# 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 х

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.

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).

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Large accelerated filer o Accelerated filer x Non-accelerated filer o (Do not check if a smaller reporting company) Smaller reporting company o

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

As of August 7, 2011, 47,994,732 shares of the	e Company's common stoc	ck, \$0.01 par value w	ere outstanding.
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Yes x No o

Yes o No o

Yes o No x

# DELCATH SYSTEMS, INC.

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# PART I:

# FINANCIAL INFORMATION

# Item 1. Condensed Consolidated Financial Statements (Unaudited)

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# Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2011				ecember 31, 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	¢		ሰ		
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)		(110,055,400) (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 Mon Septem	 Sinded		Nine Mon Septem		Lindea	(.	Cumulative from Inception Aug 5, 1988) to eptember 30,
		2011	2010	2011 2010			2010		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.

# **Condensed Consolidated Statements of Cash Flows**

	Nine Months Ended September 30, 2011 2010					Cumulative om inception ug. 5, 1988) to ptember 30, 2011
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:				<u> </u>		
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		45,621,453		35,486,319		
Cash and cash equivalents at end of period	\$	40.962.993	\$	51,765,119	\$	40,962,993
	Ψ	40,502,555	Ψ	51,705,115	Ψ	40,302,333
Supplemental cash flow information: Cash paid for interest	\$	-	\$	-	\$	171,473
Supplemental non-cash activities:	_		_			
Cashless exercise of stock options and shares withheld upon restricted stock vesting	\$	(61,031)	\$	424,332	\$	1,183,563
Fair value of warrants issued	\$		\$	-	\$	6,459,979
Fair value of warrants reclassified from liability to additional paid-in capital upon exercise	\$		\$	8,541,937	\$	9,153,567
rain value of warrains reclassified from hability to additional paid-in capital upon exercise	Э	-	Э	0,541,937	<b>э</b>	9,153,567

See accompanying notes to condensed consolidated financial statements.

#### Notes to Condensed Consolidated Financial Statements

### Note 1: Description of Business

Delcath Systems, Inc. is a development stage specialty pharmaceutical and medical device company focused on oncology. Delcath's proprietary system for chemosaturation is designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers. In 2010, Delcath concluded a Phase III metastatic melanoma study, and the Company recently completed a multi-arm Phase II trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Hepatic CHEMOSAT delivery system in April 2011. The Company has not yet received FDA approval for commercial sale of its system in the United States.

#### Note 2: Consolidated Financial Statements

The unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2011 and 2010 and Cumulative from Inception (August 5, 1988) to September 30, 2011 include the accounts of Delcath Systems, Inc. and its wholly owned subsidiary, Delcath Systems Limited (collectively, the "Company").

#### Note 3: Basis of Financial Statement Presentation

The accompanying condensed consolidated financial statements are unaudited and were prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The preparation of financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company's financial statements. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amount of expenses reported for each of its periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, income taxes and research and development costs. Such assumptions and estimates are subject to change in the future as additional information becomes available or as circumstances are modified. Actual results could differ from these estimates.

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The unaudited interim condensed consolidated financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the Company's results of operations, financial position and cash flows for the interim periods ended September 30, 2011 and 2010, and cumulative from inception (August 5, 1988) to September 30, 2011.

The results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These interim financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2010, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2010 as filed with the Securities and Exchange Commission (the "SEC") on March 8, 2011 (the "2010 Form 10-K").

#### **Summary of Significant Accounting Policies**

The Company describes its significant accounting policies in Note 1 to the Company's Financial Statements contained in its Annual Report on Form 10-K for the fiscal year ended December 31, 2010. There were no significant changes in the Company's accounting policies since the end of fiscal 2010.

#### **Research and Development Costs**

Research and development costs include the costs of materials, personnel, outside services and applicable indirect costs incurred in development of the Company's proprietary drug delivery system. All such costs are charged to expense when incurred.

#### General and Administrative Costs

General and administrative costs include salaries and related expenses for the Company's executive and administrative staff, recruitment and employee retention expenses, professional license and organizational fees, business development and certain general legal activities.

#### Investments

Management determines the appropriate classification of securities at the time of purchase and reevaluates such classification as of each balance sheet date. The Company's securities are classified as either available-for-sale or held-to-maturity. Investments classified as held-to-maturity are stated at amortized cost. Investments classified as available-for-sale are stated at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity.



#### **Deferred Revenue Recognition**

Deferred revenue on the accompanying balance sheets includes payment received upon execution of a research and distribution agreement with Chi-Fu Trading Co, Ltd. The Company will amortize deferred revenue over the expected obligation period of the agreement once this amount is reasonably determinable.

#### Note 4: Recent Accounting Pronouncements

In June 2011, the FASB issued authoritative guidance aimed at increasing the prominence of items reported in other comprehensive income in the financial statements. This guidance requires companies to present comprehensive income in a single statement below net income or in a separate statement of comprehensive income immediately following the income statement. Companies will no longer be allowed to present comprehensive income on the statement of changes in shareholders' equity. In both options, companies must present the components of net income, total net income, the components of other comprehensive income and total comprehensive income. This guidance will become effective for fiscal years and interim periods beginning after December 15, 2011 and will require retrospective application for all periods presented. The adoption of this guidance may impact the presentation of the company's condensed consolidated financial statements, but it will not change the items that must be reported in other comprehensive income must be reclassified to net income.

In May 2011, the FASB provided amendments to achieve a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. The amendments change certain fair value measurement principles and enhance the disclosure requirements particularly for Level 3 fair value measurements. These amendments will be effective prospectively for interim and annual periods beginning after December 15, 2011. The Company is currently evaluating the impact of adopting these amendments, but currently believes there will be no significant impact on its condensed consolidated financial statements.

#### **Note 5: Stock Incentive Plans**

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 3,000,000, and 4,200,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. A stock option grant allows the holder of the option to purchase a share of the Company's common stock in the future at a stated price. The Plans are administered by the Compensation and Stock Option Committee of the board of directors which determines the individuals to whom awards shall be granted as well as the type, terms and conditions of each award, the option price and the duration of each award.

#### Stock Options

During 2004 and 2009, respectively, the 2004 and 2009 Stock Incentive Plans became effective. Options granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee and expire over varying terms, but not more than ten years from the date of grant. Stock option activity for the nine month period ended September 30, 2011 is as follows:

	The Plans							
	Stock Options	Exercise Price per Share	ŀ	Veighted Average rcise Price	Weighted Average Remaining Life (Years)			
Outstanding at December 31, 2010	3,760,650	\$ 1.23 - \$15.54	\$	4.88	6.65			
Granted	648,591	3.46 – 9.18		6.52				
Forfeited	(136,900)	1.40 - 9.93		4.65				
Exercised	(45,327)	2.44 - 3.28		3.18				
Outstanding at September 30, 2011	4,227,014	\$ 1.23 - \$15.54	\$	5.05	6.42			



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For the three and nine months ended September 30, 2011, the Company recognized stock option compensation expense of \$403,350 and \$2,210,535 respectively, relating to options granted in previous years and \$308,951 and \$710,113 respectively, relating to options granted during 2011, for a total of \$712,301 and \$2,920,648, respectively.

For the three and nine months ended September 30, 2010, the Company recognized stock option compensation expense of \$1,124,590 and \$2,667,275, respectively.

The Company uses an option pricing model to determine the fair value of stock options awarded to employees on the date of grant. The Company has expensed its stock-based compensation for share-based payments granted under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company accounts for stock-based compensation expense for non-employees using the fair-value method which requires the award to be re-measured at each reporting date until the award is vested. The Company estimates the fair value using an option pricing model. The Company has expensed its share-based compensation for non-employees under the ratable method.

The assumptions used in the option pricing model to determine the fair value of stock options awarded to employees are as follows:

	Nine Months Ende	ed September 30,
	2011	2010
Dividend yield	None	None
Expected volatility	73.88% - 79.11%	72.16% - 75.35%
Weighted average volatility	74.55%	73.62%
Risk-free interest rates	1.13% - 2.54%	1.45% - 3.11%
Expected life (in years)	5.0 - 6.0	5.0 - 6.0

#### **Restricted Stock**

For the three and nine months ended September 30, 2011, the Company recognized compensation expense of \$19,863 and \$133,033 respectively, relating to restricted stock granted in previous years. For the three and nine months ended September 30, 2011, the Company recognized \$164,461 and \$304,470 respectively, relating to restricted stock granted during 2011, for a total of \$184,324 and \$437,503, respectively.

For the three and nine months ended September 30, 2010, the Company recognized restricted stock compensation expense of \$251,849 and \$1,272,347, respectively.

#### Note 6: Assets and Liabilities Measured at Fair Value

#### **Derivative warrant liability**

The Company allocated part of the proceeds of a private placement and a public offering of the Company's common stock to warrants issued in connection with such transactions. The Company determined that these warrants should be classified as liabilities rather than equity. The valuation of the warrants is determined using an option pricing model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrant derivative liability should be classified within Level 3 of the fair-value hierarchy by evaluating each input for the model against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in FASB ASC 820-10-35. There are six inputs: the closing price of the Company's common stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath's stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of not granting dividends. The closing price of the Company's common stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (FASB ASC 820-10-35-40). The riskless rate of return is a Level 2 input as defined in FASB ASC 820-10-35-48, while the historical volatility is a Level 3 input as defined in FASB ASC 820-10-35-22. Since the lowest level input is a Level 3, the Company determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants" and together with the 2009 Warrants, the "Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of \$13.3 million in this transaction. The Company allocated \$4.3 million of the total proceeds to 2007 Warrants (see below). The 2007 Warrants were initially exercisable at \$4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at \$3.44 per share with 1,469,456 warrants outstanding at September 30, 2011. The shares were issued pursuant to an effective registration statement on Form S-3.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received gross proceeds of \$3.0 million, with net cash proceeds after related expenses from this transaction of approximately \$2.67 million. Of those proceeds, the Company allocated an estimated fair value of \$2.2 million to the 2009 Warrants (see below), resulting in net proceeds of \$476,255. The 2009 Warrants are currently exercisable at \$3.60 per share with 1,043,478 warrants outstanding at September 30, 2011 and have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

The \$2.2 million in proceeds allocated to the 2009 Warrants and the \$4.3 million in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the nine month period ended September 30, 2011, the Company recorded pre-tax derivative instrument income of \$14.9 million. The resulting derivative instrument liabilities totaled \$3.1 million at September 30, 2011, as compared to \$18.0 million at December 31, 2010. The fair value of the Warrants at September 30, 2011 was determined by using the Black-Scholes model assuming a risk free interest rate of 0.37% for the 2009 Warrants and 0.13% for the 2007 Warrants, volatility of 84.35% for the 2009 Warrants and 76.69% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 for the 2009 Warrants and September 2012 for the 2007 Warrants).

Management believes that the possibility of an actual cash settlement with a warrant holder is quite remote, and expects that the Warrants will either be exercised or expire worthless, at which point the then existing warrant liability will be credited to stockholders' equity when exercised or recorded through earnings if allowed to expire worthless.

#### **Money Market Funds**

Cash and cash equivalents includes a money market account valued at \$39.4 million.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2011, aggregated by the level in the fair value hierarchy within which those measurements fall:

## Assets and Liabilities Measured at Fair Value on a Recurring Basis at September 30, 2011

Assets		Level 1		Level 2	 Level 3		Balance at ptember 30, 2011
Marketable equity securities	\$	6,000	\$	-	\$ -	\$	6,000
Money market funds		39,364,650	•	-	-	-	39,364,650
Total Assets	\$	39,370,650	\$	-	\$ -	\$	39,370,650
Liabilities	_						
Warrant liability	\$	-	\$	-	\$ 3,140,996	\$	3,140,996
Total Liabilities	\$	-	\$	-	\$ 3,140,996	\$	3,140,996
			_				

## Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Wa	arrant Liability
Beginning balance	\$	18,005,014
Total decrease in the liability included in earnings		(14,864,018)
Ending balance	\$	3,140,996

#### Note 7: Net Loss

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. For the periods presented, basic and diluted net loss per common share are identical. Potentially dilutive securities from stock options and warrants would be antidilutive as the Company incurred a net loss. The number of shares of common stock potentially issuable at September 30, 2011 and 2010 upon exercise or conversion that were not included in the computation of net loss per share totaled 6,739,948 and 6,332,313 shares, respectively.

