

**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): **June 3, 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.	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: June 3, 2011

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

EXHIBIT INDEX

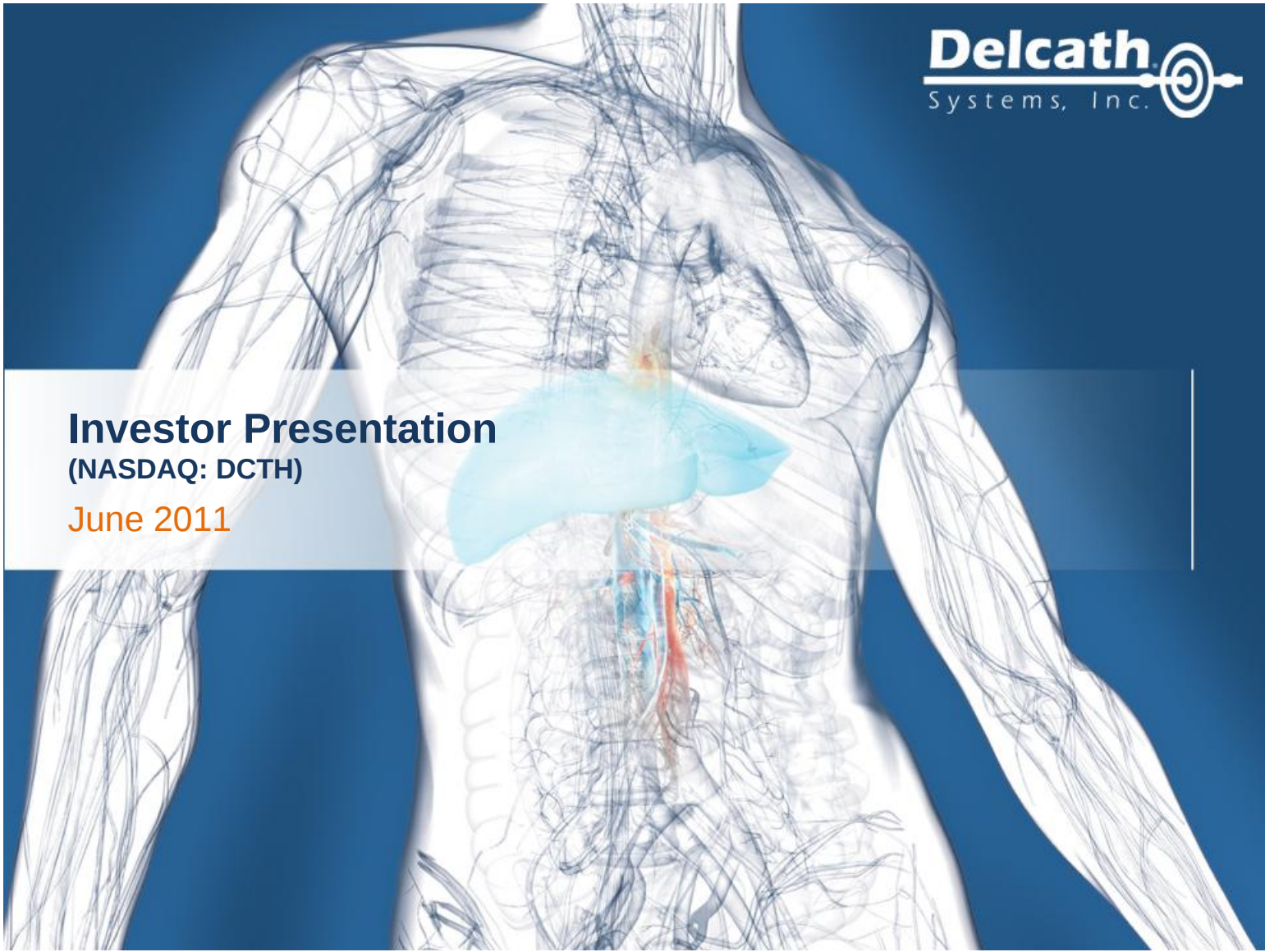
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Investor Presentation

(NASDAQ: DCTH)

