#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

#### FORM 8-K

#### CURRENT REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): March 8, 2011

#### **DELCATH SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-16133 (Commission File Number) 06-1245881 (IRS Employer Identification Number)

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

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

NONE

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 7.01. Regulation FD Disclosure.

A copy of Delcath Systems, Inc.'s updated investor presentation slides that the Company intends to use effective immediately is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The information disclosed under this Item 7.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

#### Item 9.01. Financial Statements and Exhibits.

The following exhibit is filed herewith:

(d) Exhibits.

### Exhibit No.Descrip99.1Delcath

**Description** Delcath Systems, Inc. Investor Presentation Slides

#### 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 hereunto duly authorized.

Dated: March 8, 2011

#### DELCATH SYSTEMS, INC.

By: /s/ Peter Graham

Name: Peter Graham Title: Executive Vice President, General Counsel Exhibit No.Description99.1Delcath Systems, Inc. Investor Presentation Slides

Exhibit 99.1



# Investor Presentation March 2011

**NASDAQ: DCTH** 

### **Forward-looking Statements**

This presentation contains forward-looking statements, within the meaning of federal securities laws, related to future events and future financial performance which include statements about our expectations, beliefs, plans, objectives, intentions, goals, strategies, assumptions and other statements that are not historical facts. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions, which could cause actual results to differ materially from expected results, performance or achievements expressed or implied by statements made herein. Our actual results could differ materially from those anticipated in forwardlooking statements for many reasons, including; our ability to address the issues raised in the FDA's refusal to file letter and re-submit our New Drug Application (NDA) by the end of our third quarter; acceptance of our NDA by the FDA and approval thereof; acceptance of our CE Mark Technical File by our Notified Body and approval thereof; our ability to successfully commercialize the Delcath Chemosaturation System in the United States, EEA and other foreign markets and any corresponding revenue; our ability to enter into distribution and strategic alliances in the US and foreign markets and any corresponding revenue; actions of regulatory authorities; our ability to obtain reimbursement coverage for the Chemosaturation System; the progress of our research and development programs and future clinical trials; approval of the current or future chemosaturation system for other indications; overall economic conditions; the availability of capital; and other factors described in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K and the Quarterly Reports on Form 10-Q that we file with the Securities and Exchange Commission.

# **Company Highlights**

- § Focused on making established chemotherapeutic drugs work better in target organs
- § Chemosaturation delivers ultra-high dose chemotherapy to the liver
- § Successful Phase III trial results reported
- § Filed CE Mark for Class III medical device, potential approval in mid-2011
- § Positioned to address potential \$3.0 billion European labeled market opportunity
- § Expect to re-file 505(b)(2) NDA to FDA for orphan drug and delivery apparatus by end of September 2011
- § Potential \$675 million US labeled market opportunity
- § Issued patents and orphan drug designations create competitive barriers
- § Deep and experienced management team

**Concentrating the Power of Chemotherapy** 

### **Potential \$3.75 Billion Labeled Market Opportunity\***



# **Spectrum of Liver Cancer Treatments**

Type of Treatment	Advantages	Disadvantages
Systemic	<ul><li>ü Non-invasive</li><li>ü Repeatable</li></ul>	<ul> <li>Systemic toxicities</li> <li>Limited efficacy in liver</li> </ul>
Regional (e.g., IHP)	<ul><li>ü Therapeutic effect</li><li>ü Targeted</li></ul>	<ul> <li>Invasive/limited</li> <li>repeatability</li> <li>Multiple treatments are</li> <li>required</li> </ul>
Focal	ü Isolated removal of tumor	<ul> <li>90%</li> <li>unresectable</li> <li>Invasive and/or limited</li> <li>repeatability</li> </ul>

**Existing Treatments Involve Significant Limitations** 

## **The Delcath Chemosaturation System**



#### Advantages of Chemosaturation

- § ISOLATION
  - § Treats entire liver

### § SATURATION

§ Allows for ~ 100x effective dose escalation of drug agents at tumor site

### § **FILTRATION**

§ Controls systemic toxicities

Note: Image not to scale

Converts Traumatic Open Surgery to Minimally Invasive, Repeatable Procedure

# **Melphalan Dosing & Background**

Туре	Dosing (mg/kg)
Multiple Myeloma	0.25
Cherhoembolization	0.62
Surgical Isolated Hepatic Perfusion	1.50
MyEbablation	2.50-3.50
Chemosaturation	3.00
(PHP)	