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#### Note 8: Taxes

The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to U.S. federal income tax as well as income tax of certain state jurisdictions. The Company has not been audited by the United States Internal Revenue Service (the "IRS") or any states in connection with income taxes. The periods from December 31, 2004 to December 31, 2010 remain open to examination by the IRS and state authorities. Also note that for federal and state purposes, the tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

For the nine months ended September 30, 2011, the Company recorded a state capital tax benefit of \$187,500. This benefit is a result of State of New York legislation, which allows companies to obtain cash refunds from the State of New York at a rate of 100% of their annual research and development expense credits, limited to \$250,000 per year. Since this is not an income tax benefit, it is reflected as a component of general and administrative expenses.

#### **Note 9: Subsequent Events**

On October 26, 2011, Delcath Systems, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has responded to the Company's request made in September for a pre-New Drug Application (NDA) meeting and has scheduled a date in mid-January 2012.



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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited interim condensed consolidated financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto as of and for the year ended December 31, 2010 included in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC to provide an understanding of our results of operations, financial condition and cash flows.

### Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, including the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section, contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (the "Exchange Act"). These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in the Company's Annual Report on Form 10-K in Item 1A under "Risk Factors" as well as in this report under "risk Factors" in Part II, Item 1A and Part I, Item 3 "Qualitative and Quantitative Disclosures About Market Risk". These forward-looking statements include, but are not limited to, statements about:

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

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

#### Overview

The following section should be read in conjunction with Part I, Item 1: Condensed Consolidated Financial Statements of this report and Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's Annual Report on Form 10-K.

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology, initially cancers in the liver. Since our inception, the Company has directed its research efforts towards the development and clinical study of the Delcath chemosaturation system.

The Delcath chemosaturation system allows the administration of concentrated regional chemotherapy by isolating the circulatory system of the targeted organ. Once the organ is isolated, the Delcath chemosaturation system delivers high doses of chemotherapy agents, currently melphalan hydrochloride, or melphalan, directly to the liver, while limiting systemic exposure and the related side effects by filtering the blood prior to returning it to the patient. The procedure is minimally invasive and repeatable allowing for multiple courses of treatment with chemotherapeutic drugs. We believe that the Delcath chemosaturation system is a platform technology that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body.

#### **Product Development**

The Company is developing a second generation chemosaturation system featuring higher efficiency filtration cartridges. We believe the improved filter will help to further minimize a patient's systemic exposure to the chemotherapeutic agent, melphalan hydrochloride, and may offer the patient and the physician a variety of additional benefits including reduced patient recovery times, the ability to use concominant therapies and the expanded ability for additional beneficial treatments using the system. The second generation chemosaturation system contains several modified features intended to help improve the ease of use by a physician by providing the cartridges in an easy mount system. This second generation product is expected to receive CE Mark and be available for commercial distribution in Europe in 2012.

#### **European Market Commercialization**

On April 13, 2011, we obtained the right to affix the CE Mark to the Delcath chemosaturation system featuring the first generation filtration cartridges. The right to affix the CE Mark allows us to market and sell the Delcath chemosaturation system ("ChemoSAT") in the European Economic Area (EEA). In the EEA, the Delcath chemosaturation system is regulated as a medical device indicated for the intra-arterial administration of a chemotherapeutic agent, melphalan, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote the Delcath chemosaturation system is limited to this approved indication. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the Delcath chemosaturation system and must use melphalan independently at their discretion.

We believe the Delcath chemosaturation system may ultimately fulfill an annual unmet clinical need for as many as 100,000 liver cancer patients in the EEA. We intend to focus our initial efforts on six target markets including Germany, United Kingdom, France, Netherlands, Italy and Spain. We believe these countries represent approximately 70% of the total potential liver cancer market in EEA countries. We entered into a long term lease to establish our European headquarters in Galway, Ireland and formed Delcath Systems, Limited, an Irish company under which we will establish European operations. We have initiated the renovation of our facility in Galway. We are actively recruiting for our European operations and have begun to hire key employees in specific countries in Europe. We plan to utilize third-party contract sales organizations and a direct sales force in the United Kingdom, Germany and the Netherlands and distributors in France, Italy and Spain. We are planning an initial launch and clinical training for the ChemoSAT system in select centers in Europe and, following the initial launch, intend to establish clinical training centers to educate and train physicians and healthcare payors in these countries in order to develop key opinion thought leadership and foster initial market acceptance.

#### **Clinical Trials**

The Company has completed a Phase III clinical trial using the Delcath chemosaturation system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver and a multi-arm Phase II clinical trial using the Delcath chemosaturation system with melphalan in patients with primary and metastatic liver cancer. Additionally, the Company plans to implement an Expanded Access Program (EAP) at several sites in the United States in early 2012.

Prior to initiating our Phase III clinical trial, we submitted a proposal for the clinical trial protocol's design, execution, and analysis under a Special Protocol Assessment (SPA). A SPA is an evaluation by the U.S. Food and Drug Administration (FDA), of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution, or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in a new drug application (NDA), without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins. We conducted our Phase III trial under a SPA.

In February 2010, we concluded a Phase III clinical trial for the Delcath chemosaturation system with melphalan in patients with metastatic ocular and cutaneous melanoma to the liver, which demonstrated a statistically significant improvement in hepatic progression-free survival (hPFS) compared to the best alternative care (BAC). Our Phase III trial successfully met the study's primary endpoint of extended hPFS. We recently announced updated results which include data from patients through March 2011, an additional 12 months of data maturation from our initial announcement. With respect to the study's primary endpoint of hPFS, the updated investigator-assessed results showed that patients in the chemosaturation arm demonstrated median hPFS of 8.0 months compared to 1.6 months in the BAC arm, a significant 6.4 month extension of hPFS. Median overall PFS in the chemosaturation arm was 6.7 months compared to 1.6 months in the BAC arm, an increase of 5.1 months. An analysis of survival trends by patient cohorts indicated that patients treated with chemosaturation, including crossover patients, had a median survival of 11.4 months compared to 4.1 months for BAC patients who did not receive chemosaturation. As of June 30, 2011, 11 patients treated with chemosaturation were still alive compared to two patients in the BAC arm who did not receive chemosaturation.

In addition, we completed a multi-arm Phase II clinical trial of the Delcath chemosaturation system with melphalan in patients with primary and metastatic liver cancer. The Phase II clinical trial included four patient cohorts: hepatobiliary cancers, and metastatic cancers of neuroendocrine, ocular or cutaneous melanoma, and colorectal (adenocarcinoma) origins.

There were nine patients with tumors of hepatobiliary origin: five hepatocellular carcinomas (HCC) and four cholangiocarcinomas. HCC is the most common primary cancer of the liver, with approximately 500,000 new cases diagnosed worldwide annually. Both groups had positive efficacy signals. The responses were especially encouraging in the HCC cohort where all patients received confirmed partial response or durable stable disease.

In the Phase II trial's metastatic neuroendocrine (mNET) cohort, 24 patients with unresectable mNET in the liver underwent an average of three chemosaturation procedures. The primary endpoint of overall hepatic response rate (ORR) among the 20 evaluable patients was 70%, including one patient who presented with a confirmed complete response (CR) and 13 with confirmed partial responses (PR). Currently available treatment options for patients with unresectable neuroendocrine liver metastases have response rates around 5%. Four patients had stable disease (SD) and two progressed at their first evaluation, giving a tumor growth control rate of 90%. As for secondary endpoints, the median overall survival in all 24 patients (on an intent to treat or ITT basis) was reported as 30.4 months and the median hepatic progression-free survival (hPFS) was reported as 15.5 months.

In the Phase II trial's metastatic colorectal (adenocarcinoma) cohort, sixteen patients with very late stage colorectal cancer liver metastases were recruited into this arm. No significant responses were noted among these patients as they had been heavily pre-treated with numerous chemotherapeutic and regional modalities that, along with anatomical and disease-related factors in a few, prevented sufficient melphalan exposure. The predominant accrual of very late stage patients reflects the changing referral and treatment patterns at the NCI at the time that this study was conducted, but it was not a design feature of the study. We recently conducted *in vitro* experiments evaluating colorectal tumor cell lines that were exposed to melphalan at concentrations achieved during chemosaturation, which showed encouraging signals of cell-death induction. This, combined with published reports of demonstrated efficacy with high dose melphalan delivered with surgical isolation perfusion, has convinced us to continue to study the efficacy of our chemosaturation system in this patient population that currently has few treatment options

The safety profiles of the chemosaturation system in all four cohorts of the Phase II clinical trial were consistent with the Company's Phase III melanoma trial.

#### Regulatory

#### United States

Based on our Phase III results, we submitted our Section 505(b)(2) NDA, to the FDA in December 2010, seeking an indication for the percutaneous intraarterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver. In February 2011, we received a Refusal to File RTF letter (RTF), from the FDA for the NDA. The FDA will issue an RTF if it determines upon an initial review that the NDA is not sufficiently complete to permit a substantive review. Neither the acceptance nor non-acceptance of an NDA for filing is a determination of the ultimate approvability of the drug product at issue. The RTF represented a determination by the FDA that, based on its preliminary review, the NDA is not sufficiently complete to permit a substantive review. The RTF requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in order to allow the FDA to properly assess the risk-benefit profile of the product candidate. At this time, the FDA has not requested additional studies to be conducted. We have had subsequent communications with the FDA, including a meeting in early April 2011 to discuss the issues raised and to confirm our understanding of the additional information required by the FDA in order to permit a substantive review of the application upon resubmission, which includes additional hospitalization data and clarification of the safety data submitted in our initial NDA. We continue our efforts to prepare our resubmission to the FDA, including data gathering and remonitoring, in order to address the issues raised in the RTF. The FDA recently responded to our request for a pre-NDA meeting and we are scheduled to have a meeting with the FDA to discuss our application in mid-January 2012.

#### Other Markets

Since receiving the CE Mark for the ChemoSAT system, we have been begun the process of seeking regulatory approval in several other countries where we can leverage our CE Mark. We recently completed the product notification process with the Medicines and Medical Device Safety Authority in New Zealand which allows us to sell the ChemoSAT system in New Zealand and we expect to begin supplying the system through an authorized distributor in 2012. We have also completed our regulatory filings with the Australian Therapeutic Goods Administration and Singapore Health Sciences. We intend to file and seek regulatory approval in other markets in Asia, including Hong Kong and Korea, as well as China and Japan where local clinical trials may be required, and in Latin America and the Middle East.

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## **Results of Operations**

Since our inception we have raised approximately \$149.2 million (net of fundraising expenses). We have financed our operations primarily through public and private placements of equity securities. We have incurred net losses since we were founded and we expect to continue to incur significant and increasing net losses over the year. We expect that the amount of capital required for operations including efforts to commercialize the Delcath chemosaturation system in Europe, preparation of the Company's submission to the FDA, and continued research and development activities will continue to increase for the foreseeable future.

#### Three Months Ended September 30, 2011 and September 30, 2010

Delcath has operated at a loss for our entire history. The Company had a net loss for the three months ended September 30, 2011, of \$8.3 million, which is a \$1.2 million decrease in the net loss for the same period in 2010. The decrease in net loss is due to a \$6.0 million change in the fair value of the warrant liability, which was offset by an increase of \$4.8 million in operating costs.

The Company's operating loss for the three months ended September 30, 2011 was \$12.2 million, of which approximately \$900,000 is non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans as discussed in more detail in Note 5 of this filing. This compares to an operating loss for the three months ended September 30, 2010 of \$7.4 million, of which approximately \$1.4 million was non-cash expense related to stock option and restricted stock grants made under the Company's 2004 and 2009 Stock Option Plans.

The increase in total costs can be primarily attributed to the Company's growth, which has led to an increase in payroll and overhead expenses. At the end of the third quarter of 2011 the Company had 74 full-time employees compared to 44 at the end of the third quarter of 2010. Additionally, the Company's preparations for commercialization in Europe, continued expansion of research and development (R&D) activities and regulatory expenses related to our submission to the FDA has contributed to the increase in our total costs and expenses. We anticipate continued increases in our total costs and expenses as the Company continues to aggressively move forward with our commercialization and R&D plans.

General and administrative expenses increased to \$5.7 million for the three months ended September 30, 2011, from \$3.2 million for the three months ended September 30, 2010. The Company is continuing its progress in transitioning from a development stage company to a commercial enterprise with staff dedicated to commercializing the Delcath chemosaturation system. The increase in the Company's general and administrative expenses is commensurate with our increase in staffing, as well as our European commercialization efforts.

Research and development expenses increased to \$6.4 million for the three months ended September 30, 2011, from \$4.3 million during the three months ended September 30, 2010. The increase in expenses is primarily related to our expanded research and development activities and regulatory expenses related to our submission to the FDA.