June 2011



Forward-looking Statements

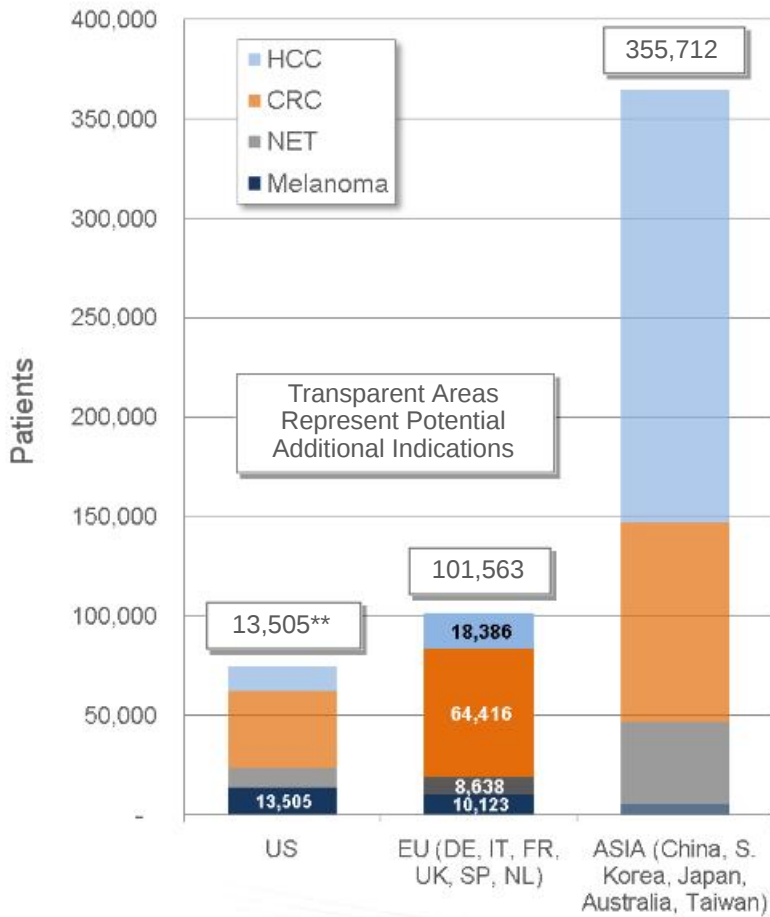
This presentation contains forward-looking statements, within the meaning of federal securities laws, related to future events and future financial performance which include statements about our expectations, beliefs, plans, objectives, intentions, goals, strategies, assumptions and other statements 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 system as a treatment for patients with cancer in the liver, availability of melphalan in the EEA, 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, our ability to leverage the CE Mark for the chemosaturation system to obtain foreign regulatory approval, 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

- Our goal - making established chemotherapeutic drugs work better in target organs
- Initial focus is high dose chemotherapy for improved disease control in the liver
- Successful and highly statistically significant 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
- Leverage CE Mark to help obtain regulatory approvals in Asia, America's (EX US), MEA, and Australia to address potential \$8 Billion 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, trade secrets and orphan drug designations create competitive barriers
- Deep and experienced management team

Concentrating the Power of Chemotherapy to Help Improve Disease Control in the Liver

Large Unmet Clinical Need = Large Commercial Opportunity



- CE Mark in EU for delivery of melphalan to the liver permits physician use on a broad range of liver cancers
- Potential \$3 Billion EU Labeled Market Opportunity*
- Leverage CE Mark for regulatory approvals in Asia, America's (EX US), MEA, and Australia
- Potential \$8 Billion Asia/Australia Market Opportunity*
- Seeking initial indication in US for melanoma mets - \$670 million ** market opportunity, with potential label expansion opportunity

*TPM Total Potential Market

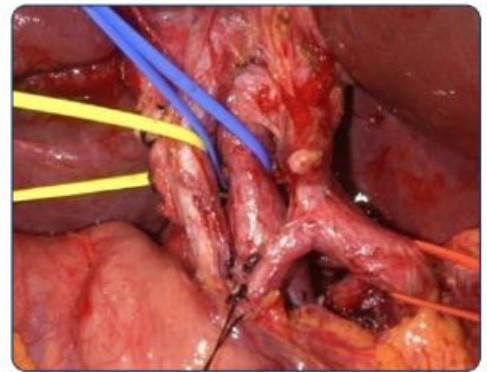
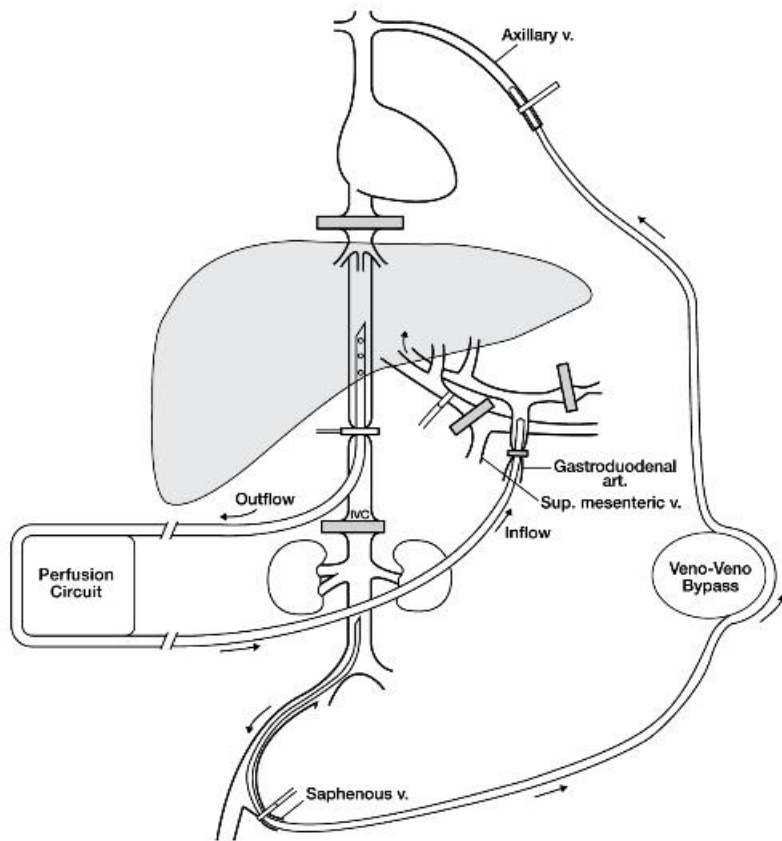
**TPM for initial U.S. labeled indication only

