

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): **April 26, 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 System, 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.	Description
99.1	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.

DELCATH SYSTEMS, INC.

Dated: April 26, 2011

By: /s/ Peter Graham
Name: Peter Graham
Title: Executive Vice President, General Counsel

EXHIBIT INDEX

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Investor Presentation

April 2011

NASDAQ: DCTH

Forward-looking Statements

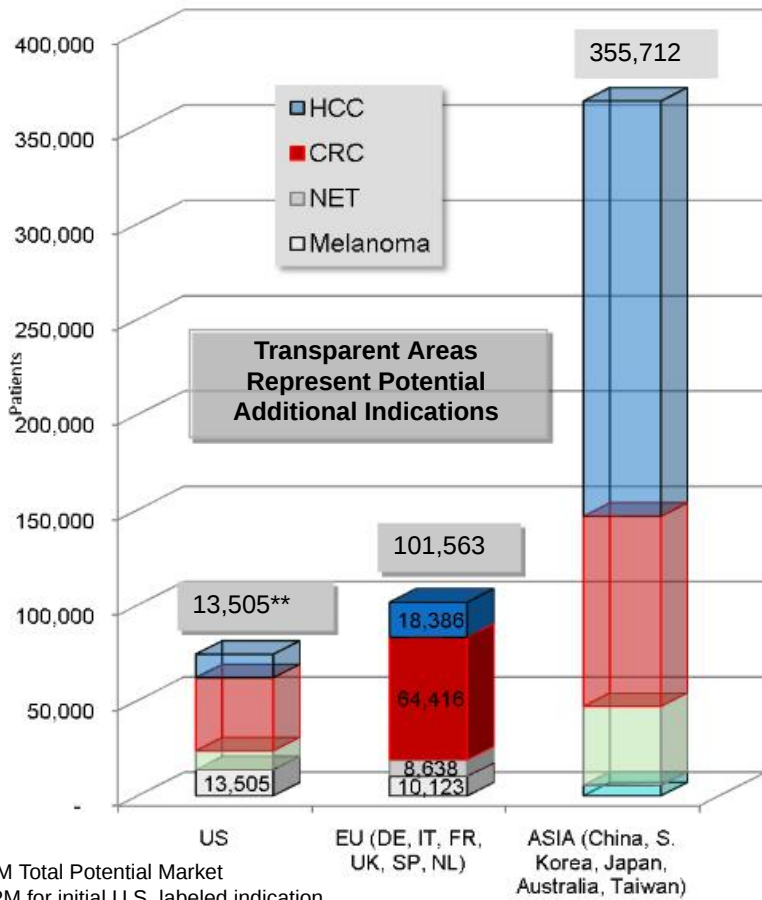
This presentation contains forward-looking statements, within the meaning of federal securities laws, related to future events and future financial performance which include statements about our expectations, beliefs, plans, objectives, intentions, goals, strategies, assumptions and other statements 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 forward-looking statements for many reasons, including; uncertainties relating to the time required to build inventory and establish commercial operations in Europe, adoption, use and resulting sales, if any, for the chemosaturation delivery system in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with cancer in the liver, acceptability of the Phase III clinical trial data by the FDA, our ability to address the issues raised in the Refusal to File letter received from the FDA and the timing of our re-submission of our NDA, re-submission and acceptance of the Company's NDA by the FDA, approval of the Company's NDA for the treatment of metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, approval of the current or future chemosaturation system for other indications or the same indication in other foreign markets, actions by the FDA or other foreign regulatory agencies, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, our ability to secure reimbursement for the chemosaturation system, progress of our research and development programs and future clinical trials, uncertainties regarding our ability to obtain financial and other resources for any research, development and commercialization activities, overall economic conditions 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
- § Received CE Mark approval for Class III medical device on April 13, 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 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*



