

DELCATH SYSTEMS INC  
Form 10-Q  
November 08, 2007

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2007

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

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

Commission file number: 001-16133

**DELCATH SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

06-1245881  
(I.R.S. Employer  
Identification No.)

600 Fifth Avenue, 23rd Floor, New York, NY 10020  
(Address of principal executive offices)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of October 31, 2007, 25,259,284 shares of the Company's Common Stock, \$0.01 par value, were issued and outstanding.



**DELCATH SYSTEMS, INC.**

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**PART I:  
FINANCIAL INFORMATION**

**Item 1: Condensed Financial Statements (Unaudited)**

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**DELCATH SYSTEMS, INC.**  
**(A Development Stage Company)**  
**Condensed Balance Sheets**

	<b>September 30, 2007 (Unaudited)</b>	<b>December 31, 2006 (Audited)</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 18,499,086	\$ 6,289,723
Certificates of deposit	551,290	2,408,302
Prepaid expenses	253,416	61,917
Total current assets	\$ 19,303,792	\$ 8,759,942
Property and equipment, net	16,340	3,719
Total assets	\$ 19,320,132	\$ 8,763,661
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable and accrued expenses	110,315	670,367
Derivative instrument liability	4,347,000	-
Total current liabilities	\$ 4,457,315	\$ 670,367
Commitments and contingencies	-	-
Stockholders' equity		
Common stock, \$.01 par value; 70,000,000 shares authorized	\$ 252,593	\$ 206,608
Additional paid-in capital	56,561,701	44,673,458
Deficit accumulated during development stage	(41,951,477)	(36,786,772)
Total stockholders' equity	\$ 14,862,817	\$ 8,093,294
Total liabilities and stockholders' equity	\$ 19,320,132	\$ 8,763,661

See accompanying notes to condensed financial statements.

**DELCATH SYSTEMS, INC.**  
**(A Development Stage Company)**  
**Condensed Statements of Operations**  
**(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative from Inception (August 5, 1988) to September 30, 2007
	2007	2006	2007	2006	
<b>Costs and expenses</b>					
General and administrative expenses	\$ 609,759	\$ 4,400,910	\$ 2,183,043	\$ 6,053,427	\$ 19,602,672
Research and development costs	1,125,573	466,207	3,208,963	1,868,064	22,986,527
Derivative instrument expense	78,000	-	78,000	-	78,000
<b>Total costs and expenses</b>	<b>1,813,332</b>	<b>4,867,117</b>	<b>5,470,006</b>	<b>7,921,491</b>	<b>42,667,199</b>
<b>Operating loss</b>	<b>(1,813,332)</b>	<b>(4,867,117)</b>	<b>(5,470,006)</b>	<b>(7,921,491)</b>	<b>(42,667,199)</b>
Interest income	101,755	178,599	305,301	483,116	2,259,300
Other income	-	-	-	-	126,500
Interest expense	-	-	-	-	(171,473)
<b>Net loss</b>	<b>\$ (1,711,577)</b>	<b>\$ (4,688,518)</b>	<b>\$ (5,164,705)</b>	<b>\$ (7,438,375)</b>	<b>\$ (40,452,872)</b>
<b>Common share data</b>					
Basic and diluted loss per share	\$ (0.08)	\$ (0.23)	\$ (0.24)	\$ (0.38)	
<b>Weighted average number of shares of common stock outstanding</b>					
	21,630,349	20,131,471	21,331,461	19,658,719	

See accompanying notes to condensed financial statements.

**DELCATH SYSTEMS, INC.**  
**(A Development Stage Company)**  
**Condensed Statements of Cash Flows**  
**(Unaudited)**

	Nine Months Ended September 30,		Cumulative from inception (Aug. 5, 1988) to September 30,
	2007	2006	2007
<b>Cash flows from operating activities:</b>			
Net loss	\$ (5,164,705)	\$ (7,438,375)	\$ (40,452,871)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock option compensation expense	1,339,776	505,282	4,915,886
Stock and warrant compensation expense issued for legal settlement, consulting services	211,250	-	856,961
Depreciation expense	3,020	3,003	44,598
Amortization of organization costs	-	-	42,165
Derivative liability fair value adjustment	78,000	-	78,000
Changes in assets and liabilities:			
(Increase) decrease in prepaid expenses	(191,499)	500	(253,416)
Decrease in interest receivable	-	91,574	-
(Decrease) increase in accounts payable and accrued expenses	(560,050)	1,445,240	110,317
Net cash used in operating activities	\$ (4,284,208)	\$ (5,392,776)	\$ (34,658,360)
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	\$ (15,641)	-	\$ (60,939)
Purchase of short-term investments	-	\$ (5,394,701)	(27,492,042)
Proceeds from maturities of short-term investments	1,856,762	11,097,790	26,940,502
Organization costs	-	-	(42,165)
Net cash provided by (used in) investing activities	\$ 1,841,121	\$ 5,703,089	\$ (654,644)