Spectrum of Liver Cancer Treatments

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

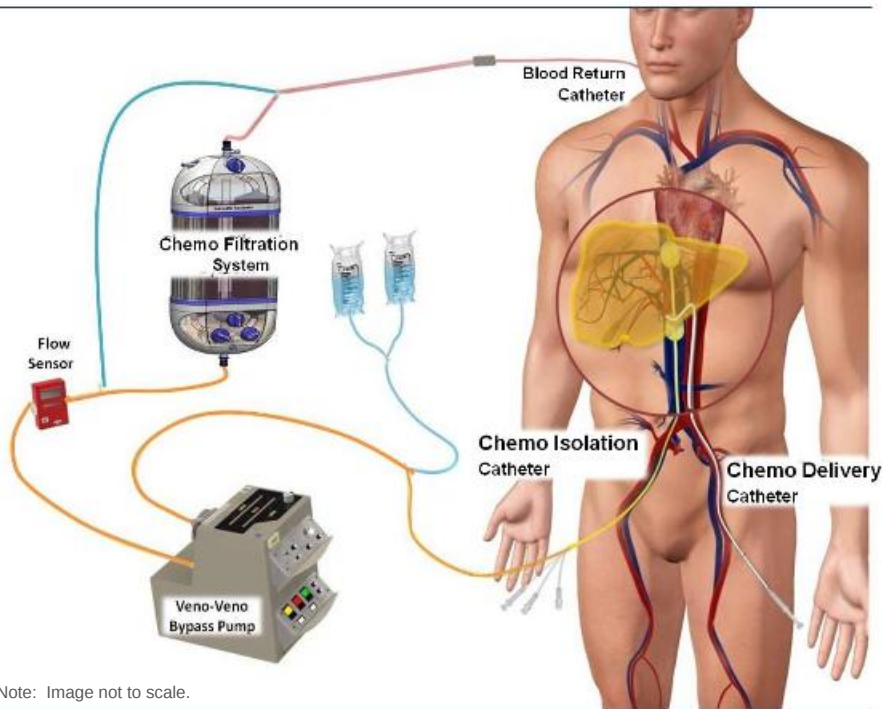
Existing Treatments Involve Significant Limitations

Open Surgical IHP - Where It All Began



Isolated Hepatic Perfusion: Proof of Concept, but High Morbidity and Non-Repeatable

The Delcath Chemosaturation System



Three Steps of Chemosaturation

- 1) *ISOLATION*
- 2) *SATURATION*
- 3) *FILTRATION*

Advantages of Chemosaturation

- Improved disease control in the liver
- Treats entire liver
- Allows for ~ 100x effective dose escalation of drug agents at tumor site
- Controls systemic toxicities
- Repeatable
- Complements systemic therapy

Minimally Invasive, Repeatable Liver Procedure That Could Complement Systemic Therapy

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:

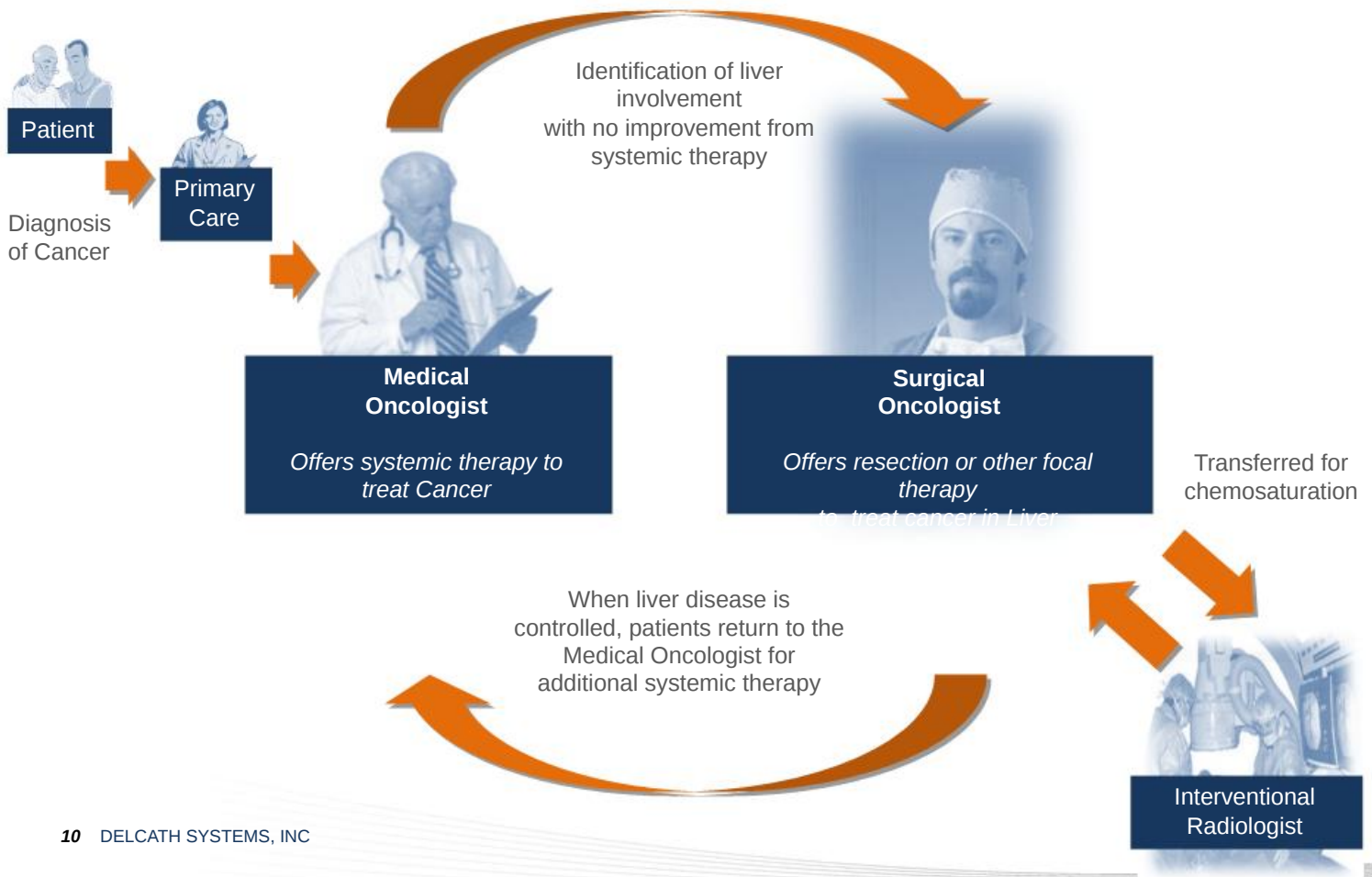
- o Significant improvement in disease control in the liver compared to standard of care in patients with unresectable hepatic melanoma mets
- o Manageable systemic toxicities
- o Time, so that primary cancers can continue to be treated

Physicians:

- o Novel, targeted liver directed treatment to complement other cancer therapies
- o Repeatable, percutaneous procedure
- o Ability to treat the entire liver, including both visible and micro tumors
- o 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, p value = 0.001, hazard ratio of .301**
 - Treatment arm shows 5x median hepatic progression free (hPFS) survival compared to control arm
 - CS/PHP median hPFS of 245 days compared to 49 days for BAC
 - 86% overall clinical benefit (CR + PR + SD)
- **Secondary endpoints support results**
 - OS Secondary endpoint - No difference in Kaplan-Meier curves due to cross over treatment response (298 days compared to 301 days)
- **OS cohort analysis favorable**
 - Median survival of 298 days for treatment arm compared to 124 in non-crossover BAC patients
 - 14 treatment patients (6 treatment, 8 crossover) and 3 BAC patients still alive at 12/31/2010
- **Safety profile - expected and consistent with currently approved labeling for melphalan**
 - 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)

Trial Outcomes Favorable and Consistent with Special Protocol Assessment

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 (Toxicity, Incomplete Treatment, Orthotopic Liver Transplantation)	4
Progressive Disease	1
Minor Response / Stable Disease	3
Partial Response (30.0% - 99.0% Tumor Reduction)	13
Complete Response (No Evidence of Disease)	<u>2</u>
Objective Tumor Response	15
Objective Tumor Response Rate	79%
	Duration (months)
Median Hepatic PFS	39
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

High Efficiency (HE) Filter Media Development

STATUS:

- o Melphalan - Achieved consistent in-vitro first pass removal efficiency of 98% or better
- o Internal development project
- o Developed trade secret manufacturing process to create new filter medium

EXPECTED BENEFITS:

- o Reduced systemic toxicity for improved safety profile
- o Concomitant Therapy (complements systemic therapies)
- o Increased utility in a wider range of patients

