DELCATH SYSTEMS INC
Form 10-Q
August 09, 2007

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, 2007

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.)

1100 Summer Street, 3rd Floor, Stamford, CT 06905
(Address of principal executive offices)

(203) 323-8668
(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 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 o Accelerated filer x Non-accelerated filer 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 July 31, 2007, 21,408,007 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)

Index to Financial Statements

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

	June 30, 2007 (Unaudited)	December 31, 2006 (Audited)
Assets		
Current assets		
Cash and cash equivalents	$ 6,416,755	$ 6,289,723
Certificates of deposit	548,587	2,408,302
Prepaid expenses	273,916	61,917
Total current assets	$ 7,239,258	$ 8,759,942
Property and equipment, net	10,522	3,719
Total assets	$ 7,249,780	$ 8,763,661
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable and accrued expenses	127,363	670,367
Total current liabilities	$ 127,363	$ 670,367
Commitments and contingencies		
Stockholders equity		
Common stock, $.01 par value; 70,000,000 shares authorized	$ 213,830	$ 206,608
Additional paid-in capital	47,148,487	44,673,458
Deficit accumulated during development stage	(40,239,900)	(36,786,772)
Total stockholders equity	$ 7,122,417	$ 8,093,294
Total liabilities and stockholders equity	$ 7,249,780	$ 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 June 30,		Six Months Ended June 30,		Cumulative from Inception (August 5, 1988) to
	2007	2006	2007	2006	June 30, 2007
Costs and expenses					
General and administrative expenses	$ 1,072,465	$ 1,090,967	$ 1,573,284	$ 1,652,517	$ 18,992,913
Research and development costs	1,194,439	635,217	2,083,390	1,401,857	21,860,954
Total costs and expenses	2,266,904	1,726,184	3,656,674	3,054,374	40,853,867
Operating loss	(2,266,904)	(1,726,184)	(3,656,674)	(3,054,374)	(40,853,867)
Interest income	87,890	160,465	203,546	304,517	2,157,545
Other income	—	—	—	—	126,500
Interest expense	—	—	—	—	(171,473)
Net loss	$ (2,179,014)	$ (1,565,719)	$ (3,453,128)	$ (2,749,857)	$ (38,741,295)
Common share data					
Basic and diluted loss per share	$ (0.10)	$ (0.08)	$ (0.16)	$ (0.14)	
Weighted average number of shares of common stock outstanding	21,352,219	19,633,405	21,179,540	19,418,425	

See accompanying notes to condensed financial statements.

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

	Six Months Ended June 30, 2007	2006
Cash flows from operating activities:		
Net loss	$ (3,453,128)	$ (2,749,857)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	1,040,498	505,282
Stock and warrant compensation expense issued for legal settlement, consulting services	98,750	—
Depreciation expense	1,937	2,143
Amortization of organization costs	—	—
Changes in assets and liabilities:		
Increase in prepaid expenses	(211,999)	(8,000)
Increase in interest receivable	—	(89,875)
(Decrease) increase in accounts payable and accrued expenses	(543,004)	558,902
Net cash used in operating activities	$ (3,066,946)	$ (1,781,405)
Cash flows from investing activities:		
Purchase of property and equipment	$ (8,740)	—
Purchase of short-term investments	—	$ (1,800,000)
Proceeds from maturities of short-term investments	1,859,715	5,606,790
Organization costs	—	—
Net cash provided by (used in) investing activities	$ 1,850,975	$ 3,806,790
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of stock options and warrants	$ 1,343,003	$ 2,783,282
Repurchases of common stock	—	—
Dividends paid	—	—
Proceeds from short-term borrowings	—	—
Net cash provided by financing activities	$ 1,343,003	$ 2,783,282
Increase in cash and cash equivalents	127,032	4,808,667
Cash and cash equivalents at beginning of period	6,289,723	1,704,131
Cash and cash equivalents at end of period	$ 6,416,755	$ 6,512,798
Supplemental cash flow information:		
Cash paid for interest	—	—
Supplemental non-cash activities:		
Cashless exercise of stock options	$ 400,498	—
Conversion of debt to common stock	—	—
Common stock issued for preferred stock dividends	—	—
Conversion of preferred stock to common stock	—	—
Common stock issued as compensation for stock sale	—	—

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 June 30, 2007 and 2006, and cumulative from inception (August 5, 1988) to June 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 $1,343,004 upon the exercise of stock options for 611,850 shares of common stock, $0.01 par value per share (the "Common Stock") during the six months ended June 30, 2007. Of those options: (i) 100,000 were exercised at a price of $0.71 per share, (ii) 120,000 were

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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.