**Cash flows from financing activities:**

Net proceeds from sale of stock and exercise of stock options and warrants	\$ 14,652,450	\$ 5,098,556	\$ 52,657,764
Repurchases of outstanding common stock	-	-	(51,103)
Dividends paid	-	-	(499,535)
Proceeds from short-term borrowings	-	-	1,704,964
Net cash provided by financing activities	\$ 14,652,450	\$ 5,098,556	\$ 53,812,090
Increase in cash and cash equivalents	12,209,363	5,408,869	18,499,086
Cash and cash equivalents at beginning of period	6,289,723	1,704,131	-
Cash and cash equivalents at end of period	\$ 18,499,086	\$ 7,113,000	\$ 18,499,086

**Supplemental cash flow information:**

Cash paid for interest	-	-	\$ 171,473
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**Supplemental non-cash activities:**

Cashless exercise of stock options	\$ 450,999	-	\$ 542,165
Conversion of debt to common stock	-	-	\$ 1,704,964
Common stock issued for preferred stock dividends	-	-	\$ 999,070
Conversion of preferred stock to common stock	-	-	\$ 24,167
Common stock issued as compensation for stock sale	-	-	\$ 510,000
Fair value of warrants issued	\$ 4,269,000		\$ 4,269,000

See accompanying notes to condensed financial statements.



**DELCATH SYSTEMS, INC.**  
**(A Development Stage Company)**  
**Notes to Condensed Financial Statements**

**Note 1: Description of Business**

Delcath Systems, Inc. (the “Company”) is a development stage company founded in 1988 for the purpose of developing and marketing a proprietary drug delivery system capable of introducing and removing high dose chemotherapy agents to a diseased organ system, while greatly inhibiting their entry into the general circulation system. It is hoped that the procedure will result in a meaningful treatment for cancer. In November 1989, the Company was granted an Investigational Device Exemption (“IDE”) and an Investigational New Drug (“IND”) status for its product by the Food and Drug Administration (“FDA”). The Company is seeking to complete clinical trials in order to obtain separate FDA pre-market approvals for the use of its delivery system using Melphalan, a chemotherapeutic agent, to treat malignant melanoma that has spread to the liver.

**Note 2: Basis of Financial Statement Presentation**

The accompanying condensed financial statements are unaudited and were prepared by the Company in accordance with accounting principles generally accepted in the United States of America (“GAAP”). Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the results for the interim periods ended September 30, 2007 and 2006, and cumulative from inception (August 5, 1988) to September 30, 2007.

The results of operations 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, 2006, which are contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission (the “SEC”) on March 16, 2007 (the “2006 Form 10-K”).

**Note 3: Costs and Expenses**

*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 the Company’s general and administrative operating expenses.

**Note 4: Stockholders’ Equity**

The Company received a net amount of \$1,349,184 upon the exercise of stock options for 617,850 shares of common stock, \$0.01 par value per share (the “Common Stock”) during the nine months ended September 30, 2007. Of those options: (i) 100,000 were exercised at a price of \$0.71 per share, (ii) 126,000 were exercised at a price of \$1.03 per share, (iii) 20,000 were exercised at a price of \$1.32 per share, (iv) 200,000 were exercised at a price of \$2.78 per share, (v) 100,000 were exercised at a price of \$3.28 per share, and (vi) 71,850 were exercised at a price of \$3.31 per share.



**DELCATH SYSTEMS, INC.**  
**(A Development Stage Company)**  
**Notes to Condensed Financial Statements**

During the nine months ended September 30, 2007, a cashless exercise of 70,000 options with an exercise price of \$2.78 per share, 140,000 options with an exercise price of \$3.59 per share, 80,000 options with an exercise price of \$3.28 per share, and 60,300 options with an exercise price of \$3.31 per share collectively resulted in the issuance of 97,563 shares of Common Stock.

During the nine months ended September 30, 2007, the Company issued 50,000 shares of Common Stock to its Chief Executive Officer that had an issuance value of \$3.90 per share for the 25,000 issued on May 24, 2007 and \$4.49 for the 25,000 shares issued on July 2, 2007.

In September 2007, the Company completed the sale of 3,833,108 shares of its Common Stock and the issuance of warrants to purchase 1,916,558 common shares in a private placement to institutional and accredited investors. The Company received net proceeds of \$13,303,267 in this transaction. The Company allocated \$4,269,000 of the total proceeds to warrants (see below). The shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on May 25, 2007 and was declared effective on June 7, 2007 (File No. 333-143280).