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Interest income is generated from our money market account and certificates of deposit. During the three months ended September 30, 2011, the Company had interest income of \$537, as compared to \$2,949 for the same period in 2010. For the three months ended September 30, 2010, the Company earned interest from certificates of deposit which matured throughout 2010 and the first quarter of 2011, yielding lower interest income for the three months ended September 30, 2011.

#### Nine Months Ended September 30, 2011 and September 30, 2010

The Company had a net loss for the nine months ended September 30, 2011, of \$15.6 million, which is a \$16.2 million decrease in the net loss for the same period in 2010. The decrease in net loss is primarily due to a \$25.5 million change in the fair value of the warrant liability, which was offset by an increase of approximately \$9.3 million in total costs.

The Company's operating loss for the nine months ended September 30, 2011 was \$30.5 million, of which approximately \$3.4 million is non-cash expense related to stock option and restricted stock grants made under our 2004 and 2009 Stock Option Plans as discussed in more detail in Note 5 of this filing. This compares to an operating loss for the nine months ended September 30, 2010 of \$21.2 million, of which approximately \$3.9 million was non-cash expense related to stock option and restricted stock grants made under our 2004 and 2009 Stock Option Plans.

General and administrative expenses increased to \$15.1 million for the nine months ended September 30, 2011 from \$9.4 million for the nine months ended September 30, 2010. The Company is continuing its progress in transitioning from a development stage company to a commercial enterprise with staff dedicated to commercializing the Delcath chemosaturation system. The increase in the Company's general and administrative expenses is commensurate with our increase in staffing, as well as our European commercialization efforts.

Research and development expenses increased to \$15.3 million for the nine months ended September 30, 2011, from \$11.8 million during the first nine months of 2010. Our continued hiring has also contributed to an increase in research and development expenses. During 2010, the Company was incurring expenses related to wrapping up its Phase III clinical trial. The reduction in trial related expenses during 2011 was more than offset by an increase in expenses related to our expanded research and development activities and regulatory expenses related to our submission to the FDA.

Interest income is generated from our money market account and certificates of deposit. During the nine months ended September 30, 2011, the Company had interest income of \$1,202, as compared to \$6,824 for the same period in 2010. For the nine months ended September 30, 2010, the Company earned interest from certificates of deposit which matured throughout 2010 and the first quarter of 2011, yielding lower interest income for the nine months ended September 30, 2011.

#### Liquidity and Capital Resources

Our future results are subject to substantial risks and uncertainties. The Company has operated at a loss for its entire history and anticipates that losses will continue over the coming years. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its operating activities. Delcath's future liquidity and capital requirements will depend on numerous factors, including the progress of research and product development programs, obtaining regulatory approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments. The Company continues to move forward aggressively. As Delcath commences commercial sales and marketing activity in Europe and seeks FDA approval of the Delcath chemosaturation system in the U.S. we expect that both our expenses and capital expenditures will increase.

At September 30, 2011, we had cash and cash equivalents of \$41.0 million, as compared to \$51.8 million at September 30, 2010. Cash and cash equivalents does not include \$3.7 million invested in certificates of deposit at September 30, 2011 or \$2.5 million invested in certificates of deposit at September 30, 2011. During the nine months ended September 30, 2011, we used \$23.8 million of cash in our operating activities, which compares to \$16.9 million used in our operating activities during the comparable nine month period in 2010. The increase of \$6.9 million, or 40.9%, is primarily due to our preparations to commercialize the Delcath chemosaturation system, expenses related to our remonitoring efforts to prepare our submission to the FDA, as well as an increase in compensation related expenses as the Company grew from 44 employees at September 30, 2010 to 74 employees at September 30, 2011. The Company expects that our cash allocated to operating activities will continue to increase as we aggressively move forward with our commercialization plans for Europe and continue to incru regulatory expenses related to our submission to the FDA. The Company believes it has sufficient capital to fund our operating activities.

At September 30, 2011, the Company's accumulated deficit was approximately \$131.7 million. Because our business does not generate positive cash flow from operating activities, the Company may need to raise additional capital in order to fully commercialize our product or to fund development efforts. Delcath believes that we will be able to raise additional capital in the event that we find it in our best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of our capital stock, or entering into strategic alliances with appropriate partners. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to our cash requirements may differ materially from our actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of our clinical trials and costs related to commercializing our product.

In March 2010, the Company filed a registration statement on Form S-3 with the SEC, which allows the Company to offer and sell, from time to time in one or more offerings up to \$100,000,000 of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The registration statement became effective on April 13, 2010 (333-165677). The Company used this registration statement for its August 2010 public offering detailed in Note 3 to the Company's audited financial statements contained in the 2010 Annual Report on Form 10-K. In July 2011, the Company completed the sale of 5,000,000 shares of its common stock pursuant to an underwriting agreement with Jefferies & Company, Inc., raising approximately \$23.6 million after expenses. Because the maximum aggregate offering price of all securities registered is \$100,000,000, the Company's issuance of any securities will reduce the amount of other securities that it can issue pursuant to the registration statement on Form S-3.

The Company has funded our operations through a combination of private placements of our securities and through the proceeds of our public offerings in 2000, 2003, 2009, 2010, and 2011 along with our registered direct offerings in 2007 and 2009. As of July 31, 2011, Delcath had approximately \$39,750,000 aggregate amount of common stock, preferred stock, stock purchase contracts, warrants and debt securities (or a combination of these securities) available to be issued under our effective registration statement on Form S-3. The Company intends to use the net proceeds from any future offerings for general corporate purposes, including, but not limited to, obtaining regulatory approvals, commercialization of our products, funding of our clinical trials, capital expenditures and working capital. For a detailed discussion of our various sales of securities see Note 3 to the Company's audited financial statements contained in the 2010 Annual Report on Form 10-K.

## **Critical Accounting Estimates**

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 1 to the Company's financial statements contained in the 2010 Annual Report on Form 10-K. The Company is still in the development stage and has no revenues, trade receivables, inventories, or significant fixed or intangible assets, and therefore has very limited opportunities to choose among accounting policies or methods. In many cases, the Company must use an accounting policy or method because it is the only policy or method permitted under GAAP.

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

The Company considers the valuation allowance for the deferred tax assets to be a significant accounting estimate. In applying FASB ASC 740 management estimates future taxable income from operations and tax planning strategies in determining if it is more likely than not that the Company will realize the benefits of its deferred tax assets. Management believes the Company does not have any uncertain tax positions.

The Company has adopted the provisions of FASB ASC 718, which establishes accounting for equity instruments exchanged for employee services. Under the provisions of FASB ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company expenses its share-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company has adopted the provisions of FASB ASC 505-50, which establishes accounting for equity-based payments to non-employees. Measurement of compensation cost related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. Each transaction is reviewed to determine the more reliably measurable basis for the valuation. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. Non-employee stock-based compensation charges are amortized over the vesting period or period of performance of the services.

The Company has adopted the provisions of FASB ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

FASB ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, FASB ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. See Note 5 to the Company's condensed consolidated condensed financial statements contained in this Quarterly Report on Form 10-Q for assets and liabilities the Company has evaluated under FASB ASC 820.

#### Item 3. Quantitative and Qualitative Disclosure about Market Risk

The Company may be exposed to market risk through changes in market interest rates that could affect the value of its investments. However, the Company's marketable securities consist of short-term and/or variable rate instruments and, therefore, a change in interest rates would not have a material impact on the fair value of the Company's investment portfolio or related income.

The Company measures all derivatives, including certain derivatives embedded in contracts, at fair value and recognizes them on the balance sheet as an asset or a liability, depending on the Company's rights and obligations under the applicable derivative contract.

In June 2009, the Company completed the sale of 869,565 shares of its common stock and the issuance of warrants to purchase 1,043,478 common shares (the "2009 Warrants") in a subscription agreement with a single investor. The Company received gross proceeds of \$3.0 million, with net cash proceeds after related expenses from this transaction of approximately \$2.67 million. Of those proceeds, the Company allocated an estimated fair value of \$2.2 million to the 2009 Warrants, resulting in net proceeds of \$467,559. The 2009 Warrants are currently exercisable at \$3.60 per share with 1,043,478 shares outstanding at September 30, 2011 and have a five-year term.

In September 2007, the Company completed the sale of 3,833,108 shares of its common stock and the issuance of warrants to purchase 1,916,554 common shares (the "2007 Warrants") in a private placement to institutional and accredited investors. The Company received net proceeds of \$13.3 million in this transaction. The Company allocated \$4.3 million of the total proceeds to the 2007 Warrants. The 2007 Warrants were initially exercisable at \$4.53 per share beginning six months after the issuance thereof and on or prior to the fifth anniversary of the issuance thereof. As required by the 2007 Warrant agreement, both the exercise price and number of warrants were adjusted following the Company's June 9, 2009 sale of common stock. The 2007 Warrants are currently exercisable at \$3.44 per share with 1,469,456 warrants outstanding at September 30, 2011.

The \$2.2 million in proceeds allocated to the 2009 Warrants and the \$4.3 million in proceeds allocated to the 2007 Warrants are classified as derivative instrument liabilities. The terms of the 2007 Warrants and the 2009 Warrants provide for potential adjustment in the exercise price and are therefore considered to be derivative instrument liabilities that are subject to mark-to-market adjustment each period. As a result, for the nine month period ended September 30, 2011, the Company recorded the change in fair value of the warrant liability as pre-tax derivative instrument income of \$14.9 million. The resulting derivative instrument liabilities totaled \$3.1 million at September 30, 2011. The fair value of the Warrants at September 30, 2011 was determined by using an option pricing model assuming a risk free interest rate of 0.37% for the 2009 Warrants and 0.13% for the 2007 Warrants, volatility of 84.35% for the 2009 Warrants and 76.69% for the 2007 Warrants and an expected life equal to the contractual life of the Warrants (June 2014 and September 2012, respectively).

#### Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of September 30, 2011 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

## PART II: OTHER INFORMATION

Item 1. Legal Proceedings None.

# Item 1A. Risk Factors None.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds** Not Applicable.

# Item 3. Defaults upon Senior Securities Not Applicable.

Item 5. Other Information Not Applicable.

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Item 6. Exhibits

Exhibit No.	_	Description				
10.1	**	Lease Agreement, dated August 2, 2011				
31.1	**	Certification by Principal executive officer Pursuant to Rule 13a 14.				
31.2 <b>**</b> Certification by Principal financial officer Pursuant to Rule 13a 14.						
32.1 Certification of Chief executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the S of 2002		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 Principal financial officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS		XBRL Instance Document				
101.SCH		XBRL Taxonomy Extension Schema Document				
101.CAL		XBRL Extension Calculation Linkbase Document				
101.LAB		XBRL Extension Label Linkbase Document				
101.PRE		XBRL Extension Presentation Linkbase Document				
** Fil	ed here	ewith.				
*** Furnished herewith.						

### 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 9, 2011

DELCATH SYSTEMS, INC. (Registrant)

/s/Graham G. Miao

Graham G. Miao Chief Financial Officer (Principal Financial Officer)

Exhibit No.		Description
<u>10.1</u>	**	Lease Agreement, dated August 2, 2011
<u>31.1</u>	**	Certification by Principal executive officer Pursuant to Rule 13a 14.
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101.INS		XBRL Instance Document
101.SCF	ł	XBRL Taxonomy Extension Schema Document
101.CAI	Ĺ	XBRL Extension Calculation Linkbase Document
101.LAI	В	XBRL Extension Label Linkbase Document
101.PRE	3	XBRL Extension Presentation Linkbase Document
**	Filed her	ewith.
***	Furnished	l herewith.

## Dated 2nd August 2011

# SEAN KEENAN, EAMON REAY, TOM HOGAN AND EUGENE DEVANEY

#### Lessor

#### DELCATH SYSTEMS LIMITED

Lessee

## LEASE

19 Mervue Industrial Estate Mervue Galway

# LEWIS C. DOYLE & CO.

Solicitors Augustine Court St. Augustine Street GALWAY.

REF: NF. 59954(M268.2)

(AC#4196077 9.DOC)

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# Stamp Certificate

Document ID :			54135W		Date Issued: 08/	Date Issued: 08/08/2011	
Stamp Certificate ID :			24755-DD3B-020811-	F	Notice Number:		
Duty: Total: Date of Execution of Instrument:			1,544.50				
			1,544.50				
			/2011				
Parties From:	EUGENE DEVANEY						
	THOMAS GERA	RD H	OGAN				
	EAMONN REAY						
	SEAN KEENAN						
Parties To: DELCATH SYSTEMS LTD.							
Property	19 Mervue Indust	rial Es	state, Mervue				
	Non Residential:	Rent	:€153,292.00	Duty: € 1,532.00			
	Rent Review:	€1	2.50				



**BETWEEN:** <u>SEAN KEENAN, EAMON REAY, TOM HOGAN AND EUGENE DEVANEY</u> all of Mervue Business Park, Mervue Galway, trading as the "MBP Co-Ownership Group" (hereinafter called "The Lessor") of the One Part and <u>DELCATH SYSTEMS LIMITED</u> of Arthur Cox Building, Earlsfort Terrace, Dublin 2 (hereinafter called "The Lessee") of the Other Part.

