

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

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

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

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

We have obtained the right to affix the CE Mark for the Delcath chemosaturation system, and we intend to seek third-party or government reimbursement within those countries in the EEA where we expect to market and sell the Delcath chemosaturation system. Until we obtain government reimbursement, we will rely on private payors or local pre-approved funds where available. New technology payment programs may provide interim funding, but there are no assurances that we will qualify for such funding. Even if we do qualify, the amount and the duration of this funding

may be limited. There are also no assurances that third-party payors or government health agencies of members states of the EEA will reimburse the product's use in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in other EEA countries. Physicians, hospitals and other health care providers may be reluctant to purchase the Delcath chemosaturation system if they do not receive substantial reimbursement for the cost of using our product from third-party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in the EEA.

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

We do not have written contracts with all our suppliers for the manufacture of components for the Delcath chemosaturation system. If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms, we may not be able to manufacture the system in commercial quantities or in a cost-effective

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

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

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

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

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

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

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

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

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

Our collaborative relationships may never result in the successful development or commercialization of the Delcath chemosaturation system or any other product. The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our products, including research and development, market identification, marketing methods, pricing, composition of sales force and promotional activities. We are not able to control or influence the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization, marketing or distribution of our products. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with the Delcath chemosaturation system or the withdrawal of their support for our products. The failure of any such collaboration could have a material adverse effect on our business.

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

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

- difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;

  - the failure to fulfill foreign regulatory requirements to market our products on a timely basis or at all;

  - availability of, and changes in, reimbursement within prevailing foreign healthcare payment systems;

- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign sales or marketing employees and agents;

  - limited protection for intellectual property rights in some countries;

  - fluctuations in currency exchange rates;

- the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;

  - the possibility of any material shipping delays;

  - significant changes in the political, regulatory, safety or economic conditions in a country or region;

  - protectionist laws and business practices that favor local competitors; and

- trade restrictions, including the imposition of, or significant changes to, the level of tariffs, customs duties and export quotas.

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

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

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

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

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

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

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

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

The loss of key personnel could adversely affect our business.

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

## Risks Related to Patents, Trade Secrets and Proprietary Rights

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

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

will expire beginning in 2012 through 2016.

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

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

- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor's patent;

- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and

- we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

If others file patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could also be costly and could divert our attention from our business. If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources. Use of our limited funds to enforce or to defend our intellectual property rights or to defend against legal proceedings alleging infringement of third party proprietary rights may also affect our financial condition adversely. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before the Delcath chemosaturation system or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our U.S. patent rights have corresponding patent rights effective in Europe or other foreign jurisdictions. Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

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

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



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

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

### Risks Related to Products Liability

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

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

### Risks Related to Our Common Stock

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

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

- results of our clinical trials;
- regulatory delays, non-acceptance or non-approval of our product;
- manufacturing difficulties;
- unexpected adverse events caused by the Delcath chemosaturation system;
- product recalls;
- actual or anticipated quarterly variations in our operating results;
- changes in expectations as to our future financial performance or changes in financial estimates, if any, of public market analysts;
- announcements relating to our business or the business of our competitors;

a challenge to one of our patents, either in court or via administrative proceedings in the United States Patent and Trademark Office;

conditions generally affecting the healthcare and cancer treatment industries;

the success of our operating strategy;

our ability to repay our debt;

future sales of equity or equity-related securities; and

general financial, economic, domestic, international and other market conditions.

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

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Our insiders beneficially own a significant portion of our stock.

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

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

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

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

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

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

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

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

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

Our common stock is listed on The NASDAQ Capital Market.

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

We are also required to maintain certain corporate governance requirements. In the event that in the future we are notified that we no longer comply with NASDAQ’s corporate governance requirements, and we fail to regain

compliance within the applicable cure period, our common stock could be delisted from The NASDAQ Capital Market.

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

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

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

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

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

We are not restricted from issuing additional shares of our common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. As of June 30, 2011, we had an aggregate of 26,795,836 shares of common stock authorized but unissued. Subject to certain volume limitations imposed by The NASDAQ Capital Market, we may issue all of these shares without any action or approval by our shareholders. We may expand our business through complementary or strategic acquisitions of other companies and assets, and we may issue shares of common stock in connection with those acquisitions or otherwise. The market price of our common stock could decline as a result of our issuance of a large number of shares of common stock, particularly if the per share consideration we receive for the stock we issue is less than the per share book value of our common stock or if we are not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share we are generating before we issue the additional shares. In addition, any shares issued in connection with these activities, the exercise of stock options or otherwise would dilute the percentage ownership held by our investors. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our common stock.

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.



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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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Extension Calculation Linkbase Document
101.LAB	XBRL Extension Label Linkbase Document
101.PRE	XBRL Extension Presentation Linkbase Document
**	Filed herewith.
***	Furnished herewith.

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SIGNATURES

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

August 4, 2011

DELCATH SYSTEMS, INC.  
(Registrant)

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



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**	Filed herewith.
***	Furnished herewith.