

DELCATH SYSTEMS INC  
Form 10-Q  
November 09, 2011

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, 2011.

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

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

Commission File Number: 001-16133

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

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

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

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

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

Yes  No

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

Yes  No

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

Large accelerated

Accelerated filer

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filer

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

Smaller reporting company

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

As of August 7, 2011, 47,994,732 shares of the Company's common stock, \$0.01 par value were outstanding.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

DELCATH SYSTEMS, INC.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

PART I:  
FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Condensed Consolidated Balance Sheets  
(Unaudited)

|  | September 30,<br>2011 | December 31,<br>2010 |
|--|-----------------------|----------------------|
| Assets:  |                       |                      |
| Current assets   |                       |                      |
| Cash and cash equivalents  | \$ 40,962,993         | \$ 45,621,453        |
| Investments – Certificates of deposit  | 3,735,000             | 1,492,000            |
| Prepaid expenses and other assets  | 1,028,902             | 1,784,276            |
| Total current assets   | 45,726,895            | 48,897,729           |
| Property, plant and equipment  |                       |                      |
| Land   | 154,224               | -                    |
| Furniture and fixtures   | 2,067,289             | 669,296              |
| Computers and equipment  | 1,089,398             | 548,586              |
| Leasehold improvements   | 1,121,366             | 939,518              |
|  | 4,432,277             | 2,157,400            |
| Less: accumulated depreciation   | (1,200,798)           | (477,420)            |
| Property, plant and equipment, net   | 3,231,479             | 1,679,980            |
| Total assets   | \$ 48,958,374         | \$ 50,577,709        |
| Liabilities and Stockholders' Equity:  |                       |                      |
| Current liabilities  |                       |                      |
| Accounts payable   | \$ 657,929            | \$ 610,457           |
| Accrued expenses   | 4,377,291             | 2,581,853            |
| Warrant liability  | 3,140,996             | 18,005,014           |
| Total current liabilities  | 8,176,216             | 21,197,324           |
| Deferred revenue   | 300,000               | 300,000              |
| Commitments and contingencies  | -                     | -                    |
| Stockholders' equity   |                       |                      |
| Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding   | -                     | -                    |
| Common stock, \$.01 par value; 70,000,000 shares authorized; 48,232,774 and 43,028,146 shares issued and 47,993,732 and 42,932,460 outstanding at September 30, 2011 and December 31, 2010, respectively | 482,328               | 430,281              |
| Additional paid-in capital   | 171,762,847           | 144,782,807          |
| Deficit accumulated during the development stage   | (131,671,714)         | (116,055,400)        |
| Treasury stock, at cost; 28,100 shares at September 30, 2011 and December 31, 2010   | (51,103)              | (51,103)             |
| Accumulated other comprehensive loss   | (40,200)              | (26,200)             |
| Total stockholders' equity   | 40,482,158            | 29,080,385           |
| Total liabilities and stockholders' equity   | \$ 48,958,374         | \$ 50,577,709        |

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Condensed Consolidated Statements of Operations and Comprehensive Income  
(Unaudited)

|  | Three Months Ended |               | Nine Months Ended |                | Cumulative      |
|--|--------------------|---------------|-------------------|----------------|-----------------|
|  | September 30,      |               | September 30,     |                | from            |
|  | 2011               | 2010          | 2011              | 2010           | Inception       |
|  |                    |               |                   |                | (Aug 5, 1988)   |
|  |                    |               |                   |                | to              |
|  |                    |               |                   |                | September 30,   |
|  |                    |               |                   |                | 2011            |
| Costs and expenses:  |                    |               |                   |                |                 |
| General and administrative expenses  | \$5,744,142        | \$3,165,414   | \$15,148,228      | \$9,413,709    | \$55,013,310    |
| Research and development costs   | 6,437,186          | 4,256,048     | 15,333,306        | 11,800,267     | 71,923,470      |
| Total costs and expenses   | 12,181,328         | 7,421,462     | 30,481,534        | 21,213,976     | 126,936,780     |
| Operating loss   | (12,181,328)       | (7,421,462)   | (30,481,534)      | (21,213,976)   | (126,936,780)   |
| Change in fair value of warrant liability, net                                   | 3,871,727          | (2,111,543)   | 14,864,018        | (10,164,567)   | (5,834,584)     |
| Interest income  | 537                | 2,949         | 1,202             | 6,824          | 2,872,481       |
| Other income and interest expense  | -                  | -             | -                 | -              | (274,226)       |
| Net loss   | (8,309,064)        | (9,530,056)   | (15,616,314)      | (31,371,719)   | (130,173,109)   |
| Other comprehensive income (loss)  | (3,000)            | (3,000)       | (14,000)          | (4,000)        | (40,200)        |
| Total comprehensive loss   | \$(8,312,064)      | \$(9,533,056) | \$(15,630,314)    | \$(31,375,719) | \$(130,213,309) |
| Common share data:   |                    |               |                   |                |                 |
| Basic and diluted loss per share   | \$(0.18)           | \$(0.24)      | \$(0.35)          | \$(0.83)       |                 |
| Weighted average number of shares of common stock outstanding, basic and diluted |                    |               |                   |                |                 |
|  | 46,961,123         | 39,712,207    | 44,315,838        | 37,703,577     |                 |