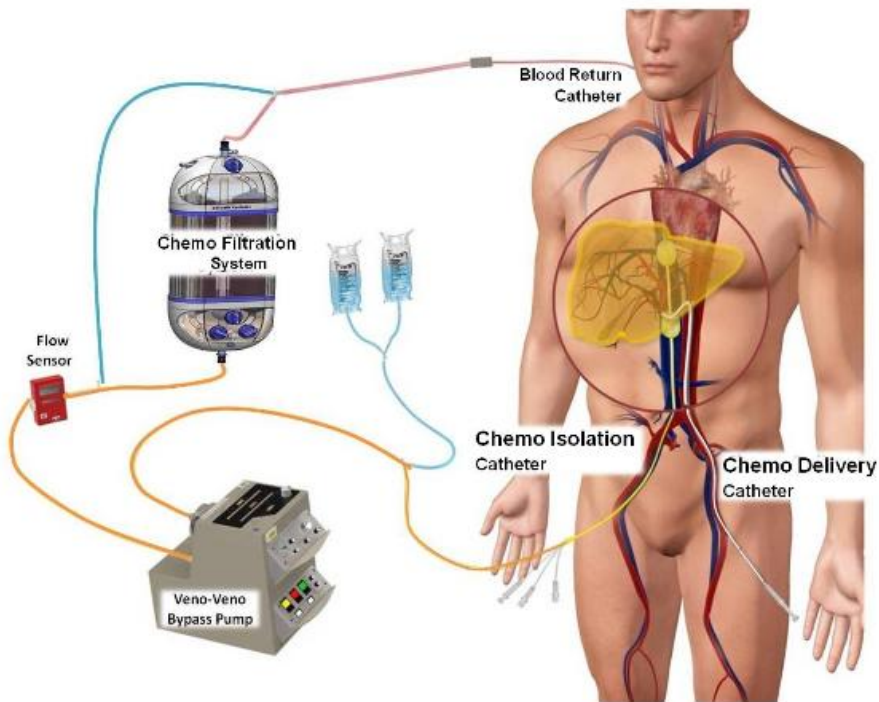
- Seeking initial indication for Melanoma liver mets in USA
- CE Mark in EU for delivery of melphalan to the liver permits physician use on a broad range of liver cancers
- Asia potentially requires long term clinical development pathway
- Australia Niche opportunity (high melanoma incidence) – device approval following EU CE Mark
- Significant potential label expansion opportunity

Spectrum of Liver Cancer Treatments

Type of Treatment	Advantages	Disadvantages
Systemic	<ul style="list-style-type: none">ü Non-invasiveü Repeatable	<ul style="list-style-type: none">- Systemic toxicities- Limited efficacy in liver
Regional (e.g., IHP)	<ul style="list-style-type: none">ü Therapeutic effectü Targeted	<ul style="list-style-type: none">- Invasive/limited repeatability- Multiple treatments are required
Focal	<ul style="list-style-type: none">ü Isolated removal of tumor	<ul style="list-style-type: none">- 90% unresectable- Invasive and/or limited repeatability

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

Type	Dosing (mg/kg)
Multiple Myeloma (label)	0.25
Chemoembolization	0.62
Surgical Isolated Hepatic Perfusion (IHP)	1.50
Myeloablation	2.50-3.50
Chemosaturation (PHP)	3.00

- § 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 **10x higher** than FDA-approved dose via systemic IV chemotherapy
- § Dose delivered to tumor is approximately **100x higher** than that of systemic IV chemotherapy

A Promising Drug For Liver Cancer Therapy

What Chemosaturation Offers

Patients:

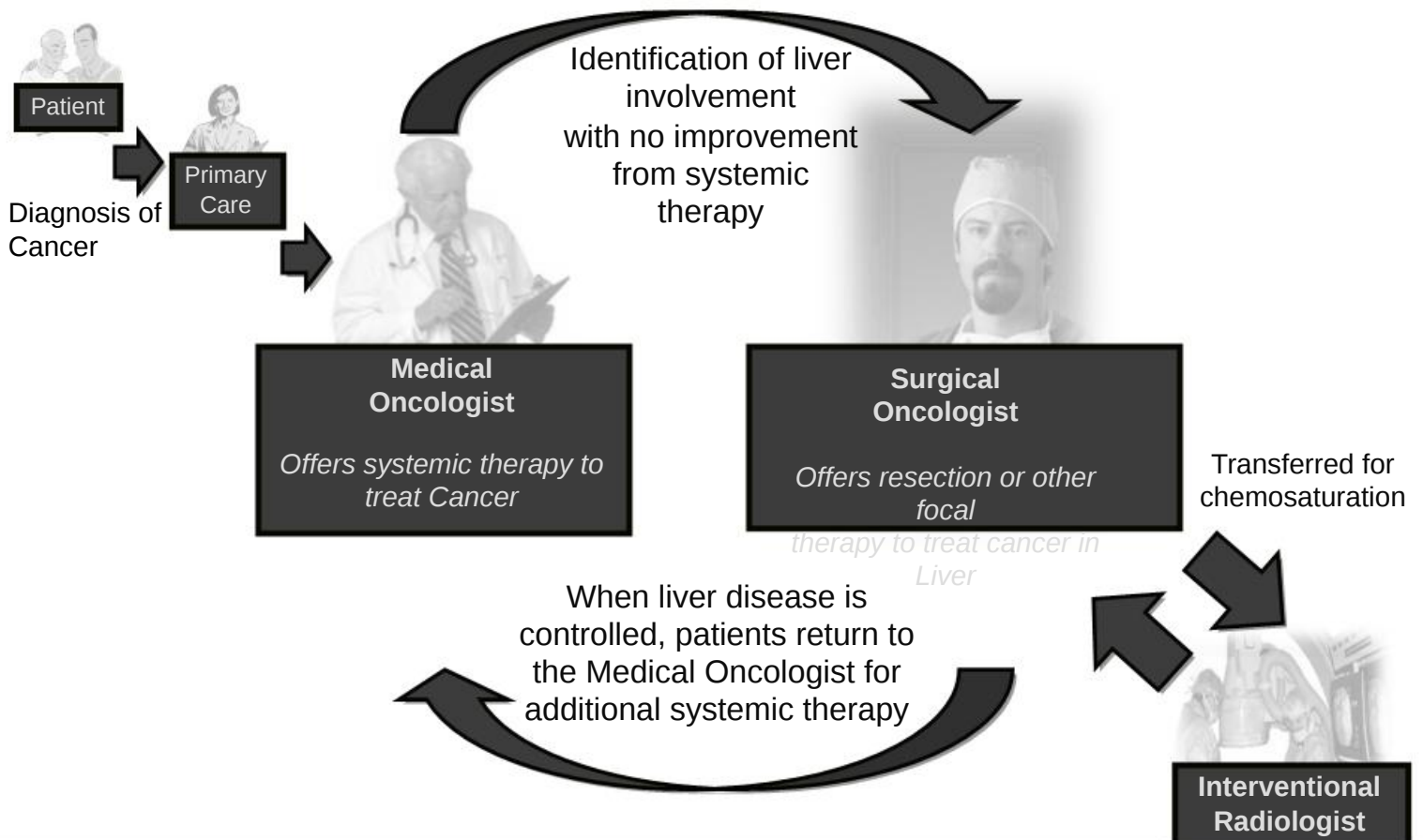
- § Significant improvement in disease control in the liver compared to standard of care in patients with unresectable hepatic melanoma mets
- § Manageable systemic toxicities
- § Time, so that primary cancers can continue to be treated

Physicians:

- § Novel, targeted liver directed treatment to complement 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