HE Filter Expected to Significantly Enhance Procedure and Market Opportunity

Product Development Pipeline

	Initial Opportunity	Near Term (2-5 years)	Intermediate Term (> 5 years)
EU	<ul style="list-style-type: none"> All liver cancers - melphalan Class III device 3rd party melphalan Additional data generation in HCC, mCRC and mNET 	<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"> Leverage CE Mark approval HCC clinical trial 3rd party melphalan 	<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

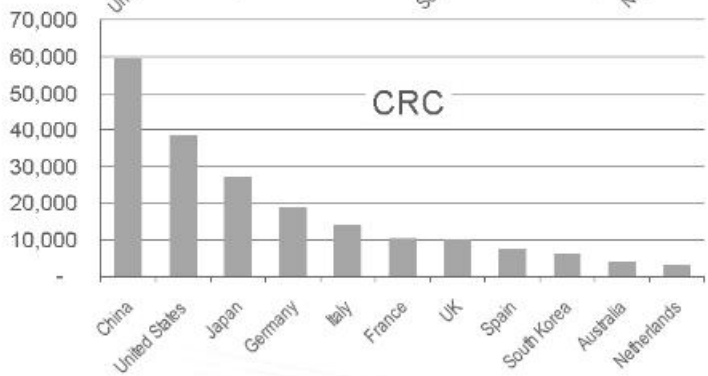
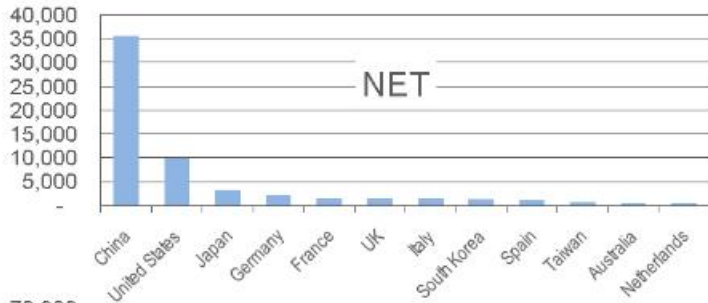
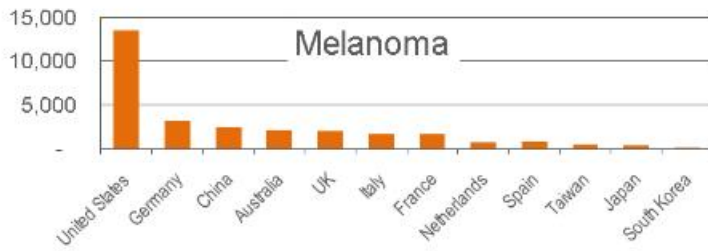
Robust Development Program Planned

Clinical Data Development Goals

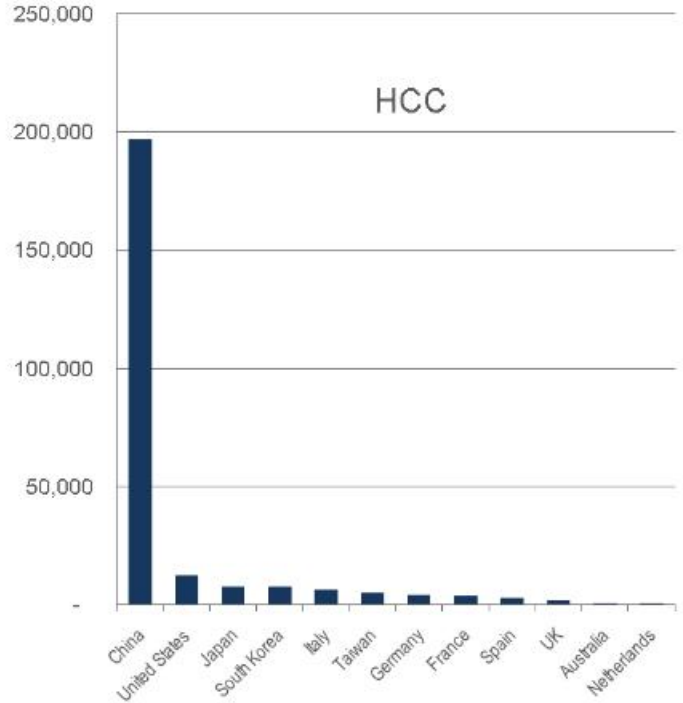
- Generate data to establish Chemosaturation as the Standard Of Care (SOC) for disease control in the liver.
- Utilize High Efficiency (HE) Filter
 - Concomitant therapy to complement standard of care treatments
 - Increase safety of procedure
- Potential clinical trials to expand data:
 - HCC: 1L sorafenib +/- Chemosaturation; 1L sorafenib vs Chemosaturation; Chemosaturation for sorafenib *refractory*;
 - mCRC: 1L liver-mets only SOC vs Chemosaturation; 1L/2L SOC +/- Chemosaturation; 3L cetuximab +/- Chemosaturation
 - NET: SOC +/- Chemosaturation
 - Cutaneous Melanoma: ipilimumab +/- Chemosaturation