- § Well understood, dose dependant, tumor preferential, alkylating cytotoxic agent that demonstrates no hepatic toxicity
- § Manageable systemic toxicities associated with Neutropenia and Cytopenia
- § Drug dosing over **<u>10x higher</u>** than FDA-approved dose via systemic IV chemotherapy
- § Dose delivered to tumor is approximately <u>100x higher</u> than that of systemic IV chemotherapy

A Promising Drug For Liver Cancer Therapy

## **What Chemosaturation Offers**

### Patients:

§ Significant improvement in disease control in the liver compared to standard of care in patients with unresectable hepatic melanoma mets

§ Manageable systemic toxicities

§Time, so that primary cancers can continue to be treated

### Physicians:

§ Novel, targeted liver directed treatment to <u>complement</u> other cancer therapies

§ Repeatable, percutaneous procedure

§ Ability to treat the entire liver, including both visible and micro tumors

§ Ability to continue treating patients for extra-hepatic disease

**Attractive Clinical and Economic Proposition For Patient and Providers** 

## **Current Patient Referral Path**



## **Future Patient Referral Path**



## **Summary of Phase III Results**

- § Primary endpoint exceeded
- § Secondary endpoints support results
- § OS cohort analysis favorable
- § Safety profile expected and consistent with currently approved labeling for melphalan

**Trial Outcomes Favorable and Consistent with Special Protocol Assessment** 

# **Phase III Clinical Trial Design**



Fully Powered, 93 Patient, Randomized, Multi-Center NCI Led Study

### **ASCO Presentation of Phase III Clinical Trial Results**

- § Trial results <u>exceed primary endpoint expectations;</u> p value = 0.001
- § Treatment arm shows 5x median hPFS compared to control arm
- § CS/PHP median hPFS of 245 days compared to 49 days for BAC
- § Hazard Ratio = .301
- § Patients failed prior therapies (radiation, chemo, immuno, image guided local)
- § 90% Ocular, 10% Cutaneous No difference in response
- § Overall PFS 186 vs. 46 days for BAC
- § 34% response rate for CS/PHP compared to 2% for BAC
- § 52% stable disease for CS/PHP compared to 27% for BAC
- § 86% overall clinical benefit (CR + PR + SD)

**Strong Clinical Trial Results** 

### **ASCO** Presentation of Phase III Clinical Trial (cont.)

- § Majority of BAC patients crossed over and obtained similar response from treatment
- § Total 93 patient trial 10 months median OS vs. 4 months expected <sup>1</sup> (due to cross over provision, most patients received PHP/CS treatment)
- § OS cohort analysis all positive trends
  - a) Median survival of 298 days for treatment arm compared to 124 in non-crossover BAC patients
  - b) Median survival of 398 days for BAC Cross Over patients vs. 124 non-cross over BAC patients
- § OS Secondary endpoint No difference in Kaplan-Meier curves(due to cross over treatment response)
- § Safety profile as expected in line with current FDA approved labeling for IV administration of Melphalan and Phase I CS/PHP study results
  - § Treatment related Deaths: 3/40 patients (7.5%) 3/116 procedures (2.6%)
  - § Neutropenic Sepsis (n=2) 5%, Hepatic Failure (n=1) 2.5% (95% tumor burden)
  - § Current approved labeling for Melphalan 3% to 10% mortality rate.

<sup>1</sup> Source: Unger et. al. Cancer 2001;91: 1148

**Encouraging Survival Data With Expected Safety Profile** 

# **Phase I/II NCI Trials – Neuroendocrine**

### **Neuroendocrine Tumor Trial Results (n=23)\***

	Nun	nber
Primary Tumor	(n)	
Histolngki		3
Pancreatic Islet		17
Cell Response		
Not Evaluable (Toxicity, Incomplete Treatment) Orthopic		4
Pivegressive		1
Diadanteesigeigee		3
/ Stable Disease Partial Response		13
Complete Restonse (No Evidence of		2
Bigerive tumor Response		15
Objective Tumor Response Rate		<b>79</b> %
	Duration	
Median Hepatic	(months)	39
BFS Overall Survival After CS		40



\*Presentation at American Hepato-Pancreo-Biliary Association 2008 annual meeting

**Promising Initial Response Rate in Attractive Market** 

# **Regulatory Status**

### Europe:

- § Submitted technical file for CE Mark as Class III medical device on December 6, 2010
- § ISO 13485 certification for manufacturing facility received February 17, 2011
- § Goal remains to receive CE Mark approval by mid-2011