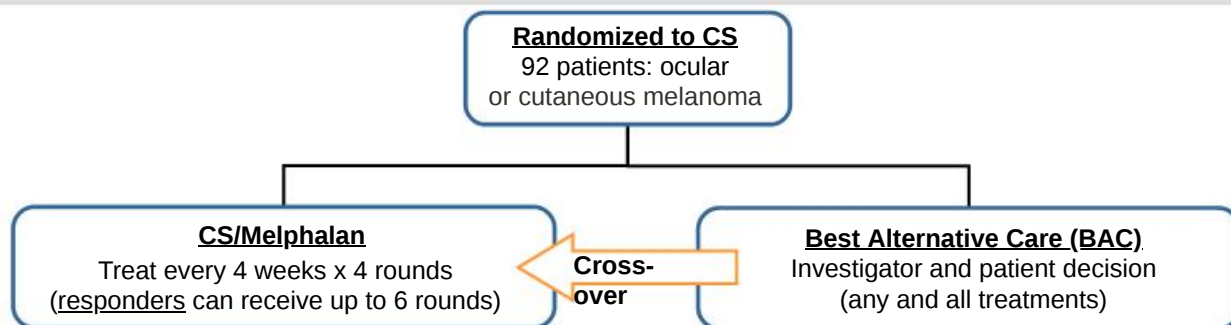


Summary of Phase III Results

- § 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



Primary Trial Endpoint

- § Statistically significant difference in Hepatic Progression Free Survival ("hPFS"): $p < 0.05$
- § Over 80% of Oncologic drugs approved by FDA between 2005 – 2007 on endpoints other than overall survival

Modeled hPFS for Trial Success:

7.73 months (CS)
vs.
4 months (BAC)

Secondary Trial Endpoints

- § **Hepatic response** and duration of hepatic response
- § **Overall response** and duration of overall response
- § **Overall Survival – Diluted by Cross Over**
- § **SAP calls for analysis of various patient cohorts**
Hepatic Response – Metastatic Melanoma



Pre-CS (Baseline)



Post-CS (22+ Months)

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

ASCO 2010 Presentation of Phase 3 Clinical Trial Results

- § Trial results exceed primary endpoint expectations; 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 2010 Presentation of Phase 3 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 ¹ (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.

¹ 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)*

	Number (n)
Primary Tumor Histology	
Carcinoid	3
Pancreatic Islet Cell	17
Response	
Not Evaluable	4
CR	1
PR	3
SD	13
Complete Response (No Evidence of Tumor Reduction)	2
Objective Tumor Response	15
Objective Tumor Response Rate	79%
Duration (months)	
Median Hepatic	39
BFS	40
Overall Survival After CS	40



Pre-CS
(Baseline)

Post-CS #1
(+6 Weeks)

Post-CS #2
(+4 Months)

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

Promising Initial Response Rate in Attractive Market

Regulatory Status

Europe: approved as a Class III medical device

- § ISO 13485 certification for manufacturing facility received February 17, 2011
- § Received CE Mark approval as a Class III medical device April 13, 2011
- § Melphalan already approved and available in 14 EU countries

United States: goal is to resubmit by end of 2011

- § 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
- § Current expectation is to resubmit NDA by end of 2011