During the six months ended June 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, and 80,000 options with an exercise price of $3.28 per share collectively resulted in the issuance of 85,394 shares of Common Stock.

During the six months ended June 30, 2007, the Company issued 25,000 shares of Common Stock to its Chief Executive Officer that had an issuance value of $3.90 per share.

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 (options for an aggregate of 150,000 shares), and $.99 for those options with a 150% of grant date exercise price (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.

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 a grant date exercise price (options for an aggregate of 50,000 shares) and $1.22 for those options with a 150% of grant date exercise price (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 six months ended June 30, 2007:

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(A Development Stage Company)
Notes to Condensed Financial Statements

	Common Stock, $0.01 Par Value Issued and Outstanding		Additional Paid	Deficit Accumulated During Development	
	No. of Shares	Amount	in Capital	Stage	Total
Balance at December 31, 2006	20,660,763	$ 206,608	$ 44,673,458	$ (36,786,772)	$ 8,093,294
Exercise of stock options	697,244	6,972	1,736,529		1,743,501
Shares issued as compensation	25,000	250	98,500		98,750
Issuance of stock options			640,000		640,000
Net loss for six months ended June 30, 2007				(3,453,128)	(3,453,128)
Balance at June 30, 2007	21,383,007	$ 213,830	$ 47,148,487	$ (40,239,900)	$ 7,122,417

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.

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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. Stock option activity for the six-month period ended June 30, 2007 is as follows:

	The Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2006	1,465,650	$ 0.71 – $3.59	$2.87	3.57
Granted	500,000	$ 3.90 – $7.14	$5.41	
Expired	202,500	$ 3.59	$3.59	
Exercised	901,850	$ 0.71 – $3.59	$2.55	
Outstanding at June 30, 2007	861,300	$ 1.03 – $7.14	$4.51	4.41

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. 9" ("FIN No. 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 consolidated 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

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Notes to Condensed Financial Statements

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 their balance sheet under the provisions of FIN No. 48. In addition, there is no impact to accumulated deficit at the date of adoption as a result of the implementation of FIN No. 48 and there is no interest or penalties accrued as management believes the Company has no uncertain tax positions at June 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.

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 is 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 1, "Description of Business," 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 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." 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 for inoperable primary liver cancer and adenocarcinomas and neuroendocrine cancers that have metastasized to the liver using Melphalan.

In 2006, we started enrolling and treating patients in a Phase III protocol 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.

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 Six Months Ended June 30, 2007

The Company has operated at a loss for its entire history. We had a net loss for the six months ended June 30, 2007, of $3,453,128, which is $703,271 more than the net loss from continuing operations for the same period in 2006. This increase is primarily due to 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 quite important in 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 from $1,652,517 during the six months ended June 30, 2006, to $1,573,284 for the six months ended June 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 in May and June 2007. Further, the cashless exercise of options by outgoing members of the Board of Directors resulted in additional charges to general operations.

During the six months ended June 30, 2007, we incurred $2,083,390 in research and development costs, as compared to $1,401,857 during the first six 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 will hasten the progress toward final approval.

Interest income shown is from our money market accounts and certificate of deposit ("CD") investments. During the six months ended June 30, 2007, the Company had interest income of $203,546, as compared to interest income of $304,517, or a 33.2% 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 six months ended June 30, 2007 or the comparable period in 2006.

Results of Operations for the Three Months Ended June 30, 2007

We had a net loss for the three months ended June 30, 2007, of $2,179,014, which is $613,295 more than the net loss from continuing operations for the same period in 2006. This increase is primarily due to expenses relating to the five-year CRADA extension discussed above.

General and administrative expenses decreased from $1,090,967 during the three months ended June 30, 2006, to $1,072,465 for the three months ended June 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 in May and June 2007. Further, the cashless exercise of options by outgoing members of the Board of Directors in April 2007 resulted in additional charges to general operations.

During the three months ended June 30, 2007, we incurred $1,194,439 in research and development costs, as compared to $635,217 during the corresponding period in 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 drug delivery system which management believes will hasten the progress toward final approval.