### **United States:**

- § Submitted 505(b)(2) NDA to FDA on December 22, 2010
- § Refusal to file (RTF) letter received February 18, 2011
  - § Manufacturing plant inspection timing
  - § Product and sterilization validation
  - § Additional safety data
  - § Additional statistical analysis clarification
- § Currently assembling the requested information
- § Will meet with FDA to clarify our understanding of requirements to move forward
- § Current expectation is to resubmit NDA by end of September 2011

**Europe Appears on Track While U.S. is Delayed by 6-9 Months** 

## **Product Development Pipeline**



## Market Opportunity\* by Disease (patients)



## **EU – Landscape**

- § CE Mark approval covers European Economic Area (EEA)
- § EEA includes 32 countries
- § 14 countries currently have Melphalan for injection commercially available
  - § Belgium (BE), Czech Republic (CZ), Germany (DE), Estonia (EE), Spain (ES), France (FR), Ireland (IE), Italy (IT), Lithuania (LT), Luxembourg (LU), Netherlands (NL), Sweden (SE), Slovakia (SK), United Kingdom (UK).
- § 6 initial target countries (DE, UK, FR, IT, SP, NL) represent 85%-90% of total potential market

Large European Market Opportunity Concentrated in Six Countries

### Market by Disease – EU Device Only Initial Target Markets (DE, UK, FR, IT, SP, NL)

	Germany (Direct)	UK (Direct)	France (Indirect)	Italy (Indirect)	Spain (Indirect)	Netherlands (Direct)	Total Potential (patients)	Potential Market (\$ millions) <sup>1,2,3</sup>
	Total Potential Market #Patients							
Ocular Melanoma	403	296	294	284	197	79	1,553	\$46.6
Cutaneous Melanoma	2,834	1,735	1,314	1,398	628	662	8.571	\$257.1
CRC	18,978	10,155	10,490	13,952	7,694	3,151	64,420	\$1,932.6
HCC (Primary)	3,941	1,734	3,645	6,253	2,616	197	18,386	\$551.6
NET	2,168	1,624	1,645	1,579	1,185	438	8,639	\$259.2
TOTAL	25,087	13,513	15,780	21,784	11,495	3,786	91,445	\$3,047.1

1. Assumes 2.5 treatments per patient

2. Assumes ASP of \$12K (device only)

3. Assumes mix of direct sales and distributors

**Europe is Potential \$3.0 Billion Market Opportunity for Device Only** 

### Market by Disease - EU Including Drug Initial Target Markets (DE, UK, FR, IT, SP, NL)

	Germany (Direct)	UK (Direct)	France	Italy (Indirect)	Spain (Indirect)	Netherlands	Total Potential	Potential Market
	(Direct)	(Direct)	(indirect)	(muneci)	(munect)	(Direct)	(patients)	(\$ mmons)-,-,5
							0	
	Total Potential Market #Patients							
Ocular Melanoma	403	296	294	284	197	79	1,553	\$62.1
Cutaneous Melanoma	2,834	1,735	1,314	1,398	628	662	8.571	\$342.8
CRC	18,978	10,155	10,490	13,952	7,694	3,151	64,420	\$2,576.8
HCC (Primary)	3,941	1,734	3,645	6,253	2,616	197	18,386	\$735.5
NET	2,168	1,624	1,645	1,579	1,185	438	8,639	\$345.6
TOTAL	25,087	13,513	15,780	21,784	11,495	3,786	91,445	\$4,062.8

1. Assumes 2.5 treatments per patient

2. Assumes ASP of \$16K, when Delcath branded melphalan is available

3. Assumes mix of direct sales and distributors

Europe Represents Potential \$4.1 Billion Market Opportunity for Drug & Device

# **Market by Disease - USA**

Liver Metastasis	Potential Market # Patients	Potential Market # Procedures (Avg 2.5/patient)	Potential Market (\$MM) \$20K ASP **
Ocular Melanoma	1,622	4,055	\$81.1
Cutaneous Melanoma	11,883	29,708	\$594.2
TOTAL (MELAENDENIA)	13,505	33,763	\$675.3
Label) CRC	38,423	96,057	\$1,921.1
HCC (Primary)	12,386	30,964	\$619.3
NET	9,986	24,965	\$499.3
TOTAL OTHER (Potential Label	60,794	151,985	\$3,039.7
*TPM Total Potential Market ** Estimated ASP			