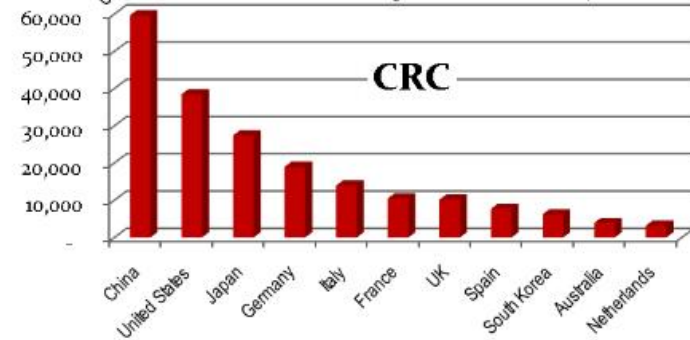
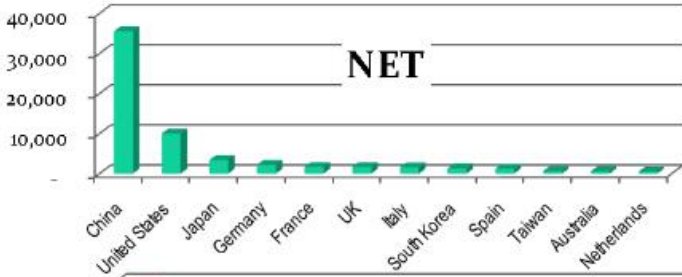
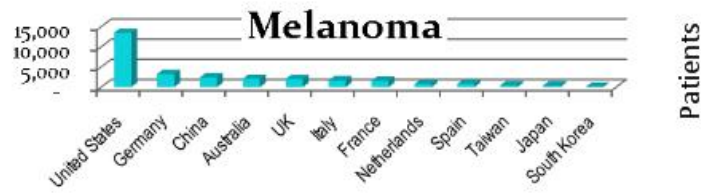
Approved in Europe With U.S. Decision Expected in 2H 2012

Product Development Pipeline

	Initial Opportunity	Near Term (< 5 years)	Intermediate Term (> 5 years)
EU	<ul style="list-style-type: none"> All liver cancers – melphalan Class III device 3rd party melphalan 	<ul style="list-style-type: none"> Proprietary melphalan drug approval Apparatus improvements 	<ul style="list-style-type: none"> Additional drugs Other organs
US	<ul style="list-style-type: none"> Melanoma liver mets Proprietary drug-melphalan & apparatus 	<ul style="list-style-type: none"> Broaden label Other liver cancers – melphalan Apparatus improvements 	<ul style="list-style-type: none"> Additional drugs Other organs
ASIA		<ul style="list-style-type: none"> Primary liver cancer (HCC) Drug-melphalan & apparatus 	<ul style="list-style-type: none"> Broaden label Other liver cancers – melphalan Additional drugs Other organs

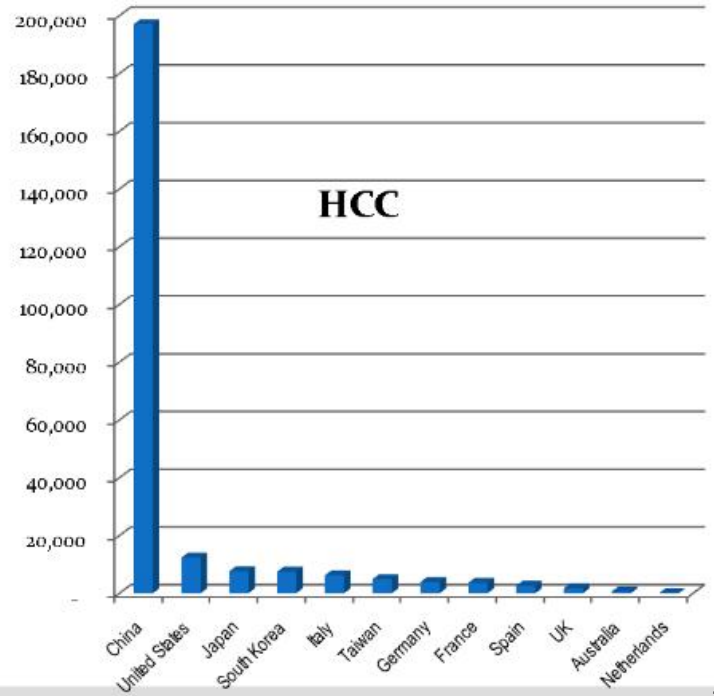
Robust Development Program Planned

Market Opportunity* by Disease (patients)



*TPM Total Potential Market

- US – largest opportunity for Melanoma
- China – largest opportunity for HCC
- CRC – largest opportunity worldwide