The \$4,269,000 in proceeds allocated to the warrants was classified as a liability in accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own Stock." The warrants may require cash settlement in the event of certain circumstances, including the Company's inability to deliver registered shares upon the exercise of the warrants by such warrant holders. The warrants also contain a cashless exercise feature in certain circumstances. Accordingly, the warrants have been accounted for as derivative instrument liabilities which are subject to mark-to-market adjustment in each period. As a result, for the nine-month and three-month periods ended September 30, 2007, the Company recorded a pre-tax charge for derivative instrument expense of \$78,000. The resulting derivative instrument liability totaled \$4,347,000 at September 30, 2007. Management believes that the possibility of an actual cash settlement with a warrant holder of the recorded liability is quite remote, and expects that the warrants will either be exercised or expire worthless, at which point the then existing derivative liability will be credited to equity. The fair value of the warrants was determined by using the Black-Scholes model assuming a risk free interest rate of 4.20%, volatility of 81.30% and an expected life equal to the September 24, 2012 contractual life of the warrants.

The per share weighted average fair value of five-year stock options granted to new members of the Board of Directors in May 2007 was \$1.51 for those options with a grant date exercise price equal to the common stock value at the date of grant (options for an aggregate of 150,000 shares) and \$.99 for those options with an exercise price equal to 150% of the common stock value at the date of grant (options for an aggregate of 200,000 shares), estimated on the date of grant using the Black-Scholes option-pricing model. The expected term was estimated using a midpoint between the date of grant and the expiration date as required by the Simplified Method of term calculation in accordance with SFAS 123R (See Note 5). The weighted-average assumption of a risk free interest rate of 4.64% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 58% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

**DELCATH SYSTEMS, INC.**  
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**Notes to Condensed Financial Statements**

The per share weighted average fair value of five-year stock options granted to a new member of the Board of Directors in June 2007 was \$1.85 for those options with an exercise price equal to the common stock value at the date of grant (options for an aggregate of 50,000 shares) and \$1.22 for those options with an exercise price equal to 150% of the common stock value at the date of grant (options for an aggregate of 100,000 shares), estimated on the date of grant using the Black-Scholes option-pricing model. The expected term was estimated using a midpoint between the date of grant and the expiration date as required by the Simplified Method of term calculation in accordance with SFAS 123R (See Note 5). The weighted-average assumption of a risk free interest rate of 4.64% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 58% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

The per share weighted average fair value of stock options that will vest incrementally over three years during the term of employment granted to newly hired employees in June 2007 was \$1.92 for those options granted in April 2007 with an exercise price equal to the fair value of the common stock at the date of grant (options for an aggregate of 50,000 shares), \$1.75 for those options granted in May 2007 with an exercise price equal to the fair value of the common stock at the date of grant (options for an aggregate of 50,000 shares), and \$1.22 for those options granted in May 2007 with an exercise price equal to 150% of the fair value of the common stock at the date of grant (options for an aggregate of 25,000 shares), estimated on the date of acceptance using the Black-Scholes option-pricing model. The expected term was estimated to be the full three year vesting period as the Company does not have a calculable history of forfeitures by employees granted options. The weighted-average assumption of a risk free interest rate of 4.60% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 58% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future.

The per share weighted average fair value of five-year stock options granted to the President and Chief Executive Officer in July 2007 was \$1.89 for those options with an exercise price below the grant date common stock value (options for an aggregate of 50,000 shares) and \$1.31 for those options with an exercise price greater than the grant date common stock value (options for an aggregate of 100,000 shares), estimated on the date of grant using the Black-Scholes option-pricing model. The expected term was estimated using a midpoint between the date of grant and the expiration date as required by the Simplified Method of term calculation in accordance with SFAS 123R (See Note 5). The weighted-average assumption of a risk free interest rate of 4.64% was based on the implied yield available on a U.S. Treasury note with a term equal to the estimated term of the underlying options as indicated above. The expected volatility of 58% was estimated based upon the historical volatility of the Company's share price. The Company used a dividend yield percentage of zero based on the fact that the Company has not paid dividends in the past nor does it expect to pay dividends in the future. The following table sets forth changes in stockholders' equity during the nine months ended September 30, 2007:

**DELCATH SYSTEMS, INC.**  
**(A Development Stage Company)**  
**Notes to Condensed Financial Statements**

	Common Stock, \$0.01 Par Value Issued and Outstanding		Additional Paid in Capital	Deficit Accumulated During Development Stage		Total
	No. of Shares	Amount				
Balance at December 31, 2006	20,660,763	\$ 206,608	\$ 44,673,458	\$ (36,786,772)		\$ 8,093,294
Exercise of stock options	715,413	7,154	1,793,029	-		1,800,183
Shares issued as compensation	50,000	500	210,500	-		211,000
Sale of stock						
Compensation expense for issuance of stock options	3,833,108	38,331	8,995,936	-		9,034,267
	-	-	888,778	-		888,778
Net loss for nine months ended September 30, 2007	-	-	-	(5,164,705)		(5,164,705)
Balance at September 30, 2007	25,259,284	\$ 252,593	\$ 56,561,701	\$ (41,951,477)		\$ 14,862,817