#### WITNESSETH AS FOLLOWS:

#### 1. DEFINITIONS AND INTERPRETATION

1.1 In this Lease unless the context otherwise requires the following expressions have the meaning assigned to them respectively that is to say:-

"LESSOR" shall where the context so admits include the Reversioner for the time being immediately expectant on the Term hereby granted.

"LESSEE" shall include the Lessee's successors in title and assigns.

"DEMISED PREMISES" means the premises more particularly described in the First Schedule hereto and shall be deemed to include the fixtures, fittings and rights hereby demised subject to and with the benefit of the rights and easements set out in the Second and Third Schedules.

"PLANNING ACTS" means the Planning and Development Acts 2000 to 2010 and any Act or Acts for the time being in force amending or replacing the same and any orders regulations or directions issued under or by virtue of the said Acts for the time being in force or replacing the same

"INSURED RISKS" means all or any loss or damage or prospective loss or damage by fire, flooding, water, storm, tempest, lightning, explosion, earthquake, weather conditions, impact of aircraft and articles dropped therefrom and such further risks or perils to or in connection with the Demised Premises and the fixtures and fittings thereof together such reasonable fees, expenses, charges and monies of and incidental to the rebuilding and/or reinstatement or loss (whether total or otherwise) of the Demised Premises or any part thereof as the Lessor may from time to time reasonably deem it desirable to insure against including but not by way of limitation:-

- (a) Loss of two years rent from time to time payable out of the Demised Premises.
- (b) All expenditure or anticipated expenditure in the demolition and clearance of the Demised Premises.
- (c) A sum equivalent to fifteen per cent of the full replacement and reinstatement value of the Demised Premises in respect of Architects, Quantity Surveyors Engineers, and other professional and Consultancy fees.
- 1.2 Words importing the masculine gender only include the feminine gender.
- 1.3 Words importing the singular number only include the plural number and vice versa and where there are two or more persons included in the expressions the "Lesser" or the "Lessee" shall be deemed to be made by such persons jointly and severally.
- 1.4 Any reference to a statute or statutes (whether specifically specified or not) or to any sections sub-sections therein shall include any amendments or re-enactments thereof for the time being in force and all Statutory Instruments, Orders, Notices,

Regulations, Consents and Directions for the time being made, issued or given thereunder or deriving validity therefrom.

- 1.5 Notwithstanding any provisions to the contrary contained in this Lease, the parties hereby expressly agree that any rights conferred on the Lessor to have access to or entry upon the Demised Premises shall be construed as extending to such other persons as may from time to time be properly authorised by the Lessor in writing, including agents and professional advisors and the Lessor in turn hereby covenants to ensure that any parties exercising such rights shall:
  - (a) use all reasonable endeavours to do so outside the Lessee's normal business hours;
  - (b) ensure that as little damage or disturbance is done to the Demised Premises or any fixtures or fittings therein or any goods thereat and as little inconvenience is caused to the Lessee's business as is reasonably practicable;
  - (c) only resort to the Demised Premises where the purpose of the proposed entry cannot otherwise be practically and conveniently effected;
  - (d) effect any works in accordance with good building practice and in substantial compliance with all relevant consents, such works to be carried out by persons carrying or covered by an appropriate level of public liability and employer's liability insurance;
  - (e) make good without delay any damage to the Demised Premises that may be caused by such exercise; and
  - (f) give the Lessee no less than 72 hours prior notice in writing in respect of inspection and no less than 10 working days notice in respect of any works (except in the case of emergency).
- 1.6 Each covenant by the Lessee not to do any act or thing shall be deemed to include a covenant not to knowingly permit or suffer that act or thing to be done.

## 2. DEMISE HABENDUM AND REDDENDUM

In consideration of the rent and covenants on the part of the Lessee hereinafter reserved and contained the Lessor hereby demises unto the Lessee **ALL THAT** the Demised Premises **TO HOLD** the Demised Premises subject as aforesaid unto the Lessee from 2nd August 2011 (the "Term Commencement Date") to 1st August 2021 (hereinafter referred to as the "Term") **YIELDING AND PAYING** therefore during the said term unto the Lessor the following yearly rents plus VAT (if applicable) clear of all deductions by equal quarterly payments in advance on the 1st of July, October, January and April of each year of this demise:

- (a) Year 1 €1 06,051.00
- (b) Year 2- €134,974.00
- (c) Year 3 €159,076.50
- (d) Year 4- €183,179.00
- (e) Year 5 €183,179.00

(f) Year 6 to 10 inclusive from and including the Review Date (as hereinafter defined) such yearly rent as becomes payable pursuant to the Fourth Schedule hereof, and in every case the same is to be paid by standing order or otherwise in the manner notified from time to time by the Lessor

PROVIDED ALWAYS that in the event of the said rent or any monies payable hereunder or any part thereof being in arrear for more than 14 days the Lessee shall pay interest thereon calculated on a daily basis at a rate of four per cent per annum above the three months European Inter Bank Offer Rate as quoted by the European Central Bank or if there shall be no such rate the corresponding or nearest appropriate rate thereto at the date upon which the said sums fall due or become payable or if there shall be no such rate at the rate per centum per month which shall exceed by one half per centum per month the monthly rate of interest for the time being chargeable under Section 1080 of the Taxes Consolidation Act, 1997 (or such other monthly rate of interest as may from time to time be chargeable upon arrears of tax)from the date on which it becomes payable until the date payment is made.

AND ALSO YIELDING AND PAYING from time to time the following additional sums (hereinafter referred to as "the additional sums") that is to say:-

- (a) such sum or sums as shall be equal to the amount which the Lessor may expend in effecting and maintaining the insurance (but not plate glass or double glazing insurance) of the Demised Premises against the Insured Risks such sum or sums to be paid within 14 days of written demand. The Lessee shall be entitled to inspect the Policy of the Insurance obtained by the Lessor in respect of the Insured Risks as often as shall be reasonably necessary but in any event at least once in every year throughout the Term (the "Insurance Premium").
- (b) all rates (including water rates) taxes, duties, charges, assessments, impositions and outgoings whatsoever whether Parliamentary, Municipal Parochial Local or of any other description now or hereafter to be assessed, charged or imposed upon or payable in respect of the Demised Premises or any part thereof PROVIDED THAT the Lessee shall not be responsible for any preexisting liabilities in this regard which have accrued prior to the Term Commencement Date and PROVIDED FURTHER THAT it is agreed between the parties that the following abatements shall apply regarding rates, insurance premiums and annual service charge (if any)s payable hereunder during the Term:
  - (i) Year I 50% reduction in rates, Insurance Premium and annual service charge (if any)
  - (ii) Year 2 35% reduction in rates, Insurance Premium and annual service charge (if any)
  - (iii) Year 3 20% reduction in rates, Insurance Premium and annual service charge (if any)
  - (iv) Year 4 I 0% reduction in rates, Insurance Premium and annual service charge (if any)

There shall be no further reductions for the remainder of the Term unless otherwise agreed by the parties and the Lessee shall pay all of the rates, the Insurance Premium and annual service charge (if any) for the remainder of the Term without reduction.

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### 3. THE LESSEE HEREBY COVENANTS WITH THE LESSOR AS FOLLOWS:-

- 3.1 To pay the rent hereby reserved and the additional sums at the times and in the manner aforesaid.
- 3.2 To pay for all gas, electricity, and water consumed on the Demised Premises and to observe and perform at the Lessee's expense all present and future regulations and requirements of the gas electricity and water supply Authorities PROVIDED THAT the Lessee shall not be responsible for any pre-existing liabilities in this regard which have accrued prior to the Term Commencement Date.
- 3.3
- (a) Henceforth from the Term Commencement Date to comply in all respects with the provisions of every enactment (which expression in this clause includes every Act of Parliament or of the Oireachtas already or hereafter to be passed as well as every instrument regulation and bye-law already or hereafter to be made thereunder) and every notice or order or proposal for a notice or order or licence, consent, permission or direction given or made thereunder so far as the same shall relate to or affect the Demised Premises or the user thereof any fixtures, machinery, plant or chattel for the time being fixed thereto or placed thereon and to execute all works which under any enactment shall be required to be executed upon the Demised Premises PROVIDED THAT the Lessee shall not be responsible for any pre-existing liabilities in this regard which have accrued prior to the Term Commencement Date.
- (b) Within 14 days of the receipt by the Lessee of the same, to supply a copy to the Lessor of any notice or order or proposal for a Notice or Order or Licence consent, permission or direction given or made under any enactment or otherwise and relating to the Demised Premises and to permit the Lessor (subject to observance the provisions of clause 1.5 of this Lease) to enter upon the Demised Premises to inspect the same for any purpose in connection with any such enactment or any such Notice, Order, proposal licence consent, permission or direction as aforesaid.
- (c) At the request and cost of the Lessor, to join with the Lessor in making any objection, representation, or appeal in respect of any such Notice, Order Proposal or direction as aforesaid or any refusal of or condition imposed under any such Licence, consent or permission as aforesaid SAVE where any such objection, requisition or appeal is not in the best interests of the Lessee (acting reasonably).

3.4

(a) To repair, maintain and keep the interior of the Demised Premises and every part thereof, together with all drains and other pipes, lights, signs, electric installations, sanitary and water apparatus and all other apparatus, to include the air handlers and air conditioners (if any) exclusively serving the Demised Premises in good order, repair and condition (usual wear and tear being excepted) and in the like condition to yield up the same at the expiration or sooner determination of the demise

**PROVIDED ALWAYS** that the Lessee shall not be liable for damage caused by any of the Insured Risks or the Uninsured Risks (as hereinafter defined) unless the relative policy or policies of insurance shall have been dered void or voidable or payment of the whole or any part of the insurance moneys in respect thereof shall have been refused in consequence of some wilful and knowing act or default on the part of the Lessee or the employees, servants, agents, licensees or invitees of the Lessee

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**PROVIDED THAT** nothing in this Lease shall oblige the Lessee to put the Demised Premises into a better state of repair than exists at the Term Commencement Date as evidenced by the Schedule of Condition annexed to this Lease, including incurring any expenditure on the renewal and/or for replacement of items or elements of the Demised Premises (including plant and equipment) where as a consequence of such expenditure the Demised Premises would be in a better state of repair or condition than that described in the Schedule of Condition.

- (b) The Lessor and the Lessee hereby agree that (save where the reason for the replacement being required is due to an act or default of the Lessee) in the event that any of the Lessor's plant, machinery, fixtures, fittings or equipment in the Demised Premises become beyond economic repair and therefore require to be replaced, the reasonable and properly vouched cost of (i) the removal of the defunct piece of plant, machinery, fixture, fitting or equipment, (ii) the purchase of the replacement and (iii) the installation of such replacement in the Demised Premises, shall be borne equally between the parties on a 50/50 basis.
- (c) The Lessee covenants to paint the interior of the Demised Premises at the end of every third year of the Term.
- 3.5 To keep the Demised Premises clean and tidy and free from deposits of materials or refuse and not to bring or keep or suffer to be brought or kept on the Demised Premises any dump or rubbish or scrap heap or anything which is unclean, unsightly, noisome, or offensive to it or its environs but so often as it shall be necessary or desirable to remove from the Demised Premises all such material, refuse, rubbish and scrap which may accumulate or be there **PROVIDED ALWAYS** that if the Lessee does not comply with this covenant within a period of 14 days of being so notified the Lessor may (without prejudice to its other remedies under this Lease or otherwise) remove any such material, refuse, rubbish, or scrap and the Lessee shall pay to the Lessor the reasonable and properly vouched cost of the same within 21 days of written demand.
- 3.6 Not any time during the said Term without the previous consent in writing of the Lessor (such consent not to be unreasonably withheld, conditioned or delayed) and except in accordance with Plans, elevations, sections and specifications previously submitted to and approved by the Lessor, to erect any additional building upon the Demised Premises nor to make or suffer to be made any alteration or addition whatsoever in or to the Demised Premises or remove or injure or suffer to be removed or injured any of the principal walls, windows, timbers, girders, iron or steel work, ceilings, roofs, floors, tiles, thereof or make any alterations in the Plan or elevation of any of the buildings for the time being in or on the Demised Premises either internally or externally nor to erect any poles, masts or wires on or from the Demised Premises **PROVIDED THAT** the Lesser shall be permitted to make internal, non-structural alterations to the Demised Premises without the need for obtaining the Lessor's consent. The Lessor may as a condition of giviflg any consent under this clause require the Lessee to enter into such reasonable covenants with the Lessor as the Lessor shall require in regard to the execution of any alteration or addition to the Demised Premises and the reinstatement thereof at the determination of the lease or otherwise. In connection with any application for the Lessor's approval or consent under this clause, the Lessee shall pay the Lessor's Architects and/or Surveyors reasonable and properly vouched costs relating thereto, regardless of whether or not consent is granted