See accompanying notes to condensed consolidated financial statements.

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DELCATH SYSTEMS, INC.  
(A Development Stage Company)

Condensed Consolidated Statements of Cash Flows  
(Unaudited)

|   | Nine Months Ended<br>September 30, |                 | Cumulative<br>from inception<br>(Aug. 5, 1988)<br>to<br>September 30,<br>2011 |
|---|------------------------------------|-----------------|---|
|   | 2011                               | 2010            |   |
| Cash flows from operating activities:                                       |                                    |                 |   |
| Net loss  | \$ (15,616,314)                    | \$ (31,371,719) | \$ (130,173,109)  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                    |                 |   |
| Stock option compensation expense   | 2,920,648                          | 2,667,275       | 13,698,907  |
| Restricted stock and warrant compensation expense                           | 437,503                            | 1,272,047       | 3,993,450   |
| Depreciation expense  | 723,379                            | 318,886         | 1,255,413   |
| Amortization of organization costs  | -                                  | -               | 42,165  |
| Loss on disposal of furniture and fixtures                                  | -                                  | 6,730           | 10,172  |
| Warrant liability fair value adjustment                                     | (14,864,018)                       | 10,164,567      | 5,834,584   |
| Non-cash interest income  | (533)                              | (4,467)         | (12,268)  |
| Changes in assets and liabilities:  |                                    |                 |   |
| Decrease (increase) in prepaid expenses and other assets                    | 741,907                            | (211,149)       | (1,018,538)   |
| Increase (decrease) in accounts payable and accrued expenses                | 1,842,910                          | (42,186)        | 5,035,220   |
| Deferred revenue  | -                                  | 300,000         | 300,000   |
| Net cash used in operating activities                                       | (23,814,518)                       | (16,900,016)    | (101,034,004)   |
| Cash flows from investing activities:                                       |                                    |                 |   |
| Purchase of property, plant and equipment                                   | (2,274,877)                        | (1,341,930)     | (4,497,264)   |
| Proceeds from sale of equipment   | -                                  | -               | 200   |
| Purchase of short-term investments  | (3,735,000)                        | (3,235,000)     | (48,381,452)  |
| Purchase of marketable equity securities                                    | -                                  | -               | (46,200)  |
| Proceeds from maturities of short-term investments                          | 1,492,000                          | 747,000         | 44,654,356  |
| Organization costs  | -                                  | -               | (42,165)  |
| Net cash used in investing activities                                       | (4,517,877)                        | (3,829,930)     | (8,312,525)   |
| Cash flows from financing activities:                                       |                                    |                 |   |
| Net proceeds from sale of stock and exercise of stock options and warrants  | 23,673,935                         | 37,008,746      | 149,155,196   |
| Repurchases of common stock   | -                                  | -               | (51,103)  |
| Dividends paid on preferred stock   | -                                  | -               | (499,535)   |
| Proceeds from short-term borrowings   | -                                  | -               | 1,704,964   |
| Net cash provided by financing activities                                   | 23,673,935                         | 37,008,746      | 150,309,522   |
| (Decrease) increase in cash and cash equivalents                            | (4,658,460)                        | (16,278,800)    | 40,962,993  |
| Cash and cash equivalents at beginning of period                            |                                    |                 |   |