**Note 5: Stock Option Plan**

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" (SFAS 123R). This Statement is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), and supersedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), and its related implementation guidance. SFAS 123R establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123R, 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). Prior to January 1, 2006, the Company accounted for share-based compensation to employees in accordance with APB 25, as permitted by SFAS No. 123, and, accordingly, did not recognize compensation expense for the issuance of options with an exercise price equal to or greater than the market price at the date of grant. The Company also followed the disclosure requirements of SFAS 123 as amended by SFAS 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." Effective January 1, 2006, the Company adopted the modified prospective approach and, accordingly, prior period amounts have not been restated. Under this approach, the Company is required to record compensation cost for all share-based payments granted after the date of adoption based upon the grant date fair value, estimated in accordance with the provisions of SFAS 123R, and for the unvested portion of all share-based payments previously granted that remain outstanding based on the grant date fair value, estimated in accordance with the original provisions of SFAS 123. The Company has expensed its share-based compensation for share-based payments granted after January 1, 2006 under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company periodically grants stock options for a fixed number of shares of Common Stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair market value of our Common Stock at the date of the grant. The Company estimates the fair value of stock options using a Black-Scholes valuation model. Key inputs used to estimate the fair value of stock options include the exercise price of the award, the expected post-vesting option life, the expected volatility of our stock over the option's expected term, the risk-free interest rate over the option's expected term, and our expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.



**DELCATH SYSTEMS, INC.**  
**(A Development Stage Company)**  
**Notes to Condensed Financial Statements**

The required adoption of SFAS No. 123R as of January 1, 2006 has significantly increased compensation expense for future grants. The actual impact on future years will be dependent on a number of factors, including our stock price and the level of future grants and awards. In addition, costs related to accounting and valuation services of stock options currently outstanding in accordance with SFAS No. 123R would have been cost prohibitive to the Company if the Company had not adopted certain measures. Based on these considerations and after discussion of applicable accounting literature, the Compensation Committee of the Board of Directors approved accelerating the vesting of all unvested stock options effective January 1, 2006. The acceleration of vesting resulted in the recognition of a non-cash compensation expense of \$505,282 on January 1, 2006 which is included in costs and expenses in the statements of operations for 2006.

The Company established its Incentive Stock Option Plan, Non-Incentive Stock Option Plan, 2000 Stock Option Plan, 2001 Stock Option Plan and 2004 Stock Incentive Plan (collectively, the "Plans"), under which stock options, stock appreciation rights, restricted stock, and stock grants may be awarded. 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 the options shall be granted as well as the terms and conditions of each option grant, the option price and the duration of each option.

During 2000, 2001 and 2004, respectively, the 2000 and 2001 Stock Option Plans and 2004 Stock Incentive Plan became effective. Options granted under the Plans vest as determined by the Company and expire over varying terms, but not more than five years from the date of grant. All currently outstanding options are fully vested except for those issued to recently hired employees whose options shall vest incrementally over three years based on continued employment. Stock option activity for the nine-month period ended September 30, 2007 is as follows:

	Stock Options	The Plans		Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
		Exercise Price per Share			
Outstanding at December 31, 2006	1,465,650	\$ 0.71 - \$3.59	\$	2.87	3.57
Granted	775,000	\$ 3.90 - \$7.14	\$	5.26	
Expired	(202,500)	\$ 3.59	\$	3.59	
Exercised	(968,150)	\$ 0.71 - \$3.59	\$	2.59	
Outstanding at September 30, 2007	1,070,000	\$ 2.78 - \$7.14	\$	4.71	4.13

At September 30, 2007, \$190,222 of compensation expense remains to be amortized over the vesting period for options issued to certain employees in 2007.

**DELCATH SYSTEMS, INC.**  
**(A Development Stage Company)**  
**Notes to Condensed Financial Statements**

**Note 6: Income Taxes**

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109" ("FIN 48"), on January 1, 2007. FIN No. 48 requires that the impact of tax positions be recognized in the financial statements if they are more likely than not of being sustained upon examination, based on the technical merits of the position. As discussed in the financial statements in the 2006 Form 10-K, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion, or all of its deferred tax assets, will not be realized. The Company has not recognized any unrecognized tax benefit under the provisions of FIN 48. In addition, there is no impact to accumulated deficit at the date of adoption as a result of the implementation of FIN 48 and there is no interest or penalties accrued as management believes the Company has no uncertain tax positions at September 30, 2007.