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- 3.7 Not to give permission for any new window, lights, opening, doorway path, passage, drain or other encroachment or easement to be made into, against or upon the said Demised Premises which might be or grow to be an annoyance or inconvenience to the Lessor and in case any such window, light, opening, doorway, path, passage, drain or other encroachment or easement shall be made or attempted to be made to give immediate notice thereof to the Lessor upon becoming aware of same and at the request and cost of the Lessor adopt such means as maybe reasonably required or deemed proper by the Lessor for preventing any such encroachment or the acquisition of any such easement.
- 3.8 Not to place or affix to the front of the Demised Premises any water, ventilating, or other pipe and not to alter cover up or change any of the architecture or architectural decorations or the external colour of such building or to make any addition, temporary or otherwise to the Demised Premises either in height or projection without in every case obtaining the prior consent in writing of the Lessor (such consent not to be unreasonably withheld, conditioned or delayed).
- 3.9 Not to paint, place, attach or exhibit or suffer to be painted, placed, attached or exhibited on the exterior of the Demised Premises or in the interior thereof so as to be visible from the outside any inscription, bill, sign, blind, signboard, fascia or advertisement or other item (except as shall have been previously approved by the Lessor, with such approval not to be unreasonably withheld, conditioned or delayed).
- 3.10 To keep the Demised Premises in good decorative order repair and condition throughout the Term
- 3.11 Subject to observance the provisions of clause 1.5 of this Lease and at all times during an emergency, to permit the Lessor with or without its agents, surveyors, workmen and others as the case may be:
  - (a) To enter and examine the conditions of the Demised Premises for any defects, decays, defects wants of reparation to the same for which the Lessee shall be liable hereunder and to give to the Lessee or leave on the Demised Premises notice thereof in writing together with notice of the hours within which repairs and works may be executed and if the Lessee shall not within twenty one days after such notice (or forthwith in case of emergency) commence and proceed diligently with the execution of such repairs and works it shall be lawful for the Lessor and its Contractors, Agents and workmen (but without prejudice to the right of re-entry hereinafter containedr to enter the Demised Premises and execute all such repairs and works and do such acts as may be necessary to comply with. the said notice and the reasonable and properly vouched costs thereof shall be a debt due from the Lessee to the Lessor
  - (b) To enter the Demised Premises for the purpose of taking Schedules or Inventories of fixtures fittings and things in the Demised Premises to be yielded up at the expiration or sooner determination of this demise

PROVIDED THAT the person or persons so entering shall cause as little damage to the Demised Premises as possible and shall make good all damage thereto occasioned by any such entry without unreasonable delay and to the Lessee's reasonable satisfaction, but without payment of compensation for any inordinate annoyance noise, vibration or inconvenience caused to the Lessee or their employees.

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- 3.12 To use the Demised Premises for manufacturing purposes with ancillary offices or otherwise in accordance with planning permission and not without the Lessor's consent in writing, which consent shall not unreasonably be withheld, conditioned or delayed, to use or permit or suffer the same or any part thereof to be used for any other purpose.
- 3.13
- (a) Subject as hereinafter mentioned not to mortgage, assign, underlet or part with or share the possession or occupation of the Demised Premises or any part thereof, or suffer any person to occupy or use the Demised Premises or any part thereof as Licensee, or permit any assignment or sub-letting BUT SO THAT NOTWITHSTANDING the foregoing the Lessor shall not unreasonably withhold, condition or delay its consent to an assignment or underletting of the entire of the Demised Premises

PROVIDED THAT the Lessee shall be permitted to sub-let or share occupation of all or any part of the Demised Premises with any related company (meaning any company related to Delcath Systems Limited within the meaning of Section 140(5) of the Companies (Amendment) Act 1990) without having to obtain Lessor's consent SUBJECT ALWAYS to the conditions that in the case of sharing possession of the Demised Premises no relationship of landlord and tenant shall be created or allowed to arise and in the case of a sub-letting where a landlord and tenant relationship exists, a deed of renunciation in respect of any rights of renewal pursuant to Landlord and Tenant legislation shall be executed by the said related company;

- (b) Upon the Lessor consenting to any assignment of the Demised Premises to procure that the assigns enter into a covenant with the Lessor in such form as the Lessor shall reasonably require to pay the rents hereby reserved and perform and observe the covenants on the part of the Lessee herein contained during the residue of the Term hereby granted.
- (c) Upon the Lessor consenting to any under-letting of the Demised Premises or any part thereof to enter into such covenants and procure the sub-tenant to enter into such covenants with the Lessor as the Lessor shall reasonably require in regard to the form and contents of the under-lease or tenancy agreement to be granted or made by the Lessee or otherwise in connection therewith.
- (d) Within one month after any permitted assignment or under-letting of the-· Demised Premises or any part thereof or any devolution of the interest of the Lessee therein or any devolution or creation of any interest in the Demised Premises for which the consent of the Lessor is required, to give notice thereof in writing to the Lessor and to produce to the Solicitors for the time being of the Lessor or to the Lessor the assurance, counterpart, under-lease, Probate and Will, Letters of Administration, Order of Court or other instrument under which such devolution shall have occurred and to pay for the registration fees thereof and also such additional fee as maybe charged for registration by the Superior Lessor.
- 3.14 To permit the Lessor during the three months immediately preceding the determination of this demise (whether by effluxion of time or otherwise) to affix and retain upon any part of the exterior of the Demised Premises a notice for the disposal of the same and to permit persons with written authority from the Lessor or its agents at all reasonable times to view the Demised Premises PROVIDED THAT such notice or sign does not materially interfere with the visibility of the Demised Premises.



- 3.15 To give notice to the Lessor as soon as reasonably practicable after becoming aware of any notice of claims affecting the Demised Premises or any part thereof.
- 3.16 To indemnify and keep indemnified the Lessor against any reasonable and properly vouched expenses, costs, claims, demands, damages and other liabilities in respect of the injury to or death of any person or damage to any property arising directly out of the following: -
  - (a) The state of repair and condition of the Demised Premises.
  - (b) The existence of any alterations thereto or the state of repair or conditions of such alterations.
  - (c) The use of the Demised Premises by the Lessee.
  - (d) Any work carried out or in the course of being carried out thereto by the Lessee.
  - (e) Anything now or hereafter attached to or projecting therefrom.

PROVIDED ALWAYS that the foregoing indemnity shall be limited to the extent that the relevant actions, expenses, costs, claims, damages and other liabilities are the responsibility of the Lessor, management company (if any) or the superior landlord (if any) or are caused by the negligent act or default of the Lessor, the management company (if any) or the superior landlord (if any) or their respect servants or agents AND FURTHER PROVIDED that the Lessor shall use reasonable endeavours to mitigate any loss, claim or other costs in this regard and shall not pay settle or compromise any actions, suits, claims or demands by any third party without the Lessee's prior written consent (not to be unreasonably withheld or delayed).

FOR THE AVOIDANCE OF DOUBT this indemnity will not extend to any expenses, costs, claims, demands, damages and other liabilities whatsoever in respect of the injury or death of any person or damage to any property howsoever arising out of the disrepair and condition of the Demised Premises as of the date hereof.

3.17 At the expiration or sooner determination of this demise peaceably and in good and substantial repair and condition as aforesaid (damage by the Insured Risks, the Uninsured Risks and fair wear and tear excepted) to surrender and yield up the Demised Premises unto the Lessor together with all fixtures and additions thereto **PROVIDED HOWEVER** that the Lessee shall not be obliged to remove any of the Lessee's trade fixtures and any fixtures, fittings, materials and things of whatsoever nature installed or fixed on or attached to the Demised Premises by the Lessee in pursuance of a written consent in that behalf given by the Lessor (including, for the avoidance of doubt, the Lessee's original fit out)

**PROVIDED FURTHER THAT** the Lessee shall not be obliged to reinstate the Demised Premises to any better state of repair or condition than that which exists at the Term Commencement date as evidenced by the Schedule of Condition.

3.18 Not to do or knowingly permit to be done anything in or upon the Demised Premises or any part thereof which may be or become a nuisance, damage, disturbance or danger to the Lessor or the Owners or Lessee or occupiers of adjoining or neighbouring premises.



- 3.19 Not to permit or knowingly suffer the Demised Premises or any part thereof to be used for an illegal or immoral purpose or for any offensive, disreputable, noisy or dangerous trade, business, Pursuit or occupation or for residential or sleeping purposes.
- 3.20 Not, without the consent of the Lessor, such consent not to be unreasonably withheld or delayed, to install any machinery on the Demised Premises which shall be noisy or cause vibration or which shall be either dangerous or a nuisance to the Lessor or other occupants or the owners or Lessee or Occupiers of adjoining premises or of neighbouring premises PROVIDED THAT the Lessee is hereby expressly permitted to install such machinery on the Demised Premises which is normally required or used for or in connection with the business or activities carried on by the Lessee from time to time at the Demised Premises.
- 3.21 Not to do or permit or knowingly suffer to be done any act or things which may render any increased premiums payable for the insurance of the Demised Premises or which may make void or voidable any policy or policies of insurance thereon and (without prejudice to the Lessor's right of action in respect of a breach of the provisions contained in this paragraph) to repay to the Lessor all sums paid by way of increased premiums and all reasonable and property vouched expenses incurred by a direct consequence of a breach of the provisions contained in this paragraph.
- 3.22 Not to knowingly stop up or obstruct or permit or suffer to be stopped up or obstructed the drains, sewers, gutters, pipes, channels and water courses of the Demised Premises or of the adjoining premises or to suffer oil, grease or other deleterious substances to enter them.

To indemnify and keep indemnified the Lessor against all and any expenses, costs, claims, demands, damages and other liabilities whatsoever in respect of the injury or death of any person or damage to any property howsoever arising directly out of:

- (a) The state of repair or condition of the Demised Premises;
- (b) The existence of any alterations carried out by the Lessee thereto or the state of repair or condition of such alterations;
- (c) The user of the Demised Premises;
- (d) Any work carried out or in the course of being carried out to the Demised Premises by the Lessee, its servants or agents or sub-tenants;
- (e) Anything now or hereafter attached to or projecting therefrom;

PROVIDED ALWAYS that the foregoing indemnity shall be limited to the extent that the actions, expenses, costs, claims, damages and other liabilities are the responsibility of the Lessor pursuant to the terms of this Lease or are caused by the negligent act or default of the Lessor or the management company (if any) or their respective servants or agents and shall exclude all loss of profits or other heads of loss that are not reasonably foreseeable by the Lessee AND FURTHER PROVIDED that the Lessor shall use reasonable endeavours to mitigate any loss, claim or other costs in this regard.

3.23 To pay the cost of stamping and registering this Indenture.

3.24 To use reasonable endeavours to observe and perform all the covenants and conditions on the Lessee's part to be observed and performed contained in the Head Lease, being the Lease made the 25th day of June 1997 between Industrial Development Agency (Ireland) of the One Part and Multis Limited of the Other Part (other than payment of rent, rates and other outgoings and the provisions of clauses 14 and 15 of the Second Schedule of the Head Lease PROVIDED THAT in the event of any conflict between the tenns of this Lease and the Head Lease, or in the event of the obligations under the Head Lease being more onerous than those imposed by this Lease, the tenns of this Lease shall prevail.

## 4. THE LESSOR HEREBY COVENANTS WITH THE LESSEE AS FOLLOWS:

- 4.1 That the Lessee paying the rent hereby reserved and the additional sums hereby made payable and observing and perfonning the covenants, conditions and stipulations on their part herein contained shall peaceably hold and enjoy the Demised Premises during this demise without any interruption by the Lessor or any person rightfully claiming under or in trust for it.
- 4.2 To perform and observe the covenants on its part under the Head Lease and to use their best endeavours to procure that the Head Lessor and the Management Company (if any) similarly perform and observe the covenants and conditions on the part of the Head Lessor and the Management Company contained in the Head Lease.
- 4.3 To effect and maintain at all times throughout this demise in an Insurance office of repute insurance of the Demised Premises against the Insured Risks in full reinstatement value thereof at competitive rates will expend all monies received (other than in respect of loss of rent) by virtue of any such insurance in reinstating the Demised Premises as soon as is reasonably possible after the destruction thereof or any damage thereto.
- 4.4 The Lessor will be liable for all structural and exterior repairs (including the remedy of any latent or inherent defects) to the Demised Premises unless the same are caused through the wilful act, neglect or default of the Lessee.