# **Market by Disease – Asia**

Initial Target Markets (China, Japan, S. Korea, Taiwan, Australia)

	<b>China</b> (Drug)	S. Korea (Drug)	<b>Japan</b> (Device)	<b>Taiwan</b> (Drug)	<b>Australia</b> (Device)	<b>Total Potential</b> (patients)	Potential Market 1,2,3,4
Total Potential Market # Patients							

HCC (Primary)	197,082	7,486	7,625	4,945	604	217,742	\$4,899.2
OTHER							
CRC	59,644	6,219	27,396	2,762	3,891	99,912	\$2,248.0
NET	35,503	1,275	3,355	608	562	41,303	\$929.3
Ocular Melanoma	1,760	66	175	31	96	2,128	\$47.9
Cutaneous Melanoma	667	74	238	429	1,996	3,404	\$76.6
OTHER TOTAL	292,229	14,980	38,376	8,315	5,057	358,957	\$8,201.0

1. Assumes 2.5 treatments per patient

2. Assumes ASP of \$9K

- 3. Assumes mix of systems with and without Delcath branded melphalan
- 4. Assumes sales by distributors

Asia Represents Potential \$8.2 Billion Market Opportunity

## **Reimbursement Strategy**

#### **United States:**

- § Have retained leading reimbursement experts
- § Seek chemosaturation specific codes:

Physician:

- While undergoing FDA review, apply for CPT Category III code
- § Convert the Category III code to Category I following FDA approval

Hospital:

- § Apply for new ICD-9/10 procedure code to capture full procedure of hepatic isolation and chemosaturation
- § Request new DRG based on costs above those of existing DRGs and clinical dissimilarity to other hepatic procedures in current DRGs

#### Europe:

- § Have retained leading reimbursement experts
- § No centralized EU reimbursement body
- § Nationalized healthcare systems in each geography dictate a country by country effort
- § Focused on highlighting clinical value proposition and demonstrating cost effectiveness

**Reimbursement is a Multi-Faceted Work in Progress** 

## **Three-Pronged Business Strategy**

### Commercialization

- § Gain regulatory approval
  - § Goal: receive CE Mark approval for Class III medical device by mid-2011
  - § Goal: re-file NDA by end of September 2011
  - § Goal: receive FDA approval of NDA in 2012
  - § Goal: receive EU approval for proprietary drug 2014
- § Direct and distribution partners OUS
- § Build out direct specialty sales force for U.S.

### **Pursue Asian Strategic Alliances**

- § Chi-Fu Trading Company Ltd. signed 2/9/2010 for Taiwan
- § Proprietary drug and delivery apparatus approval for HCC

### **Establish U.S. and EU Pharma Alliances**

§ Co-develop and fund additional indications for Delcath Chemosaturation System

**Combination of Direct Sales Model, Partnerships & Distributors** 

## **2011 European Commercialization**

### § Initially target 6 markets accounting for 85%-90% of patients

- § 7 Direct sales territories initially to cover UK, Germany, Netherlands (Sales and Medical Science Liaisons)
- § Distributors in Spain, Italy, & France
- § 5 Clinical Specialists to support site initiations and training
- § Establish EU Centers of Excellence and KOLs for training and support
- § Establish European website to facilitate patient education & awareness
- § Test market for 3-6 months to validate assumptions and finalize model
- § Full commercialization in late 2011

Direct Sales Model in Northern Europe & Distributors in Southern Europe

- § Initial focus on top 50 cancer centers and referring community hospitals
- § 12 Sales & Medical Science Liaison territories ultimately expanding to as many as 60 territories as revenues ramp
- § 5 Clinical Specialists to support site initiation and training
- § Utilize top centers from Phase III trial as Centers of Excellence for training and support

**Direct Sales Model in the United States Focused on Leading Cancer Centers** 

## **Intellectual Property**

### **Patent Protection**

- § 7 issued U.S. patents, 10 foreign patents issued and 4 pending
- § Primary device patent set to expire August 2016
- § Post FDA approval up to 5 years of patent extension possible

### **FDA Protection**

- § Orphan Drug Designation granted for melphalan in the treatment of ocular melanoma, cutaneous melanoma and metastatic neuroendocrine tumors, as well as for doxorubicin in the treatment of HCC
- § Additional Orphan Drug applications to be filed for other drugs and indications, including HCC and CRC