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 I.R.S. or any states in connection with income taxes. The periods from 2003 - 2006 remain open to examination by the I.R.S. and state authorities.

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

### FORWARD LOOKING STATEMENTS

Certain statements in this Quarterly Report on Form 10-Q, including statements of our and management's expectations, intentions, plans, objectives and beliefs, including those contained in or implied by "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended, that are subject to certain events, risks and uncertainties that may be outside our control. These forward-looking statements may be identified by the use of words such as "expects," "anticipates," "intends," "plans" and similar expressions. They include statements of our future plans and objectives for our future operations and statements of future economic performance, information regarding our expansion and possible results from expansion, our expected growth, our capital budget and future capital requirements, the availability of funds and our ability to meet future capital needs, the realization of our deferred tax assets, and the assumptions described in this report underlying such forward-looking statements. Actual results and developments could differ materially from those expressed in or implied by such statements due to a number of factors, including without limitation, those described in the context of such forward-looking statements, our expansion strategy, our ability to achieve operating efficiencies, industry pricing and technology trends, evolving industry standards, domestic and international regulatory matters, general economic and business conditions, the strength and financial resources of our competitors, our ability to find and retain skilled personnel, the political and economic climate in which we conduct operations, the risks discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 filed with the Securities and Exchange Commission (the "SEC") on March 16, 2007 (the "2006 Form 10-K"), under Item 1A, "Risk Factors" and other risk factors described from time to time in our other documents and reports filed with the SEC. We do not assume any responsibility to publicly update any of our forward-looking statements regardless of whether factors change as a result of new information, future events or for any other reason. We advise you to review any additional disclosures we make in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and Annual Reports on Form 10-K, and any amendments thereto, filed with the SEC.

#### Overview

Since our founding in 1988 by a team of physicians, we have been a development stage company engaged primarily in developing and testing the Delcath drug delivery system for the treatment of liver cancer. A substantial portion of our historical expenses have been for the development of our medical device and the clinical trials of our product, and the pursuit of patents worldwide, as described in our 2006 Form 10-K under Item 1, "Patents, Trade Secrets and Proprietary Rights" and our Current Report on Form 8-K filed with the SEC on September 18, 2007. We expect to continue to incur significant losses from costs for product development, clinical studies, securing patents, regulatory activities, manufacturing and establishment of a sales and marketing organization without any significant revenues. A detailed description of the cash used to fund historical operations is in the financial statements and the notes thereto. Without an FDA-approved product and commercial sales, we will continue to be dependent upon existing cash and the sale of equity or debt to fund future activities. While the amount of future net losses and time required to reach profitability are uncertain, our ability to generate significant revenue and become profitable will depend on our success in commercializing our device.

During 2001, Delcath initiated the clinical trial of the drug delivery system for isolated liver perfusion using the chemotherapeutic agent Melphalan. Enrollment of new patients in the Phase I trial was completed in 2003.

In 2004, we commenced a Phase II clinical trial protocol for the study of the Delcath drug delivery system using Melphalan for inoperable primary liver cancer and adenocarcinomas and neuroendocrine cancers that have metastasized to the liver.

In 2006, we started enrolling and treating patients in a pivotal Phase III trial for the study of the Delcath drug delivery system for inoperable melanoma in the liver using Melphalan under the FDA's Fast Track and Special Protocol Assessment approved protocol.

On October 23, 2007, we announced that we received on the afternoon of October 22, 2007, a letter from the FDA recommending that we temporarily suspend enrollment in the Phase III and Phase II trials of the Delcath System, and submit an analysis of adverse events in anticipation of a meeting with the FDA to discuss certain gastrointestinal ("GI") safety concerns. The recommendation was issued by the FDA following reports of four serious adverse GI events that were submitted to the FDA, the National Cancer Institute's Institutional Review Board and the Data Safety Monitoring Board, which may have been related to the infusion of Melphalan. Following receipt of this letter, we decided to voluntarily defer accrual of new patients in our Phase III and Phase II trials.

We plan to work as expeditiously as possible with the FDA to resolve the FDA's safety concerns. The Phase III and Phase II trials are still ongoing, and patients currently enrolled in the trials will continue to receive their treatments under the approved protocols.

Over the next 12 months, we expect to continue to incur substantial expenses related to the research and development of our technology, including Phase III and Phase II clinical trials using Melphalan with the Delcath system. Additional funds, when available, will be committed to pre-clinical and clinical trials for the use of other chemotherapy agents with the Delcath system for the treatment of liver cancer and other cancers, and the development of additional products and components. We will also continue efforts to qualify additional sources of the key components of our device, in an effort to further reduce manufacturing costs and minimize dependency on a single source of supply.