Exciting Clinical Study Possibilities to Expand Existing Platform

Market Opportunity* by Disease (patients)



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



EEA Landscape

- CE Mark approval covers 30 countries in the European Economic Area (EEA)
- Product Name: Delcath Hepatic CHEMOSAT™ Delivery System
- Approved device indication: “For intra-arterial administration of chemotherapeutic agent (melphalan hydrochloride) to the liver with additional extracorporeal filtration of the venous blood return”
- Melphalan for injection approved in 14 countries, but commercially available in remaining EEA countries
- Physicians will obtain Melphalan for injection separately
- Estimate potentially applicable to ~100,000 patients annually
- 6 top countries (DE, UK, FR, IT, SP, NL) represent ~70% of total patient population

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

European Commercialization Plans



Objective: Broad Commercial Adoption

Major Assumptions:

- § High Efficiency (HE) filter available for commercial launch
- § 6-8 Centers of Excellence for initial training
- § Initiate test market in 2011 for ~ 6 months to validate assumptions and finalize model
- § Full commercialization in 2012

Strategy and Tactics to Address All Key Constituents

European Commercialization Plans



Tactics & Execution:

- § Market to medical oncologists via contract sales organization (CSO)
- § Sell to hospital-based interventional radiologists and surgeons with combination of direct sales and distributors
- § Establish European patient education & awareness programs (PR, website)
- § Leverage existing new technology reimbursement channels, while pursuing permanent procedure reimbursement via Health Technology Assessment (HTA)
- § Clinical trials to generate additional data for HCC, CRC, NET, and MEL

Strategy and Tactics to Address All Key Constituents

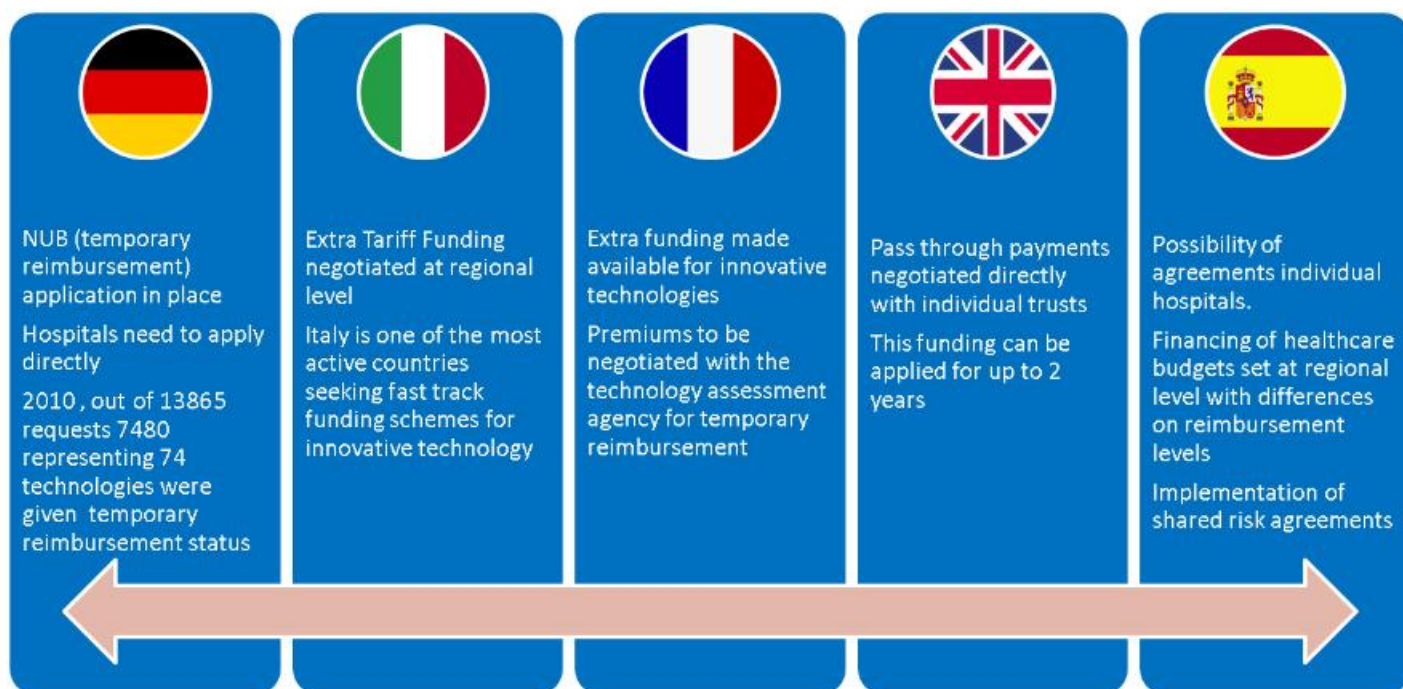
European Marketing Considerations

Reimbursement:

- No centralized EEA device reimbursement body - regional and national systems
- Devices typically reimbursed under DRG as part of a procedure
- Immediate reimbursement plans:
 - Utilize existing codes where permitted until permanent reimbursement established (e.g. Italy)
 - Apply for funding under new technology programs (e.g. NUB in Germany and HAS in France)
 - Other oncology therapies currently reimbursed, despite lacking randomized data
- Retaining reimbursement experts to obtain new procedure specific coding and payment
- Developing Health Technology Assessment (HTA)
- Focused on highlighting clinical value proposition and demonstrating cost effectiveness

Reimbursement Pathways in Primary EEA Markets

European Interim New Technology Reimbursement Programs



Interim New Technology Payment Programs Already Exist in Major European Markets

- ***Melphalan:***
 - Delcath will market the Hepatic CHEMOSAT delivery system in the EEA for the intra-arterial administration of melphalan to the liver
 - Physicians will procure melphalan independently
 - Clinical experience in EEA and publications support use of melphalan for disease control in the liver

Melphalan is Readily Available to Physicians in the EEA

Clinical Data:

- Delcath Phase 3 and Phase 2 data supplements extensive surgical IHP data with melphalan
- Expect to initiate additional studies with Standard of Care (SOC) in 2012 with availability of HE filter in;
 - HCC (primary liver cancer)
 - CRC metastatic to the liver
 - NET metastatic to the liver
- Marketing to medical oncologists will be data driven

Expand On Our Clinical Data

U.S. FDA Regulatory Status

- On February 22, 2011, received Refusal to File (RTF) letter from the FDA
 - § Manufacturing plant inspection timing
 - § Product and sterilization validation
 - § Additional statistical analysis clarification
 - § Additional safety data
- RTF stated that safety information provided was insufficient to allow FDA to accept our application and review the overall risk/benefit profile
- FDA & SPA approved CRF's did not collect all hospitalization data in the patient records in an effective manner
- Follow-up **correspondence and** meeting with FDA held in April 2011 to review proposed plan of action which includes:
 - Collection of all available safety information in new CRF for all 186 patients in the Phase I, II and III clinical trials
- No additional studies or generation of new data requested

Intend to Submit Revised NDA By End of 2011

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

U.S. Commercialization Strategy

- Initial focus on leading cancer centers and referring community hospitals
- Market to Medical Oncologists via CSO
- Direct Strategy to sell to Interventional Radiologists and Surgeons: 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 Supplemented With CSO Detailing Program

U.S. Reimbursement Strategy

Strategy: intend to seek chemosaturation specific codes based upon value proposition relative to other cancer therapies

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

Pursuing New Specific Codes For Chemosaturation Procedure

Strategy For Asia, Ex US America's, MEA and Australia

- Intend to leverage CE Mark to help obtain reciprocal regulatory approvals for our Delcath Hepatic CHEMOSAT System
- Utilize existing 3rd party melphalan available to physicians
- Seek to secure strategic partners and specialty distributors
- Intend to initiate melphalan HCC trial in Taiwan with partner Chi-Fu in 2012

Combination of Direct Sales, Strategic Partnerships & Specialty Distributors

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
4. Assumes sales by distributors

Asia Represents Potential \$8.2 Billion Market Opportunity

Intellectual Property

Patent Protection

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

Trade Secret Protection

- Developed High Efficiency (HE) filter media via new manufacturing processes

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
 - Provides 7 years of marketing exclusivity post FDA approval
- Additional Orphan Drug applications to be filed for other drugs and indications, including melphalan for 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	CFO	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
Harold Mapes	EVP Global Operations	AngioDynamics, Mallinkrodt	25
John Purpura	EVP, Regulatory Affairs & Quality Assurance	E-Z-EM, Sanofi-Aventis	27
Bill Appling	SVP Operations & Medical Device R&D	AngioDynamics	25
Bernie Tyrrell	SVP N. American Sales & Marketing	Epicept, Otsuka, Astra Zeneca, Johnson & Johnson, Eli Lilly	33
Dan Johnston, Ph.D.	VP, Pharma R&D	Pfizer, Wyeth	10

FINANCIALS



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, 2011
- Debt: None
- Shares Out: 43.1 million (49.8 million fully diluted*)
- Institutional Ownership: ~ 28% at March 31, 2011
- Market Capitalization: ~ \$262 million as of May 27, 2011
- Avg. Daily Volume (3 mos) ~ 850,000

As of April 30, 2011 fully diluted includes an additional 4.1 million options at \$5.07, 2.5 million warrants at \$3.51, and 150,790 unvested restricted shares.

