DELCATH SYSTEMS INC
Form 10-Q
August 04, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

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

For the quarterly period ended June 30, 2011.

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

For the transition period from _____ to _____

Commission File Number: 001-16133

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes o No o

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

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

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

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

DELCATH SYSTEMS, INC.
(A Development Stage Company)

DELCATH SYSTEMS, INC.

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DELCATH SYSTEMS, INC.
(A Development Stage Company)

PART I:
FINANCIAL INFORMATION

Item 1. Consolidated Condensed Financial Statements (Unaudited)

Index to Financial Statements

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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	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	2010	2011
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

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
Assets				
Marketable equity securities	$9,000	$-	$-	$9,000
Money market funds	30,985,111	-	-	30,985,111
Total Assets	$30,994,111	$-	$-	$30,994,111
Liabilities				
Warrant liability	$-	$-	$7,012,723	$7,012,723
Total Liabilities	$-	$-	$7,012,723	$7,012,723

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited interim 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 termi often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (the "Exchange Act"). These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in the Company's Annual Report on Form 10-K in Item 1A under "Risk Factors" as well as in this report under "risk Factors" in Part II, Item 1A and Part I, Item 3 "Qualitative and Quantitative Disclosures About Market Risk". These forward-looking statements include, but are not limited to, statements about:

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

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

Overview

The following section should be read in conjunction with Part I, Item 1: 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 flirtation 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 FFDCA 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 milllion 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 certificaties 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 FFDCA, 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.

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While we have obtained the right to affix the CE Mark, we will be subject to significant ongoing regulatory obligations and oversight in the EEA and in any other country where we receive marketing authorization or approval.
In April 2011, we obtained the required certification from our European Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Devices Directive and affix the CE Mark to the Delcath chemosaturation system. In order to maintain the right to affix the CE Mark in the EEA, we are subject to compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we will be subject to ongoing audits by our European Notified Body, and the right to affix the CE Mark to the Delcath chemosaturation system may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product.

To the extent that the Delcath chemosaturation system is approved by the FDA or any other regulatory agency, we will be subject to similar ongoing regulatory obligations and oversight in those countries where we obtain approval. For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices, or GCPs, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any clinical trials that we conduct post-approval. In addition, post-marketing requirements for the Delcath chemosaturation system may include implementation of a REMS to ensure that the benefits of the product outweigh its risks. A REMS may include a Medication Guide, a patient package insert, a communication plan to healthcare professionals and/or other elements to assure safe use of the product.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, Warning Letters or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

If we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

The development and approval process in the United States may take many years, require substantial resources and may never lead to the approval of the Delcath chemosaturation system by the FDA for use in the United States.
We cannot sell or market the Delcath chemosaturation system with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of an NDA for the Delcath chemosaturation system. Although melphalan and other drugs have been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required

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 FFDCA 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