Interest income shown is from our money market accounts and CD investments. During the three months ended June 30, 2007, the Company had interest income of $87,890, as compared to interest income of $160,465 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 June 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. In addition, the Company intends to hire one additional employee.

At June 30, 2007, we had cash and cash equivalents of $6,416,755, as compared to $6,289,723 at December 31, 2006 and $6,512,798 at June 30, 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 six months ended June 30, 2007, we used $3,066,946 of cash in our operating activities. This amount compares to $1,781,405 used in our operating activities during the comparable six-month period in 2006. The increase of $1,285,541 was primarily due to payments to NCI as part of our newly extended

CRADA agreement, final payments to various parties as part of the settlements of the lawsuits that had commenced in 2006, and payments to various medical consultants to accelerate our 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. In the six months ended June 30, 2007, we received approximately $1.3 million on exercise of warrants and options.

While the Company has sufficient capital to conduct its operations through the end of 2007, it requires additional capital for research and development and for additional clinical trials. Accordingly, on May 25, 2007, the Company filed a Registration Statement on Form S-3 (the "Registration Statement") to register a "shelf" offering of common stock, preferred stock, debt securities, warrants, stock purchase contracts and stock purchase units, as may from time to time be issued, with a maximum offering price of $30,000,000, in order to raise additional funds. This Registration Statement became effective on June 7, 2007. However, there are no assurances that the Company will successfully consummate any transactions under the offerings, nor can the Company estimate when, if such offerings are successful, these offerings may close and capital will become available to the Company. If the offerings are successful, the Company intends to use the funds raised for research and development, furthering our clinical trials, FDA compliance, and general corporate purposes, including working capital.

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 six months ended June 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. 9" ("FIN No. 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 consolidated 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

benefits in their balance sheet under the provisions of FIN No. 48. In addition, there is no impact to accumulated deficit at the date of adoption as a result of the implementation of FIN No. 48 and there is no interest or penalties accrued as management believes the Company has no uncertain tax positions at June 30, 2007.

In December 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123R (revised 2004), Share-Based Payment (SFAS 123R) which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. SFAS 123R supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends SFAS No. 95, Statement of Cash Flows. Generally, the approach in SFAS No. 123R is similar to the approach described in SFAS No. 123. However, SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. The Company adopted SFAS 123R in 2006.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The Company does not use derivative financial instruments. 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 costs.

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.

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 were notified by the NASDAQ Capital Market on one occasion that we failed to meet the minimum bid price requirement and on two occasions that we did not meet the requirement that we meet one of the following conditions: that the market value of our Common Stock be at least $35 million; that we have stockholders' equity of not less than $2.5 million; or that we meet certain income tests. We have since complied 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 comply 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 (i.e., by 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

On June 5, 2007, the Company held its 2007 Annual Meeting of Stockholders. At the meeting, the stockholders voted on the election of the Company's two Class I directors to hold office until the Annual Meeting of Stockholders in 2010 and until their successors are duly elected and qualified.

The stockholders voted 17,777,337 shares in favor of electing Harold S. Koplewicz, MD to serve as a Class I director and withheld authority to vote 1,718,140 shares. The stockholders voted 17,751,701 shares in favor of electing Robert B. Ladd to serve as a Class I director and withheld authority to vote 1,743,776 shares.

Each of the Company's other directors, Richard L. Taney and Samuel Herschkowitz, MD, Class II directors, and Dr. Laura A. Philips and Jonathan J. Lewis, MD, Class III directors, is currently serving a term of office that continued after the meeting. The term of office for the Class II and Class III directors will continue until the Annual Meeting of the Company's Stockholders in 2008 and 2009, respectively.

In addition, the stockholders voted on a proposal to ratify the Board's selection of Carlin, Charron, & Rosen, LLP as the Company's independent auditors for the fiscal year ending December 31, 2007. Votes *for* the proposal to ratify the Company's independent auditors were 17,879,848; votes *against* the proposal were 1,530,132; and votes *abstaining* were 85,497.

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

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.

SIGNATURES

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

August 9, 2007

DELCATH SYSTEMS, INC.
(Registrant)

s/ Paul M. Feinstein
Paul M. Feinstein
Chief Financial Officer and Treasurer (on behalf of the registrant and as the principal financial and accounting officer of the registrant)

EXHIBIT INDEX

No.	Description
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