### **Results of Operations for the Nine Months Ended September 30, 2007**

The Company has operated at a loss for its entire history. We had a net loss for the nine months ended September 30, 2007, of \$5,164,705, which is \$2,273,670, or 30.6%, less than the net loss from continuing operations for the same period in 2006. This substantial decrease is primarily due to the resolution of various legal matters that had been instituted in 2006, and their related costs which were incurred in 2006. There were, however, additional expenses relating to a five-year extension to the Company's Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("NCI") that initially expired in December 2006. This extension was necessary for continuing and expanding the collaboration between the Company and the NCI, but will result in greater costs to the Company. The agreement with the NCI required that the annual payments to them be increased five-fold from the previous agreement.

General and administrative expenses decreased by 63.9% from \$6,053,427 during the nine months ended September 30, 2006, to \$2,183,043 for the nine months ended September 30, 2007. While legal fees incurred during the current period were substantially less than those incurred in 2006 and would have resulted in a greater reduction in period-to-period expenses due to the resolution of various legal matters, additional charges to general operations were incurred during this period by share-based compensation for options granted to new members of the Board of Directors, options granted to the President and Chief Executive Officer, and options granted to newly hired management employees. Further, the cashless exercise of options by outgoing members of the Board of Directors resulted in additional charges to general operations.



During the nine months ended September 30, 2007, we incurred \$3,208,963 in research and development costs, which is a 71.8% increase as compared to \$1,868,064 of research and development costs during the first nine months of 2006. This increase is primarily due to increased expenses with the NCI, as discussed above, as well as accelerated clinical development costs relating to all facets of the Delcath system which has required greater expense but is expected to hasten the progress toward final approval. In addition, a portion of the share-based compensation for options discussed above is allocated to research and development.

Interest income shown is from our money market accounts and certificate of deposit ("CD") investments. During the nine months ended September 30, 2007, the Company had interest income of \$305,301, as compared to interest income of \$483,116, or a 37 % change, for the same period in 2006. This decrease is primarily due to a reduced cash position in 2007 from that in 2006. There was no other income during the nine months ended September 30, 2007 or the comparable period in 2006. The net proceeds from the sale of our Common Stock and warrants in September 2007 were received on the last day of the quarter and had minimal effect on interest income.

### **Results of Operations for the Three Months Ended September 30, 2007**

We had a net loss for the three months ended September 30, 2007, of \$1,711,577, which is \$2,976,941, or 63.5% less than, the net loss from continuing operations for the same period in 2006. This decrease as stated above is primarily due to the resolution of various legal matters that had been instituted in 2006, and their related costs which were incurred in 2006.

General and administrative expenses decreased by 86.1% from \$4,400,910 during the three months ended September 30, 2006, to \$609,759 for the three months ended September 30, 2007. While legal fees incurred during the current period were substantially less than those incurred in 2006 and would have resulted in a greater reduction in period-to-period expenses due to the resolution of various legal matters, additional charges to general operations were incurred during this period by share-based compensation for options granted to the President and Chief Executive Officer and newly hired management employees. Further, the cashless exercise of options by an outgoing member of the Board of Directors resulted in additional charges to general operations.

During the three months ended September 30, 2007, we incurred \$1,125,573 in research and development costs, as compared to \$466,207 during the corresponding period in 2006, which is a 141% increase. This increase is primarily due to increased expenses with the NCI, as discussed above, as well as accelerated clinical development costs relating to all facets of the Delcath drug delivery system which management believes will hasten the progress toward final approval. Additionally, as mentioned above, a portion of the share-based compensation for options is allocated to research and development.

Interest income shown is from our money market accounts and CD investments. During the three months ended September 30, 2007, the Company had interest income of \$101,755, as compared to interest income of \$178,599 for the same period in 2006. This decrease is primarily due to a reduced cash position in 2007 from that in 2006. There was no other income during the three months ended September 30, 2007 or the comparable period in 2006.

### **Liquidity and Capital Resources**

The Company's future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and there can be no assurance of its ever achieving consistent profitability. The Company is not projecting any capital expenditures that will significantly affect the Company's liquidity during the next 12 months. However, our future liquidity and capital requirements will depend on numerous factors, including the progress of our research and product development programs, including clinical studies; the timing and costs of making various United States and foreign regulatory filings, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements overseas; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At September 30, 2007, we had cash, cash equivalents and certificates of deposit of \$19,050,376, as compared to \$8,698,025 at December 31, 2006. Because money market rates have been equal to or greater than what the Company could receive in CDs, nearly all of our funds are currently invested in money market accounts which are shown in our financial statements as part of "Cash and Cash Equivalents."