### 5. PROVIDED ALWAYS IT IS HEREBY AGREED AND DECLARED as follows:

- 5.1 Notwithstanding and without prejudice to any other remedies or powers herein contained or otherwise available to the Lessor, if any of the following events shall occur:
  - (a) If the rent hereby reserved and made payable or any part thereof shall be unpaid for twenty-one days after same shall have become payable and demanded in writing
  - (b) In the event of any material breach, non-performance or non-observance by the Lessee of any covenant on its part herein or of any proviso or condition herein contained and on its part to be performed and observed
  - (c) If the Lessee being a company shall enter into liquidation whether compulsory or voluntary (save only a voluntary liquidation for the purpose of reconstruction of amalgamation)
  - (d) If the Lessee being an individual shall (or being more than one individual any one of them shall) become bankrupt or enter into a composition or arrangement with his creditors or seek the protection of the Court or suffer any distress or execution to be levied on his goods

THEN and in any such case it shall be lawful for the Lessor at any time thereafter to re-enter the Demised Premises or any part thereof in the name of the whole and thereupon this demise shall absolutely cease and determine but without prejudice to any right of action or remedy of either party in respect of any antecedent breach of the covenants on the other's part therein contained.

- 5.2 If the Demised Premises or any part thereof(including the access thereto) shall at any time be destroyed or so damaged by any of the Insured Risks so as to be unfit for occupation or use and the relative policy or policies of insurance effected by the Lessor shall not have been vitiated or payment of the policy monies refused in whole or in part due to any act or default on the part of the Lessee then the rent and additional sums hereby reserved or a fair and just proportion thereof according to the nature and extent of the damage sustained shall be suspended and cease to be payable until the Demised Premises shall again have been rendered fit for occupation and use and in the case of a dispute as to the proportion or period of abatement the same shall be referred to arbitration in accordance with the clause in that behalf hereinafter contained. If the Lessor is prevented (for whatever reason) from rebuilding or reinstating the Demised Premises within a period of two years from the date of same or destruction, notwithstanding its use of all reasonable endeavours to so reinstate, the Lessor shall be relieved from such obligation and shall be solely entitled to all insurance monies. However, in the event that the Lessor is or relieved from such obligation, the Lessee shall be entitled to recover the cost of any improvements it made to the Demised Premises.
- 5.3 In such an event, and if this Lease has not already been terminated by frustration, the Lessor or the Lessee may at any time after the expiry of such period of two years by written notice given to the other determine this demise but without prejudice to any claim by either party against the other in respect of any antecedent breach of covenant.
- 5.4 The Lessor shall ensure that in the event of destruction of or damage to the Demised Premises or the access thereto by any Insured Risk insured against as aforesaid all monies paid under or by virtue of any such policy of insurance as aforesaid (except monies received for loss of rent and additional sums (if applicable)) shall as soon as possible be paid out and applied in re-building repairing or otherwise re-instating the Demised Premises (making up any shortfall out of the Lessor's own monies) as aforesaid and the Lessor shall use reasonable endeavours to reinstate the Demised Premises to have substantially the same gross external area as the existing gross external area of the Demised Premises with substantially the same accesses and facilities commensurate with those enjoyed as of the date hereof.
- 5.5 In the event that the Demised Premises is destroyed or damaged by any event or act normally insured against under property reinstatement insurance policies in Ireland, for premises such as the Demised Premises which is/are not at the time of said damage actually insured against by the Lessor (save however where the reason the risk is an Uninsured Risk is due to an act or default of the Lessee) or in respect of which the Lessor is unable to obtain insurance (the "Uninsured Risks") which renders the Premises unfit for occupation and use THEN:
  - (a) within six (6) months of the date of the damage or destruction in question the Lessor shall give written notice to the Lessee (the "Election Notice") stating whether or not it proposes to rebuild or reinstate the Demised Premises;
  - (b) in the event that the Election Notice states that the Lessor does propose to rebuild or reinstate the Demised Premises then for the purposes of this Lease the damage caused by the Uninsured Risk shall be deemed to have been damage caused by an Insured Risk and the provisions of clause 5.2 shall apply;

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- (c) if the Election Notice states that the Lessor does not propose to rebuild or reinstate the Demised Premises, or if the Lessor does not serve an Election Notice within the said period of six (6) months, or if the Lessor serves an Election Notice but the Demised Premises has not been reinstated within two (2) years of the date of the damage or destruction, or during the last 18 months ofthe Term, within 90 days of the date of the damage or destruction, then the Lessee may determine this Lease at any time thereafter by giving one month's notice in writing to the Lessor;
- (d) the Lessee shall be entitled to the benefit of the provisions of Clause 5.2 in respect of rent and additional sums suspension from the date on which the Demised Premises is damaged or destroyed until the Demised Premises is reinstated so as to be fit for occupation and use or until termination of the Lease (whichever is the earlier) notwithstanding that such destruction or damage shall not have been caused by an Insured Risk.

# 6. **PRESCRIPTION**

The Lessee shall not be entitled to any right of light and air to the Demised Premises or to any other right or easement whatsoever (other than those hereby expressly granted) which would or might restrict or interfere with the free user, reconstruction, rebuilding, extension or increase of adjoining premises.

# 7. NOTICES

In addition to any other prescribed mode of service any notices requiring to be served on the Lessee hereunder shall be validly served if left addressed or sent by ordinary pre-paid post to him (or if there shall be more than one then to any of them) at the Demised Premises or at his or their last known address or addresses in the Republic of Ireland which shall be presumed to be the address herein unless written notice to the contrary is received.

## 8. **DISPUTE RESOLUTION**

If any dispute shall arise:-

- (a) between the parties hereto with regard to the construction or effect of this Indenture or any provision hereof or otherwise in connection with the Demised Premises or
- (b) between the Lessee and the Lessor tenant or occupier of any part of the Lessors premises relating to any easement or privilege in connection with the Demised Premises and such adjoining premises and relating to the party or other walls appertaining to the Demised Premises or to the amount of any contribution payable by the Lessee or such Lessee's tenant or occupier of such adjoining premises either in respect of rates or otherwise.

Then and in any such event either of such parties in dispute or difference as aforesaid may give notice in writing of such dispute or difference to such other party as the case maybe and each dispute or difference shall be and is hereby referr,:-ed to arbitration and to the final decision of an arbitrator to be appointed by agreement between the parties or in default of such agreement by the President for the time being to the Incorporated Law Society of Ireland. The award of such Arbitrator shall be final and binding on the parties. The Arbitrator shall have power to determine all matters in dispute which shall be submitted to him of which notice shall have been given as aforesaid. Upon every or any such reference the cost of and incidental to the reference and Award respectively shall be in discretion of the Arbitrator who may determine the amount thereof or direct the same to betaxed as between Solicitor and client or as between party and party and shall direct by whom and to whom and in what manner the same shall be borne and paid. The submission shall be deemed to be a submission to arbitrate within the meaning of the Arbitration Act 2010, and both the submission and any Award to be made thereunder maybe made a Rule or Order of the High Court. Any Arbitration held in pursuance of this proviso shall be heard and determined at such venue as the Arbitrator may direct in the Republic ofIreland.

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### 9. BREAK OPTION

- 9.1 The Lessee may terminate this Lease as of the expiration of the fifth year of the Term, that being 2nd August 2016 ("the Option Date") subject strictly to the following terms and conditions:
  - (a) The Lessee shall serve on the Lessor a notice in writing exercising the said right ("the Notice") at least six months prior to the Option Date and in this regard time shall be of the essence. If the Notice is not served within this time limit, then the option to terminate the Lease shall be lost; and
  - (b) The Lessee shall continue to be responsible for rent and all outgoings payable on foot of this Lease up to the Option Date.
- 9.2 The Lessee shall on or prior to the Option Date deliver to the Lessor the original of this Lease, together with all related title documentation, including a release or discharge of all mortgages, charges and other incumbrances affecting the Lessees interest, whether registered or not), and shall as beneficial owner deliver duly executed and stamped transfer or surrender of this Lease and ( if applicable) shall procure the cancellation of its registration in the Land Registry.
- 9.3 Any such termination shall be without prejudice to any antecedent breach by either the Lessor or the Lessee of any of their respective covenants herein contained
- 9.4 In the event of the Lessee who first entered into this Lease assigning it with the Lessor's consent to a third party the provisions contained in this clause shall not apply to such Third Party or any subsequent successors in title thereto.
- 10. **VAT** 
  - 10.1 The Lessor hereby exercises its option to tax the rents payable under this Lease pursuant to Section 97(1) of the Value Added Tax Consolidation Act 2010, as amended (the "VAT Act") (the "Lessor's Option to Tax"). The Lessee shall pay to the Lessor all VAT on the rents payable and other payments under this Lease following the delivery by the Lessor to the Lessee of a valid VAT invoice.

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# **GUARANTEE**

At the request of the Lessee herein and in consideration of the letting hereinbefore contained, **DELCATH SYSTEMS, INC.** hereby jointly and severally guarantees to the Lessor that the Lessee will at all times duly pay the rent hereinbefore reserved and performed and observe the covenants and agreements on the Lessee's part hereinbefore contained and further that any forbearance or giving of time to the Lessee shall not release us or either of us from liability hereunder and we jointly and severally agree with the Lessor that in the event that at any time during the Term any rent payable under the within Lease Agreement shall at any time be in arrears for fourteen days after the same shall become payable, then and in any such case and as often as the same may happen we or any one of us shall pay the rent so arrear to the Lessor.

Dated the 2nd August 2011

**SIGNED** for and on behalf of **DELCATH SYSTEMS,** INC. By:

/s/ EAMONN P. HOBBS EAMONN P. HOBBS Authorised Signatory

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## FIRST SCHEDULE

Description of Demised Premises:-

ALL THAT AND THOSE the premises situate at 19 Mervue Industrial Estate, Mervue, Galway and forming part the property comprised in Folio 4609L County Galway, shown outlined in red on the map attached.hereto and including:-

- 1. the internal plaster surfaces and finishes of all structural or load bearing walls and columns therein or which enclose the same, but not any other part of such walls and columns;
- 2. the entirety of all non-structural or non-load bearing walls and columns therein;
- 3. the inner half severed medially of the internal non-load bearing walls (if any) that divide the same from other parts of the building;
- 4. the floor finishes thereof and all carpets save that the lower limit of the Demised Premises shall not extend to anything below the floor finishes except that raised floors and the cavity below them shall be included;
- 5. the ceiling finishes thereof, including all suspended ceilings (if any) and light fittings save that the upper limit of the Demised Premises shall not extend to anything above the ceiling finishes except that the cavity above any suspended ceilings shall be included;
- 6. all glass in the windows and all doors, door furniture and door frames;
- 7. all sanitary and hot and cold water apparatus and equipment therein and exclusively serving same and the radiators (if any) therein and all fire fighting equipment and hoses therein;
- 8. all Conduits therein and exclusively serving the same.

BUT EXCLUDING all structural parts thereof.

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## SECOND SCHEDULE

Easements and Rights granted to the Lessee:

- 1. Full right and liberty for the Lessee, its employees, servants and Licenses and invitees (in common with the Lessor and all other persons who now have or shall hereafter have the like right) for purposes of ingress and egress and delivery of goods to and from the Demised Premises from time to time and at all times to pass and repass over the estate roads within which the Demised Premises is located.
- 2. The right (in common with the Lessor and lessees of the other parts of the Estate and all other persons entitled thereto) to the uninterrupted passage of water, soils and waste of all kinds, gas, electricity, telephone and other communication systems, telegraphic, fire fighting and fire prevention systems and equipment and other services through and from the gutters, gullies, pipes, drains, sewers, mains, watercourses, channels, trunks, ducts, flues, wires, cables and other conducting media ("Conduits") laid or to be laid on or over, under or through any other parts of the estate or any extension thereof or other contiguous or adjacent lands and premises of the Lessor.
- 3. The right (in common with the Lessor and lessees of other parts of the estate and all other persons similarly entitled or authorised) to enter on such parts of the estate (upon giving due notice to any parties affected) for the purpose of repairing any Conduits used in connection with the Demised Premises.
- 4. The right (in common with the Lessor and lessees of other parts of the estate and all other persons similarly entitled or authorised) during the Term to pass and re-pass over and use the common parts of the estate for the purpose for which each part is designated by the Lessor from time to time subject to any reasonable regulations governing the use of the common parts.
- 5. The rights of support, light and air as are currently enjoyed by the Demised Premises at the date hereof from the remainder of the estate.