EEA – 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 top 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 – EEA Device Only

	Germany (Direct)	UK (Direct)	France (Indirect)	Italy (Indirect)	Spain (Indirect)	Netherlands (Direct)	Total Potential (patients)	Potential Market (\$ millions) ^{1,2,3}
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 – 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 MELANOMA (Initial Expected Label)	13,505	33,763	\$675.3
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 Expansion)	60,794	151,985	\$3,039.7

*TPM Total Potential Market

** Estimated ASP

Market by Disease – Australia/Asia

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

	China (Drug)	S. Korea (Drug)	Japan (Device)	Taiwan (Drug)	Australia (Device)	Total Potential (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

Europe:

- § No centralized EEA reimbursement body
- § Nationalized healthcare systems in each geography dictate a country by country program
 - § Existing codes likely used until permanent reimbursement established (e.g. Italy)
 - § New technology codes available such as NUB in Germany
 - § Other oncology therapies currently reimbursed, despite lacking randomized data
- § Have retained leading reimbursement experts
- § Focused on highlighting clinical value proposition and demonstrating cost effectiveness

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

Reimbursement is a Multi-Faceted Work in Progress

Three-Pronged Business Strategy

Commercialization

- § Establish direct sales force in Northern Europe and distribution partners in the Southern Europe with commercialization expected to begin in late 2011
- § Gain additional regulatory approvals and expand commercialization
 - § Goal: leverage CE Mark to gain additional country approvals in Australia, South America, and Asia
 - § Re-file NDA by end of 2011
 - § Goal: receive FDA approval of NDA in 2012 and 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

- § Initiate test market in 2011 for 3-6 months to validate assumptions and finalize model
- § Largest 6 countries accounting for 85%-90% of patients
 - § 8-10 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 European operations
- § Develop EEA Centers of Excellence and KOLs for training and support
- § Establish European website to facilitate patient education & awareness
- § Full commercialization in 2012

Direct Sales Model in Northern Europe & Distributors in Southern Europe

US Commercialization in 2012

- § 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 initially 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 Affiliation(s)	Years of Experience
Eamonn Hobbs	President and CEO	AngioDynamics, E-Z-EM	30
David McDonald	CMO and EVP, R&D	AngioDynamics, RBC Capital Markets	28
Krishna 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 Graham, J.D.	EVP & General Counsel	Bracco, E-Z-EM	16
John Purpura	EVP, Regulatory Affairs & Quality Assurance	E-Z-EM, Z-EM	27
Bill Appling	SVP Operations & R&D	AngioDynamics, Sanofi-Aventis	25
Bernie Tyrrell	Medical SVP N. American Sales & Marketing	Epicept, Bristol-Myers Squibb & Johnson, Eli Lilly	33
Dan Johnston, Ph.D.	VP, Pharma R&D	AstraZeneca, Pfizer, Wyeth	10

Significant Combination Product Approval and Commercialization Experience

Financials

Financial Summary

Financial & Operating Overview

§ Follow On Offerings:	Raised ~ \$70 million since November 2009
§ Burn Rate:	Approximately \$2.6 million per month
§ Cash:	~ \$39 million at March 31, 2010
§ Debt:	None
§ Shares Out:	43.1 million (49.8 million fully diluted*)
§ Institutional Ownership:	~ 23% at December 31, 2010
§ Market Capitalization:	~ \$317 million as of March 31, 2011
§ Avg. Daily Volume (3 mos)	~ 1.1 million

Capital Structure Strengthened Significantly in 2010

* As of March 31, 2011 fully diluted includes an additional 4.1 million options at \$5.07, 2.5 million warrants at \$3.51, and 50,790 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
- § Received CE Mark approval for Class III medical device on April 13, 2011
- § Positioned to address potential \$3.0 billion European labeled market opportunity
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- § 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. <<http://emedicine.medscape.com/article/369936-print>>.

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.