Capital Structure Strengthened Significantly

Company Highlights

- Our goal - making established chemotherapeutic drugs work better in target organs
- Initial focus is high dose chemotherapy for improved disease control in the liver
- Successful and highly statistically significant 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
- Leverage CE Mark to help obtain regulatory approvals in Asia, America's (EX US), MEA, and Australia to address potential \$8 Billion 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, trade secrets and orphan drug designations create competitive barriers
- Deep and experienced management team

Concentrating the Power of Chemotherapy to Help Improve Disease Control in the Liver

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>>.

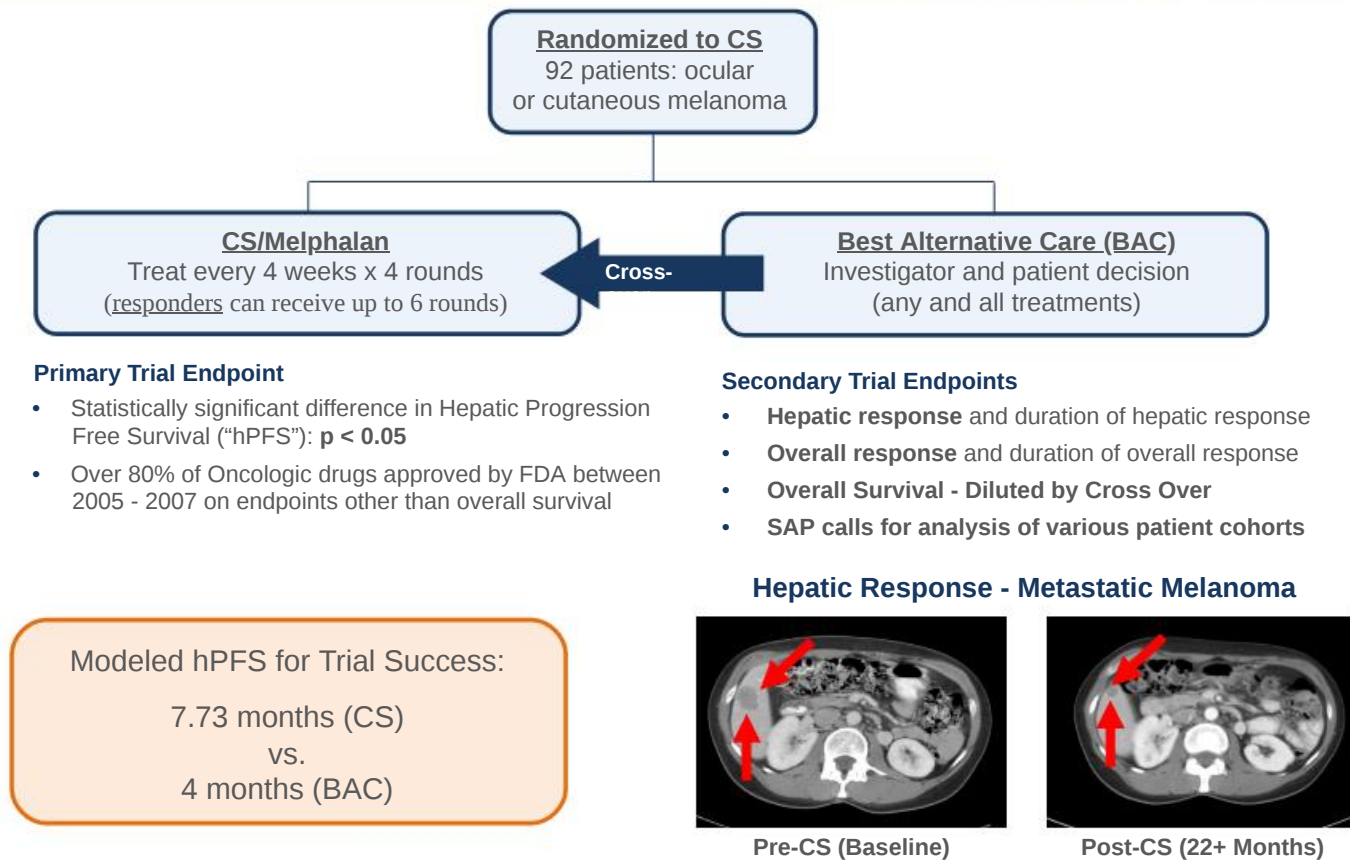
Neuroendocrine Tumors. Practice Guidelines in Oncology- v.2.2009. National Comprehensive Cancer Network (NCCN). 2009.

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.



Appendix II. - Phase 3 Pivotal Trial Details

Phase III Clinical Trial Design



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 expected¹ (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
 - o Treatment related Deaths: 3/40 patients (7.5%) 3/116 procedures (2.6%)
 - o Neutropenic Sepsis (n=2) 5%, Hepatic Failure (n=1) 2.5% (95% tumor burden)
 - o 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

Concentrating the Power of Chemotherapy™

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