During the nine months ended September 30, 2007, we used \$4,284,208 of cash in our operating activities. This amount compares to \$5,392,776 used in our operating activities during the comparable nine-month period in 2006. The decrease of \$1,108,568, or 20.5%, was primarily due to the substantial reduction in legal fees which is offset by a material decline in accounts payable, as well as the increased payments to NCI as part of our newly extended CRADA agreement and payments to various medical consultants to further advance and expand our ongoing clinical trials.

We have funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000 and 2003. Please see the detailed discussion of our various sales of securities described in Note 2 to our 2006 financial statements included in our 2006 Form 10-K. In addition, we received proceeds of approximately \$5.6 million from private placements we completed in 2004, approximately \$2.2 million on exercise of warrants and options in 2004, approximately \$2.5 million from a private placement we completed in 2005, approximately \$5.5 million on exercise of warrants and options in 2005, and approximately \$5.1 million on exercise of warrants and options in 2006. During the nine months ended September 30, 2007, we received approximately \$1.3 million on exercise of warrants and options, and approximately \$13.3 million from the registered direct offering of our Common Stock and warrants we completed in September, 2007. Although there can be no assurances, management believes that, as of September 30, 2007, the Company currently has sufficient capital to complete our existing Phase II and Phase III clinical trials.

### **Application of Critical Accounting Policies**

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 Company's 2006 Form 10-K. The Company is still in the development stage and has no revenues, trade receivables, inventories, or significant fixed or intangible assets. The Company has not adopted any significant new accounting policies or modified the application of existing policies during the nine months ended September 30, 2007.



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

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109" ("FIN 48"), on January 1, 2007. FIN No. 48 requires that the impact of tax positions be recognized in the financial statements if they are more likely than not of being sustained upon examination, based on the technical merits of the position. As discussed in the financial statements in the 2006 Form 10-K, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion, or all of its deferred tax assets, will not be realized. The Company has not recognized any unrecognized tax benefit under the provisions of FIN 48. In addition, there is no impact to accumulated deficit at the date of adoption as a result of the implementation of FIN 48 and there is no interest or penalties accrued as management believes the Company has no uncertain tax positions at September 30, 2007.

The Company accounts for employee stock-based compensation costs in accordance with Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" ("SFAS 123R"). The Black-Scholes option pricing model is utilized to estimate the fair value of employee stock based compensation at the date of grant, which requires the input of highly subjective assumptions, including expected volatility and expected life. As required under SFAS 123R, forfeitures for options granted, which are not expected to vest are estimated. Changes in these assumptions can materially affect the measure of estimated fair value of our share-based compensation.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

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 value of these securities.

### **Item 4. Controls and Procedures**

Based on an evaluation of the Company's disclosure controls and procedures performed by the Company's Chief Executive Officer and Chief Financial Officer as of the end of the period covered by this report, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures have been effective.

As used herein, "disclosure controls and procedures" means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the rules and forms issued by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer or officers and its principal financial officer or officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation described above that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## **PART II: OTHER INFORMATION**

### **Item 1. Legal Proceedings**

We have been involved in a legal proceeding that was originally filed on August 12, 2005 in the United States District Court, District of Connecticut against Elizabeth L. Enney (the "Defendant"). The named plaintiffs are Delcath Systems, Inc. and M.S. Koly (former CEO, President, Treasurer and Director of Delcath), individually and as a Director of Delcath Systems, Inc. The operative complaint seeks damages for libel. In May 2006, the libel claims were dismissed for lack of personal jurisdiction, and in July 2006, Plaintiffs filed a new libel claim in the United States District Court for the Northern District of Georgia. On November 1, 2006, Defendant filed a Motion for Judgment claiming that Plaintiffs' complaint and the attachments thereto, on their face, were insufficient to support Plaintiffs' libel claim as a matter of law. On December 22, 2006, Defendant filed a motion under Rule 11 of the Federal Rules of Civil Procedure seeking an order directing payment to the Defendant of reasonable attorneys' fees and expenses by Plaintiff. On April 19, 2007, the entire action was ordered and adjudged to be dismissed, and the Defendant was granted recovery of her court costs only; however, her motion for sanctions against the Plaintiffs was denied. On May 21, 2007 Defendant filed an appeal to the United States Court of Appeals for the 11<sup>th</sup> Circuit from the final judgment and order of the court entered on April 19, 2007 denying Defendant's motion for sanctions against the Plaintiffs.

### **Item 1A. Risk Factors**

Our 2006 Form 10-K contains a detailed discussion of certain risk factors that could materially adversely affect our business, operating results or financial condition. The following risk factor has been amended and updated to reflect recent events, and should be read in conjunction with the risk factors and information disclosed in the 2006 Form 10-K.