**Multiple Levels of Protection** 

## **Deep and Experienced Management Team**

Executive	Title	Prior	Years of Experience
Eamonn	President and	Affiliation(s) AngioDynamics,	30
Agapa Pappa	6E8	ĀīgībDynamics, RBC Capital Markets	28
McDonald Krishila Kandarpa, M.D., Ph.D.	CMO and EVP, R&D	Harvard, MIT, Cornell, UMass	37
Agustin Gago	EVP, Global Sales & Marketing	AngioDynamics, E-Z-EM	29
Peter	EVP & General Counsel	Bracco,	16
Graham, J.D. John Purpura	EVP, Regulatory Affairs & Quality	E₂Z-EM Z-	27
Bill Appling	Assurance Devications &&D	EngioDynamics Sanofi- Aventis	25
Bernie Tyrrell	Medical SVP N. American Sales & Marketing	Epicept, <b>Otbuka</b> n & Johnson, Eli	33
Dan Johnston, Ph.D.	VP, Pharma R&D	Pfizer, Wyeth Zeneca	10

Significant Combination Product Approval and Commercialization Experience



### **Financial & Operating Overview**

- **Follow On Offerings:** §
- § **Burn Rate:**
- Cash: §
- § Debt:
- **Shares Out:** §
- § Institutional Ownership:
- **Market Capitalization:** §
- Avg. Daily Volume (3 mos) ~ 1.05 million §

- Raised ~ \$70 million since November 2009
  - Approximately \$2.2 million per month
  - ~ \$47 million at December 31, 2010 None
- 43.0 million (49.3 million fully diluted\*)
- ~ 23% at December 31, 2010
- ~ \$281 million as of February 28, 2011

### **Capital Structure Strengthened Significantly in 2010**

As of February 28, 2011 fully diluted includes an additional 3.7 million options at \$4.91, 2.5 million warrants at \$3.51, and 67,590 unvested restricted shares.

# **Company Highlights**

- § Focused on making established chemotherapeutic drugs work better in target organs
- § Chemosaturation delivers ultra-high dose chemotherapy to the liver
- § Successful Phase III trial results reported
- § Filed CE Mark for Class III medical device, potential approval in mid-2011
- § Positioned to address potential \$3.0 billion European labeled market opportunity
- § Expect to re-file 505(b)(2) NDA to FDA for orphan drug and delivery apparatus by end of September 2011
- § Potential \$675 million US labeled market opportunity
- § Issued patents and orphan drug designations create competitive barriers
- § Deep and experienced management team

**Concentrating the Power of Chemotherapy** 

### **Appendix I. – Delcath Sources for Market Estimates**

American Cancer Society. Cancer Facts & Figures 2010. Atlanta: American Cancer Society; 2010.

Alexander, Richard H., David L. Bartlett, and Steven K. Libutti. "Current Status of Isolated Hepatic Perfusion With or Without Tumor Necrosis Factor for the Treatment of Unresectable Cancers Confined to the Liver." The Oncologist 5 (2000): 416-24.

Blake, Simon P., Karen Weisinger, Michael B. Atkins, and Vassilios Raptopoulos. "Liver Metastases from Melanoma: Detection with Multiphasic Contrast Enhanced CT." Radiology 213 (1999): 92-96. Print

Ferlay J, Shin HR, Bray F, Forman D, Mathers C and Parkin DM. GLOBOCAN 2008, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10 [Internet]. Lyon, France: International Agency for Research on Cancer; 2010. Available from: http://globocan.iarc.fr

Nawaz Khan, Ali, Sumaira MacDonald, Ajay Pankhania and David Sherlock. "Liver, Metastases: [Print] - EMedicine Radiology." Liver, Metastases. EMedicine - Medical Reference, 10 Feb. 2009. Web. <a href="http://emedicine.medscape.com/article/369936-print">http://emedicine.medscape.com/article/369936-print</a>.

Neuroendocrine Tumors. Practice Guidelines in Oncology- v.2.2009. National Comprehensive Cancer Network (NCCN). 2009.

Pawlik, Timothy M., Daria Zorzi, Eddie K. Abdalla, Bryan M. Clary, Jeffrey E. Gershenwald, Merrick I. Ross, Thomas A. Aloia, Steven A. Curley, Luis H. Camacho, Lorenzo Capussotti, Dominique Elias, and Jean-Nicolas Vauthey. "Hepatic Resection for Metastatic Melanoma: Distinct Patterns of Recurrence and Prognosis for Ocular Versus Cutaneous Disease." Annals of Surgical Oncology 13.5 (2006): 712-20.