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### THIRD SCHEDULE

#### Easements and Rights reserved in favour of the Lessor:

- 1. The air space above the Demised Premises.
- 2. The full, free and uninterrupted passage and running of water, soil, gas, electricity, telephone and all other services or supply to and from the adjoining premises and for the benefit of the respective owners, Lessees or occupiers for the time being thereof through the Conduits which are now or may hereafter be in upon over or under the Demised Premises.
- 3. Subject to observance the provisions of clause 1.5 of this Lease, the full and free right and liberty to enter upon the Demised Premises for the purpose of connecting, laying, inspecting, repairing, cleansing, maintaining, amending, altering replacing, relaying or renewing any Conduits and to erect, construct or lay in, under over or across the Demised Premises any sewers, drains, mains, pipes, wires, cables, holes, fixtures, or other works for the drainage of or for the supply of water, gas, electricity, telephone, heating, steam and other services to adjoining premises PROVIDED THAT the Lessor shall make good all damage or loss to the Lessee on the Demised Premises suffered as a result of the said works.
- 4. Subject to observance the provisions of clause 1.5 of this Lease, the full and free right and liberty to enter upon the Demised Premises in order to build on or into any dividing boundary or party walls or fences on the Demised Premises, subject to all damage thereby occasioned being made good with all convenient speed by the person or persons exercising such right.
- 5. Subject to observance the provisions of clause 1.5 of this Lease, the full and free right and liberty to enter upon the Demised Premises in order to execute works and repairs to the Demised Premises notwithstanding that the access to light and air for the time being enjoyed by the Demised Premises or any part thereof may thereby be temporarily interfered with PROVIDED HOWEVER that it is hereby expressly agreed that any limitation of the Lessee's right to light and air shall be only temporary and that the Lessor shall ensure that any restriction of the said light and air shall be as little as possible.
- 6. Subject to observance the provisions of clause 1.5 of this Lease, the full and free right and liberty to enter upon the Demised Premises to view the state and conditions of and to repair and maintain the adjoining premises, if the works required to be done upon same shall not otherwise be reasonably practicable but subject to any damage thereby occasioned to the Demised Premises being made good at all convenient speed by the person exercising such right.
- 7. Full and free right to build, rebuild upon or under, alter or develop or use in any manner including the erection of scaffolding on any adjoining premises owned by the Lessor or to use the same in any manner notwithstanding that any such building, rebuilding, alteration, development or user as aforesaid may temporarily affect or interfere with or diminish the light' coming to the Demised Premises PROVIDED HOWEVER it is hereby expressly agreed that the limitation of the Lessee's right to light and air shall be temporary only and the Lessor shall ensure that any restriction of the said light and air shall be as little as possible.
- 8. The full and free right of support to the extent now enjoyed by the adjoining premises from the Demised Premises.



# FOURTH SCHEDULE

#### **Rent Review**

The revised rent referred to in this Lease in respect of each the five year period commencing on the fifth anniversary of the Term Commencement Date may be agreed at any time between the Lessor and the Lessee or (in the absence of agreement) be determined not earlier than the fifth anniversary of the Term Commencement Date (the "Review Date") by applying the provisions set out below.

#### 1. **Definitions**

In this Schedule, the following expressions shall have the following meanings:

- 1.1 "Basic Rent", the rent payable by the Lessee immediately prior to the Review Date;
- 1.2 "Central Statistics Office", the Central Statistics Office, Ireland or other government department or successor or replacement office, state entity or other entity upon which the duties in connection with the Consumer Price Index shall have devolved from time to time;
- 1.3 "Consumer Price Index", the Consumer Price Index (all items) published by Central Statistics Office;
- 1.4 "**President**", the President for the time being of the Institute of Chartered Accountants in the Republic of Ireland and includes the duly appointed deputy of the President or any person authorised by the President to make appointments on his behalf;

#### 2. Rent Review

- 2.1 The rent reserved by this Lease shall be reviewed at the Review Date in accordance with the provisions of this Schedule and, from and including the Review Date, the reviewed rent shall equal the revised rent as determined in accordance with the terms of this Schedule.
- 2.2 At the Review Date, the Basic Rent shall be adjusted (as more particularly described in Clause 2.3 below) in line with the changes in the Consumer Price Index between:
  - (a) the date from which the Basic Rent was reviewed being the preceding Review Date or if there was none the Term Commencement Date;
  - (b) Review Date as provided for in Clause 2.3 below.

Such period hereinafter referred to as the "Review Period".

2.3 Calculation of the revised rent in accordance with the changes in the Consumer Price Index referred in Clause 2.2 shall be calculated by multiplying the Basic Rent by the "numerical fraction" applicable at the Review Date. The numerical fraction applicable at the Review Date shall be the fraction which shall have as its denominator the index figure which shall have been officially published by the Central Statistics Office for the most recent date or period before the date from which the Basic Rent was reviewed being the preceding Review Date or if there was none the Term Commencement Date for which an index figure was published by the Central Statistics Office for the most recent date or period before the Review Date or officially published for the most recent date or period before the Review Date for which an index figure was published for the most recent date or period before the Review Date for which an index figure was published for the most recent date or period before the Review Date for which an index figure was published by the Central Statistics Office.

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For the avoidance of doubt, the formula for calculating the amount of the revised rent on each Review Date for the purposes of Clause 2.3 of this Schedule shall be as follows:

AxB/C

Where

A = the Basic Rent;

B = the index figure which shall have been officially published by the Central Statistics Offices as the index figure for the Consumer Price Index for the most recent date or period before the Review Date for which an index figure is published.

C = the index figure which shall have been officially published by the Central Statistics Offices as the index figure for the Consumer Price Index for the most recent date or period before the date from which the Basic Rent was reviewed being the preceding Rent Review date or if there was none the Term Commencement Date for which an index figure was published.

- 3. Agreement or Determination of the Revised Rent
  - 3.1 The Lessor shall notifY the Lessee of its calculation of the revised rent no later than 3 months after each Review Date. In the event that the Lessee does not agree with the Lessor's calculation of the revised rent, either party may, by notice in writing to the other, require that the revised rent using the formula herein contained be determined by an independent expert such revised rent to be a generally respected measure of the general change in retail prices. The independent expert shall be a Chartered Accountant of at least seven years standing. In default of agreement between the Lessor and the Lessee on the appointment of the Chartered Accountant to act as independent expert, the Chartered Accountant shall be appointed by the President on the written application of either party.
  - 3.2 The independent expert for the purposes of all matters in dispute arising under this clause shall (a) act as an expert and not an arbitrator and (b) shall permit oral submissions and (if he deems appropriate) written submissions to be made by the parties hereto and by their advisors and his decision shall be final and binding on the parties. The costs of the independent expert shall be borne by the parties in such manner as the independent expert shall determine.
- 4. Interim payments pending determination

In the event that by the Review Date the amount of the reviewed rent has not been agreed or determined as aforesaid (the date of agreement or determination being herein called thp. Determination Date) then, in respect of the period (herein called the Interim Period) beginning with the Review Date and ending on the Determination Date, the Lessee shall pay to the Lessor rent at the yearly rate payable immediately before the Review Date and on the Determination Date, the Lessee shall pay to the Lessor, on demand as arrears of rent or the Lessor shall pay to the Lessee as the case may be, the amount (if any) by which the reviewed rent exceeds or is lower than the rent actually paid during the Interim Period (apportioned on a daily basis) together with interest thereon at the Base Rate from the Review Date to the date of actual payment.

## 5. Rent Restrictions

In the event of the Lessor being prevented or prohibited in whole or in part from exercising its rights under this clause and/or reviewing the Rent on any of the Review Dates by reason of any legislation, government order or decree or regulations or howsoever then the date at which the review would otherwise have taken effect shall be deemed to be extended to permit and require such review to take place on the first date thereafter upon which such right may be exercised and/or obtained in whole or in part and when in part on so many occasions as shall be necessary to revise the Rent and if there shall be a partial prevention only there shall be a further review on the first date or dates as aforesaid notwithstanding the Rent may have been increased or decreased in part on or since the date of review but in no instance shall the increase or decreased in Rent be dated back to exceed the statutory controls on increases or decreases of Rent laid down by law.

# 6. Disputes

If it becomes impossible to calculate the Rent for any Review Date by reference to the Consumer Price Index because of any change in the methods used to compile the Consumer Price Index after the date of this Lease or for any other reason whatever, of if any dispute or question whatever arises between the parties as to the construction or effect of this schedule, then the Rent for that review period or the disputed matter is to be determined by the independent expert in accordance with Clause 3 above. The independent expert is to have full power to determine, on such dates as he consider appropriate, what the increases or decreases in the Consumer Price Index would have been had it continued on the basis assumed for the operation of the rent review and in view of the information assumed to be available for it and the independent expert shall obtain all relevant information from the Central Statistic Office.

# 7. Memoranda of Reviewed Rent

As soon as the amount of any reviewed rent has been agreed or determined, memoranda thereof shall be prepared by the Lessor or its solicitors and thereupon shall be signed by or on behalf of the Lessor and the Lessee shall be responsible for and shall pay to the Lessor the stamp duty (if any) payable on such memoranda and any counterparts thereof but the parties shall each bear their own costs in respect thereof.

# 8. Time not of the Essence

For the purpose of this Schedule, time shall not be of the essence.

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IN WITNESS WHEREOF the Lessor and the Lessee have set their hands and affixed their Seals all the day and date first herein written.

# **SIGNED** and **DELIVERED** as a Deed By **THE LESSORS** In the presence of:-

illegible

/s/ SEAN KEENAN SEAN KEENAN

/s/ EAMON REAY EAMON REAY

/s/ TOM HOGAN TOM HOGAN

/s/ EUGENE DEVANEY EUGENE DEVANEY

**PRESENT** when the Commons Seal of **THE LESSEE** was affixed hereto And this Deed was delivered:

/s/ Peter J. Graham

DIRECTOR

/s/ EMMA HEDLEY For and on Behalf of Bradwell United COMPANY SECRETARY



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Email: info@abd.ie



Kevin Hough, Managing Director 13 Grattan Court Fr. Griffin Road Galway

655 Fax: +353 (0) 91 448 646 Mobil

Mobile: +353 (0) 86 263 0136

Web: www.abd.ie

**Delcath Systems** Unit 19 IDA Business & Technology Park Mervue Galway Ireland.

Date: Wednesday, 29 June 2011

## Re: CONDITIONAL SURVEY OF PROPERTY AT UNIT 19, IDA BUSINESS & TECHNOLOGY PARK, MERVUE, GALWAY, IRELAND DELCATH SYSTEMS INC:

Our Ref. Flles/700/DS/...

Instructions, Limitations and General Preamble:

We report that we carried out a survey at the above property on Wednesday, 29 June 2011, as per emailed instructions and our standard conditions of engagement.

This report shallbe for the private and confidential use of our client for whom the report is undertaken and must not be reproduced in whole or in part or relied upon by a third party without the agreement of the architect.

We will not be responsible to third parties who obtain, by any means, a copy of this report and act upon the information contained therein.

Whilst every care has been taken in completing our survey and report, the investigations have been non destructive in nature and therefore we are unable to report upon matters that are concealed at the time of the inspection, and the following assumptions have had to be made:

That high alumna cement (HAC), concrete or calcium chloride additive or other deleterious materials or techniques were not used when the original property or any subsequent additions were built.

That any wall ties that exist are not perished.

That your solicitor's or regal advisor's search will prove that the property is not subject to any unusual covenants, Local Authority restrictions, or onerous restrictions imposed by others, encumbrances or outgoings and that good title can be shown.

That future inspections of any hidden part of the structure which have not been inspected during this survey will not reveal material defects, or cause the surveyor to alter materially the conclusions drawn at the end of this report (if applicable).

We have not inspected woodwork or other parts of the structure which are not uncovered, unexposed or are inaccessible and we are therefore unable to report that the property is free from defect; however, we have done our best to draw conclusions about the construction from surface evidence visible at the time of our inspection.We have not inspected the wall cavities or wall ties. It was not possible to fully examine the floors in areas which were tiled. Corners of carpets were lifted where possible and isolated areas examined. No pressure smoke or other tests have been applied to the drains.

The survey commenced at approximately 10:00 a.m. The earty weather conditions were sunny, dry and calm with some heavy showers later in the day. References to left and right are made standing facing the front of the building. This report should be read in conjunction with our photographic record: DSCF2959- DSCF3063 [204MB].