**We may be delayed in, and limited or precluded from continuing, our clinical testing of the Delcath System for the infusion of Melphalan, given that we have voluntarily suspended enrollment in our Phase III and Phase II clinical trials, which could cause our stock price to decline.**

On October 23, 2007, we announced that we received on the afternoon of October 22, 2007, a letter from the FDA recommending that we temporarily suspend enrollment in the Phase III and Phase II trials of the Delcath System, and submit an analysis of adverse events in anticipation of a meeting with the FDA to discuss certain gastrointestinal ("GI") safety concerns. The recommendation was issued by the FDA following reports of four serious adverse GI events that were submitted to the FDA, the National Cancer Institute's Institutional Review Board and the Data Safety Monitoring Board, which may have been related to the infusion of Melphalan. Following receipt of this letter, we decided to voluntarily defer accrual of new patients in our Phase III and Phase II trials; however, both trials will continue for patients who are currently enrolled. We do not know when or if we will resume enrollment in the Phase III and Phase II clinical trials.



We plan to work as expeditiously as possible with the FDA to resolve the FDA's safety concerns and recommence enrollment of new patients, however, there can be no assurance that we will be able to do so, or if we can do so in a timely manner. We may experience a number of events that could continue to delay or prevent development of the Delcath System, including:

- the FDA may put the Phase III and/or Phase II trials on clinical hold, meaning that they will not allow for further enrollment in and/or permanently suspend our clinical trials;
  - additional serious adverse events in the clinical trials could occur;
- the Company could fail to resume enrollment in the clinical trials in a timely manner or at all; or
- other regulators or institutional review boards may not authorize, or may delay, suspend or terminate the clinical trial program due to any unresolved safety concerns.

If we cannot resume enrollment, or if the resumption is delayed, our clinical trials, and as a result, our business, operations and stock price could be materially adversely affected.

**Our Common Stock is listed on the NASDAQ Capital Market. If we fail to meet the requirements of the NASDAQ Capital Market for continued listing, our Common Stock could be delisted.**

Our Common Stock is currently listed on the NASDAQ Capital Market. To keep such listing, we are required to maintain: (i) a minimum bid price of \$1.00 per share, (ii) a certain public float, (iii) a certain number of round lot shareholders and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years ) of at least \$500,000, a market value of listed securities of at least \$35 million or a stockholders' equity of at least \$2.5 million. We are presently in compliance with these requirements.

We are also required to maintain certain corporate governance requirements. On April 30, 2007, we were notified by NASDAQ that due to the resignations of two of our independent directors on April 16, 2007, we no longer complied with NASDAQ's requirements to have a majority of independent directors on our Board of Directors, and for our Audit Committee to have three members. On May 24, 2007, the Company regained compliance with both of these requirements within the cure period allowed by NASDAQ (on or before October 13, 2007). However, in the event that in the future we are notified that we no longer comply with NASDAQ's corporate governance requirements, and we fail to regain compliance within the applicable cure period, our Common Stock could be delisted from the NASDAQ Capital Market. In addition, if we fail to meet any of the other applicable criteria, our Common Stock could be delisted from the NASDAQ Capital Market.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Submission of Matters to a Vote of Security Holders**

None.

**Item 5. Other Information**

There were no matters required to be disclosed in a Current Report on Form 8-K during the fiscal quarter covered by this report that were not so disclosed.

There were no changes to the procedures by which security holders may recommend nominees to the Company's Board of Directors since the Company last disclosed such procedures in its proxy statement filed in connection with its Annual Meeting of Stockholders held on June 5, 2007.

**Item 6. Exhibits**

10.1 Employment Agreement dated as of July 2, 2007 between Delcath Systems, Inc. and Richard L. Taney (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed July 5, 2007).

10.2 Lease Agreement between Rockbay Capital Management, L.P. and the Company, dated as of July 9, 2007 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed August 30, 2007).

10.3 Consent of Master Landlord to the Sublease, dated August 21, 2007 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed August 30, 2007).

10.4 Placement Agency Agreement dated September 18, 2007 by and among Delcath Systems, Inc., Canaccord Adams Inc. and Think Equity Partners LLC. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed September 24, 2007).

10.5 Form of Subscription Agreement in connection with the Company's September 2007 registered direct offering (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed September 24, 2007).

10.6 Form of Warrant issued to investors in connection with the Company's September 2007 registered direct offering (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed September 24, 2007).

10.7 Escrow Agreement dated September 18, 2007 between Delcath Systems, Inc., Canaccord Adams Inc., Think Equity Partners LLC and JPMorgan Chase Bank, N.A. (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed September 24, 2007).

31.1 Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.

31.2 Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.

32.1 Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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**SIGNATURES**

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

November 8, 2007

DELCATH SYSTEMS, INC.  
(Registrant)

/s/ Paul M. Feinstein

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Paul M. Feinstein  
Chief Financial Officer and Treasurer  
(principal financial and accounting officer)

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