DELCATH SYSTEMS INC Form 10-Q November 02, 2010

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, 2010.

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) Identification No.)

810 Seventh Avenue, Suite 3505, New York, New York 10019

(Address of principal executive offices)

(212) 489-2100

(Registrant's telephone number, including area code)

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

Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T

during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o No o

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

Large accelerated filer o

Accelerated filer x

Non-accelerated filer o

Smaller reporting company o

(Do not check if a 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 o

No x

As of **, ** shares of the Company's common stock, \$0.01 par value were outstanding.

DELCATH SYSTEMS, INC. (A Development Stage Company)

DELCATH SYSTEMS, INC.

Index

| | | Page | | | |
|-------------------------------|---|------|--|--|--|
| Part I: FINANCIAL INFORMATION | | | | | |
| Item 1. | Condensed Financial Statements (Unaudited) | 1 | | | |
| | Management's Discussion and Analysis of | | | | |
| Item 2. | Financial Condition and Results of Operations | 2 | | | |
| | Quantitative and Qualitative Disclosures about | | | | |
| Item 3. | Market Risk | 7 | | | |
| Item 4. | Controls and Procedures | 7 | | | |
| | | | | | |
| PART II: OTHER IN | FORMATION | 9 | | | |
| Item 1. | Legal Proceedings | 9 | | | |
| Item 1A. | Risk Factors | 9 | | | |
| | Unregistered Sales of Equity Securities and Use | | | | |
| Item 2. | of Proceeds | 9 | | | |
| Item 3. | Defaults upon Senior Securities | 9 | | | |
| Item 5. | Other Information | 9 | | | |
| Item 6. | Exhibits | 9 | | | |
| SIGNATURES | | 10 | | | |

DELCATH SYSTEMS, INC. (A Development Stage Company)

PART I:

FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited)

Index to Financial Statements

| | Page |
|--|-----------|
| Condensed Balance Sheets | |
| September 30, 2010 and December 31, 2009 | F-1 |
| | |
| Condensed Statements of Operations | |
| for the Three and Nine Months Ended September 30, 2010 and 2009 and Cumulative from Inception | |
| (August 5, 1988) to September 30, 2010 | F-2 |
| | |
| Condensed Statements of Cash Flows | |
| for the Nine Months Ended September 30, 2010 and 2009 and Cumulative from Inception (August 5, | |
| 1988) to September 30, 2010 | F-3 |
| | |
| Notes to Condensed Financial Statements | F-4 - F-8 |
| | |
| | |
| 1 | |
| | |

DELCATH SYSTEMS, INC. (A Development Stage Company)

Condensed Balance Sheets (Unaudited)

| | September 30, 2010 | | | December 31, 2009 | | |
|---|--------------------|--------------|----|-------------------|--------------|--|
| Assets: | | | | | | |
| Current assets | | | | | | |
| Cash and cash equivalents | \$ | 51,765,119 | | \$ | 35,486,319 | |
| Investments – CDs | | 2,488,000 | | | _ | |
| Prepaid expenses and other assets | | 1,011,033 | | | 799,416 | |
| Total current assets | | 55,264,152 | | | 36,285,735 | |
| Property, plant and equipment | | | | | | |
| Furniture and fixtures | \$ | 529,051 | | \$ | 36,800 | |
| Computers and equipment | | 493,373 | | | 78,063 | |
| Leasehold improvements | | 839,212 | | | 431,425 | |
| | | 1,861,636 | | | 546,288 | |
| Less: accumulated depreciation | | (324,016 |) | | (24,982) | |
| Property, plant and equipment, net | | 1,537,620 | | | 521,306 | |
| Total assets | \$ | 56,801,772 | | \$ | 36,807,041 | |
| | | | | | | |
| Liabilities and Stockholders' Equity: | | | | | | |
| Current liabilities | | | | | | |
| Accounts payable and accrued expenses | \$ | 1,799,294 | | \$ | 1,841,480 | |
| Warrant liability | | 12,829,844 | | | 11,207,214 | |
| Total current liabilities | | 14,629,138 | | | 13,048,694 | |
| | | | | | | |
| Deferred revenue | | 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; 42,893,163 | | | | | | |
| and 36,223,097 shares issued and 42,865,063 and 36,194,997 outstanding at | | | | | | |
| September 30, 2010 and December 31, 2009, respectively | | 428,932 | | | 362,231 | |
| Additional paid-in capital | | 142,258,478 | | | 92,835,174 | |
| Deficit accumulated during the development stage | | (100,743,473 | 3) | | (69,371,755) | |
| Treasury stock, at cost; 28,100 shares at September 30, 2010 and December | | | | | | |
| 31, 2009 | | (51,103 |) | | (51,103) | |
| Accumulated other comprehensive loss | | (20,200 |) | | (16,200) | |
| Total stockholders' equity | | 41,872,634 | | | 23,758,347 | |
| Total liabilities and stockholders' equity | \$ | 56,801,772 | | \$ | 36,807,041 | |

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC. (A Development Stage Company)