Access Building Design Ltd. Registered in Ireland No. 301972 VAT No. E63219721 Directors: Kevin Hough Dlp. Arch. Ech. Eleanor Hough MSc

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# The Property in General:

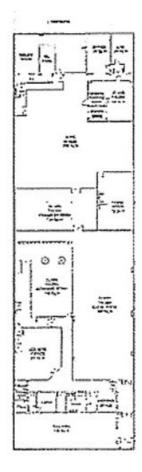
The property is situated in the IDA Business and Technology Park between the Monivea Road and the Tuam Road.Unit-19, this building, was constructed in the late 1960's and early 1970's as part of a series of starter industrial units. It is the last in a series of nine similar units which have housed companies such as Digital, Nortel and Avaya. Abbott Vascular Ireland were the most recent tenants of this building. They carried out extensive refurbishment throughout installing clean rooms, gowning rooms, canteen and other ancillary facilities. There is a small landscaped bed along the width of the building in front of which there are eight dedicated parking spaces. The dedicated parking and drop-off zone to the rear of the building has been cordoned off with galvanized steel fencing.

The overall area of the building and yards is roughly 1,800m2 [19,370sq.ft].

The site itself and surrounding lands are level. The front of the building faces north east.

### Accommodation:

Entrance Lobby and Reception Canteen **Toilet Facilities** Cleaner's Store Comms Room Locker Room Gowning Room: Class 100,000 Large Clean Room: Class 100,000 Large Transfer Room: Class 100,000 Small Clean Room: Class 100,000 Small Transfer Room: Class 100,000 Laboratory Service Corridor - Fire Protected Warehouse Shipping Offices Plant Room Various Small Plant and Services Rooms Shipping/Receiving Area Boiler Room Yard and Oil Storage Tank



#### 1. **Roofs:**

- <u>Main Roof & the Front-Offices Flat Roof</u> The externalflat roofs and pitched sections of the northlights are finished in Trocal or a similar high-performance membrane and appear to have been Installed in accordance with the manufacturer's instructions. The Trocal is laid on an · isolating membrane on high density insulation on a profiled metal deck.Structurally, the roof is formed with steel lattice girders which crank up at 45° in the northlights and together with the flat sections provide a self-supporting clear span of22.45m (73'7") at roughly 5.0m (16'5") above finished floor level. The lower level flat roof deck to the front of the building is supported on steel joists spanning from the front band beam to the corridor wall.
- <u>Main Roof Northlights</u>: The northlights to the main roof are pitched at 45°. They are Georgian wire aluminium-framed single-glazed units 21.4m wide by 1.8m high. Upstands and flashings appear to be in order and there's no apparent evidence of water ingress.
- <u>Front Offices Flat Roof Rooflights</u>: This external flat roof has a series of Georgian-wire aluminium-framed glazed rooflights installed over the toilet block area. Upstands and flashings appear to be in order and there's no apparent evidence of water ingress at present. However, the suspended ceiling tiles beneath do have signs of staining due to roof leaks in this area at some stage.
- <u>Pitched Roof to Shipping Area</u>: This roof is a single-skin profiled metaldeck with similar fascia and barge detailing. It sits on a steel mono-pitch frame with purlins and joists supports. There is a lining of thin reflective insulated material fixed to the soffite over this area. Possibly to prevent condensation. This yard area is open to the elements at one side and there are swallows nesting in the roof space.

Access Building Design Ltd.	Registered in Ireland No. 301972	VAT No. E63219721	Directors: Kevin Hough	Dlp. Arch. Ech. Eleanor Hough MSc
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"Condition: The roofs in general have been well maintained and although there are many penetrations for services there was no evidence of water ingress on the *day* of the survey. Galway has recently experienced a prolonged period of rainfall. There is some evidence of ponding on the flat roof sections but the ramwater outlets appear to be free from blockages and debris. The fall to the roof surfaces may not be adequate to disperse the water. There are patches of paint coming off the soffit (underside) for the metal decking. This roof construction would not meet with current Building Regulation standards. However, the air and atmosphere within the building was reasonably pleasant and there was no sign of musty smells associated with damp conditions.

# 2. <u>Walls:</u>

- <u>External Walls</u>:External masonry walls are finished in concrete brickwork.There is a plastered 450 x 450 reinforced concrete band beam above window level along the front elevation. This is capped with profiled steel flashing and laid over the roofing membrane. The band beam is supported by 230 x 230 reinforced concrete columns at 3.8m crs.
- Beneath the beam there are large sections of double-glazed aluminium framed windows which sit on the concrete floor slab. The lower sections of these windows are filled with lightweight Insulated panels which are painted. Other external walls to the rear and one side are either concrete brickwork or rendered concrete blockwork. The rear walls have been patched up in places where there were service ducts penetrating.
- <u>Condition</u>: This type of construction would no longer be acceptable as it doesn't comply with the Building Regulations. Structurally however, there was no evidence of subsidence or cracking in any of these elements. I checked the reveals with a moisture meter and results were negative. There are no signs of tidemarks or rising damp in the structure.
- Internal Walls: The compartment walls separating this unit from the adjoining buildings are constructed of 220mm fairfaced blockwork with 300 x 230 reinforced concrete columns at 7.62m crs. These walls for the most part have been lined with modular steel panels similar to those in the clean rooms. The dry-linings to the front office area, which has been kitted out as a canteen are dry-lined with plasterboard and skimmed. There are still some fairfaced block surfaces evident throughout the building; at the entrance and on the corridor to the toilet facilities and in the receiving area. Most of the other Internal walls to the structure I.e. clean rooms, ancillary areas and circulation corridors are constructed with 1160mm wide modular, insulated demountable steel-panels. They are roughly 80mm thick, fire-rated, with their own dedicated windows and doors. The panels are finished in polyester powder-coated galvanized steel plate coloured "Iceberg white• (near RAL 9010) and manufactured by "Dagard".
- <u>Condition</u>: The walls and ceilings to the clean rooms have been installed to a high standard to meet with the necessary regulations for this purpose: Class 100,000. The fairfaced masonry to the corridors and receiving area can be easily dry-lined if necessary. This would involve moving some of the electrical mechanical boards. Structurally, there is no evidence of subsidence or cracking in any of these elements and walls tested plumb with a spirit level throughout.

# 3. <u>Floors:</u>

- The floor is constructed in 300mm thick reinforced concrete. It is laid In bays with expansion joints between each bay. With the exception of the warehouse, the floors throughout are finished in Mipolam 500 Esprit 5001 "Ice Crystal" with matching caved skirtings. The floor to the warehouse is painted in an epoxy resin.
- <u>Condition</u>: The floors are generally in good condition. The resin coating In the warehouse Is showing signs of wear from heavy trafficking and cracking along the expansion joints. Otherwise, there is no evidence of subsidence or structural cracking.

# 4. <u>Ceilings:</u>

- The ceiling grid in the clean rooms and ancillary areas is 1200 x 600 with washable moisture proof tiles manufactured by Biogard. The tiles, light units, air-conditioning diffusers and grid are all bonded together to form an impermeable surface.
- The new ceiling grid in the canteen is 600 x 600 with standard acoustic tiles.
- The old ceiling grid in the toilets and comms room is 600 x 600 with standard moisture resistant tiles.

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<u>Condition</u>: The ceilings throughout are in good condition except in the toilets, comms room and cleaner's store where they should be replaced with new.

## 5. <u>Skirtings:</u>

• The old timber skirting boards, when tested With a moisture meter showed low levels of moisture throughout and are in good condition generally. All others are either coated metalor vinyl coved skirtings and are in good condition.

# 6. Components:

- <u>Windows and Doors to Front Elevation</u>: These are constructed in aluminium frame, double glazed with a void of less than 9mm. They are very poor quality and should be replaced with modern fenestration. This would address heat loss Issues, security problems and would also be more visually attractive
- <u>Emergency Exits</u>: The timber emergency exit doors are in reasonable condition but could do with being sanded and repainted.
- <u>Roller-Shutter Doors</u>: The old externalroller-shutter door to the delivery bay was locked shut on the day of inspection so therefore I cannot comment on its operation except to say I was informed that It works properly. The sectional roller door to the warehouse is a recent installation and is working satisfactorily.
- <u>Service Compartments</u>: The timber doors to the service compartments are in reasonable condition. These are all painted blue with identifying signage to each one. Ironmongery is in satisfactory condition.
- <u>Other Doors</u>: The doors to the toilet facilities are timber semi-solid core doors. They are of poorquality. Note: The door to the disabled WC and lobby does not meet the current Building Regulation standard width necessary for wheelchair access. Ideally this door should be directly on to a corridor and not through a lobby.

# 7. <u>Plumbing:</u>

• <u>Plumbing *in* general</u>:Plumbing looks to have been recently overhauled and in general appears satisfactory. This should however be thoroughly checked by a qualified certified plumber.

# 8. Saninitary Ware:

- <u>Toilet Facilities:</u>There are four cubicles and four wash hand basins in the female wc's. There are three urinals, two cubicles and three wash hand basins In the male wc's. There is one disabled access we.There is a slop sink in the cleaner's store.
- These facilities are dated and in need of complete overhaul.

## 9. Electrical& Mechanical:

• Both of these installations have recently been reinstated to a high standard. Some of the old boards are still insitu however and should be removed to avoid any confusion.

## 10. Sprinkler:

• There is a sprinkler system in this building. It is no longer in use and has been disconnected from the water supply. There are fire hydrants to the front and rear of the building in the event of an emergency.

# 11. Drainage:

- <u>Surface Water</u>: The rainwater outlets to all the roof areas are in satisfactory condition. There is a surface water drain running from the warehouse to the front of the building. It is accessible via sealed manholes in the concrete floor. Some of these are covered over in the clean rooms etc. The road gulley along the width of the property at the rear is completely blocked but there Is no sign of ponding.
- <u>Foul Sewer</u>: There are three internal sealed manholes in the main corridor just outside the toilet facilities. There was no evidence of foul smells and the soil vent pipes are satisfactory.
- I did not attempt to lift any of the manholes as this would involve breaking the seals. As there was no evidence of foul smells in the vicinity I would be confident that this aspect of the building is currently in satisfactory condition. Discharge from the new sanitary appliances in the gowning rooms is pumped from sumps via an overhead route to the external drainage.

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# 12. Boiler:

• It appears to be a reasonably new model and in working order.

# 13. Landscaping:

• The landscaped bed to the front of the building is in poor condition and in need of serious maintenance. I would advise that this feature be removed completely and replaced with something new and fresh to enhance the building's appearance.

**Conclusions:** Even though this building is roughly 40 years old it has been reasonably well maintained. It currently has a Building Energy Rating (BER) of D1 which is remarkable for its age and type of construction. The recent upgrades to the property are of a high standard and the roof finishes are far superior to those of the adjoining units.

Signed:	/s/ Kevin Hough		Date: 30/06/2		
	Kevin Hough For and on beha Access Building				
Access Build	ng Design Ltd.	Registered in Ireland No. 301972	VAT No. E63219721	Directors: Kevin Hough	Dlp. Arch. Ech. Eleanor Hough MSc

Dated 2nd August 2011

# SEAN KEENAN, EAMON REAY, TOM HOGAN AND EUGENE DEVANEY

Lessor

# DELCATH SYSTEMS LIMITED

Lessee

# LEASE

19 Mervue Industrial Estate Mervue Galway

# LEWIS C. DOYLE & CO.

Solicitors Augustine Court St. Augustine Street GALWAY.

REF: NF. 59954(M268.2)

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### Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act

I, Eamonn P. Hobbs, certify that:

- 1) I have reviewed this Quarterly Report on Form 10-Q of Delcath Systems, Inc;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 9, 2011

/s/Eamonn P. Hobbs

Eamonn P. Hobbs President and Chief Executive Officer (Principal Executive Officer)

### Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act

I, Graham G. Miao, certify that:

- 1) I have reviewed this Quarterly Report on Form 10-Q of Delcath Systems, Inc;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 9, 2011

/s/Graham G. Miao Graham G. Miao Chief Financial Officer (Principal Financial Officer)

#### Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes –Oxley Act of 2002

In connection with the Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2011, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eamonn P. Hobbs, the President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2011

/s/Eamonn P. Hobbs Eamonn P. Hobbs President and Chief Executive Officer (Principal Executive Officer)

#### Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes –Oxley Act of 2002

In connection with the Quarterly Report of DELCATH SYSTEMS, INC. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2011, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Graham G. Miao, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2011

/s/Graham G. Miao Graham G. Miao Chief Financial Officer (Principal Financial Officer)