Condensed Statements of Operations and Comprehensive Income

(Unaudited)

| | | | | | | | | Cυ | mulative from |
|----------------------------|------------------|------|------|-------------|--------------------|------|--------------|----|---------------|
| | | | | | | | | | Inception |
| | | | | | | | | (. | Aug 5, 1988) |
| | Three M | ontl | hs : | Ended | Nine Mon | ths | Ended | | to |
| | Septe | emb | er i | 30, | Septem | ıber | 30, | S | eptember 30, |
| | 2010 | | | 2009 | 2010 | | 2009 | | 2010 |
| Costs and expenses: | | | | | | | | | |
| General and | | | | | | | | | |
| administrative expenses | \$ 3,165,414 | | \$ | 1,430,990 | \$ 9,413,709 | \$ | 2,152,331 | \$ | 36,091,513 |
| Research and | | | | | | | | | |
| development costs | 4,256,048 | | | 2,327,167 | 11,800,267 | | 5,983,392 | | 50,834,733 |
| Total costs and expenses | \$ 7,421,462 | | \$ | 3,758,157 | \$ 21,213,976 | \$ | 8,135,723 | \$ | 86,926,246 |
| Operating loss | (7,421,462 |) | | (3,758,157) | (21,213,976) | | (8,135,723) | | (86,926,246) |
| Change in fair value of | | | | | | | | | |
| warrant liability, net | (2,111,543 |) | | (3,830,801) | (10,164,567) | | (8,296,958) | | (14,911,801) |
| Interest income | 2,949 | | | 3,054 | 6,824 | | 71,982 | | 2,867,405 |
| Other income | - | | | - | - | | 1,689 | | (102,753) |
| Interest expense | - | | | - | - | | - | | (171,473) |
| Net loss | (9,530,056 |) | | (7,585,904) | (31,371,719) | | (16,359,010) | | (99,244,868) |
| Other comprehensive | | | | | | | | | |
| income (loss) | (3,000 |) | | (8,000) | (4,000) | | 6,000 | | (20,200) |
| Total comprehensive loss | \$ (9,533,056 |) | \$ | (7,593,904) | \$ (31,375,719) | \$ | (16,353,010) | \$ | (99,265,068) |
| Common share data: | | | | | | | | | |
| Basic and diluted loss per | | | | | | | | | |
| share | \$ (0.24 |) | \$ | (0.29) | \$ (0.83) | \$ | (0.64) | | |
| | | | | | | | | | |
| Weighted average number | | | | | | | | | |
| of shares of common | | | | | | | | | |
| stock outstanding | 39,712,207 | | | 26,337,717 | 37,703,577 | | 25,753,795 | | |
| _ | | | | | | | | | |

See accompanying notes to condensed financial statements.

F-2

DELCATH SYSTEMS, INC. (A Development Stage Company)

Condensed Statements of Cash Flows

(Unaudited)

Cumulative from

inception (Aug. 5,

1988)

Nine Months Ended to September September 30, 30, 2010 2009 2010

Cash flows from

operating activities:

Net loss \$(31,371,719) \$(16,359,010) \$(99,244,869)

Adjustments to reconcile net loss to net cash used in

to net cash used operating activities:

Stock option compensation

 expense
 2,667,275
 502,534
 9,606,214

 Stockcompensation
 1,272,047
 225,083
 3,152,741

expense

Internet and Telephone Instructions

The methods below are quick, easy and available 24 hours a day, 7 day

If you vote by phone or Internet, have this proxy card in hand when you vo

To vote using the te

(within the U.S. and

Call toll free 1-888-266-6795 prior to 12:00 midnight, Eastern time, Ma

| Option 1: To vote as the Board of Directors recommends on ALL proposal 1. |
|--|
| Option 2: If you choose to vote upon each proposal separately, press 0 and |
| |
| |
| |
| |
| CONTROL NUMBER |
| |
| |
| |
| 6230 Intel Corp. |
| |
| |
| |
| |
| |
| |

| [INTEL LOGO] |
|--|
| o Mark this box with an X if you have n |
| Annual Meeting Proxy Card Please mark vote in box in the following manner using dark ink only The Board of Directors recommends a vote FOR the liste |
| 1. Election of Directors 01 - Craig R. Barrett |
| 02 - John P. Browne |
| 03 - Winston H. Chen |
| 04 - Andrew S. Grove |
| 05 - D. James Guzy |
| 06 - Reed E. Hunt |
| 07 - Paul S. Otellini |
| |

08 - David S. Pottruck

| ů ů | |
|-----|--|
| | 09 - Jane E. Shaw |
| | 10 - David B. Yoffie |
| | 11 - Charles E. Young |
| | PLEASE REFER TO THE REVERSE SIDE FOR INTERNET AND Authorized Signatures - Sign Here - This section must be completed for NOTE: Please sign exactly name appears hereon. For joint accounts both of Signature 1 |
| | 6230 Intel Corp. |
| | |
| | |
| | |
| | |
| | |
| | |

QuickLinks

Notice of Annual Stockholders' Meeting May 22, 2002 10:00 a.m. Pacific Time TABLE OF CONTENTS
PROXY STATEMENT

PROPOSAL 1: ELECTION OF DIRECTORS

PROPOSAL 2: RATIFICATION OF SELECTION OF INDEPENDENT AUDITORS