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): August 14, 2012

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

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

810 Seventh Avenue, 35th Floor, 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.

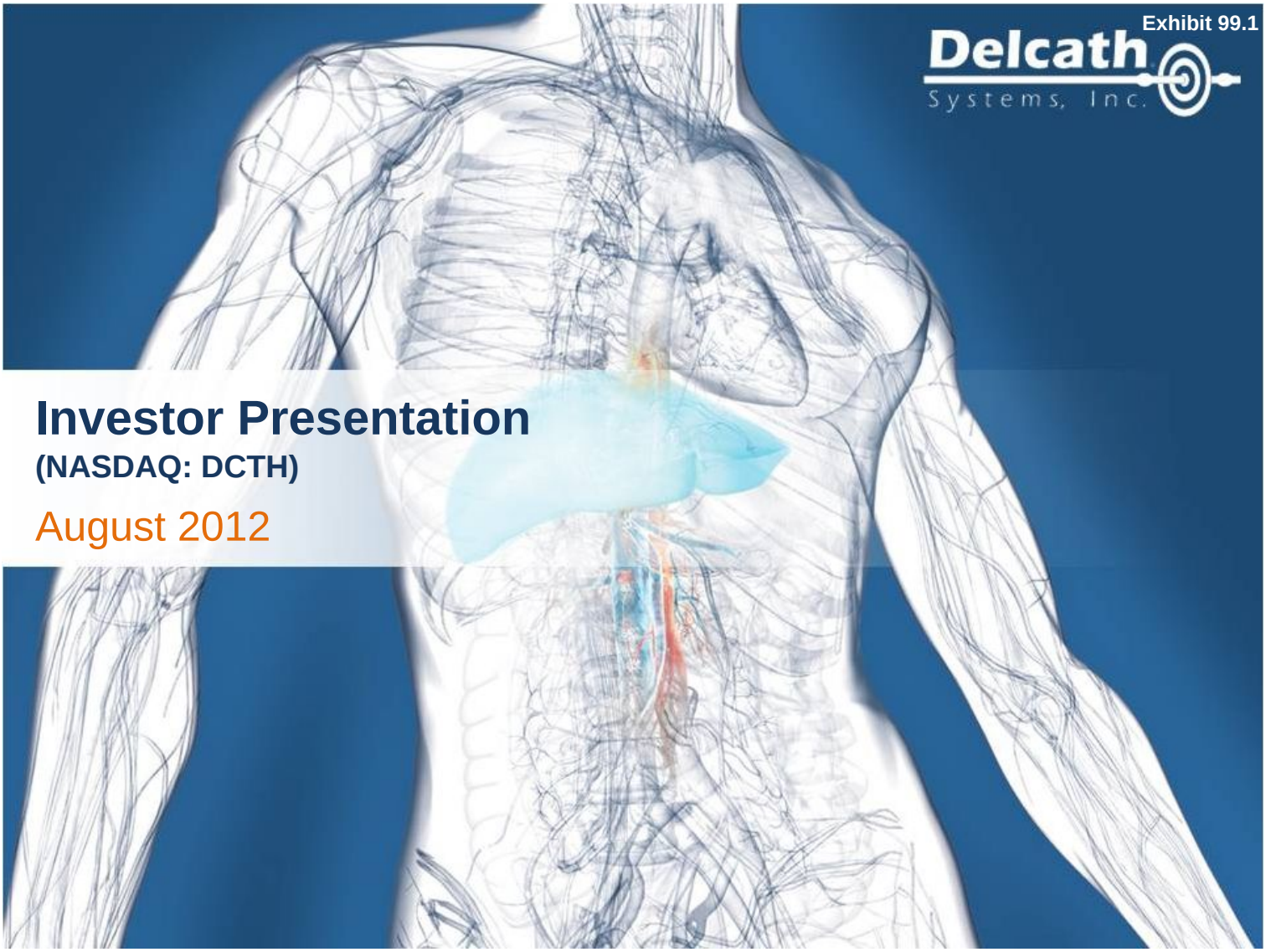
Dated: August 14, 2012

By: /S/ PETER GRAHAM
Name: Peter Graham
Title: Executive Vice President,
General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Delcath Systems, Inc. Investor Presentation Slides

Exhibit 99.1



Investor Presentation

(NASDAQ: DCTH)

August 2012

Forward-looking Statements

This presentation contains forward-looking statements within the meaning of the Safe Harbor Provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statement are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the benefits of the Gen 2 CHEMOSAT system and market acceptance of the same, patient outcomes using the Gen 2 CHEMOSAT system, agreements with additional early launch centers in Europe, our ability to manufacture CHEMOSAT systems and the time required to build inventory and establish commercial operations in Europe, adoption, use and resulting sales, if any, for the CHEMOSAT 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 cancers 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 CHEMOSAT system in foreign markets, approval of the current or future chemosaturation system for other indications and/or with other chemotherapeutic agents, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for the CHEMOSAT system, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, uncertainties relating to the timing and results of research and development projects and future clinical trials, acceptance of our IND amendment, submission and publication of the Phase II and III clinical trial data, the timing and use, if any, of the line of credit from SVB and our ability to access this facility, and uncertainties regarding our ability to raise additional capital and obtain financial and other resources for any research, development and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission including our annual report on Form 10-K and our reports on Forms 10-Q and 8-K. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

Our Mission

- We are a cancer therapy company
- Our technology offers the opportunity to gain control of tumors in the liver
- The liver is a site where uncontrolled disease is often life-limiting or leads to withdrawal of systemic treatments in favor of palliative care
- We plan on being a fully-integrated company and are building the infrastructure to develop and commercialize our products in Europe and North America
  - In Europe our first product is approved and we have begun selling it
- We believe that our first product, CHEMOSAT, may extend the lives of a large number of cancer patients

Concentrating the Power of Chemotherapy for Disease Control in the Liver

The Problem

- Metastatic disease to the liver, brain or lungs is often the life-limiting location of solid tumors
  - In contrast to the brain and lungs, where systemic chemotherapy and radiation can exert some degree of local control, tumors in the liver are not particularly responsive to chemotherapy and radiation therapy
- Existing treatments to control tumors in the liver include:
  - ❑ Surgical resection
  - ❑ Radioembolization (SIRT)
  - ❑ Chemoembolization (TACE)
  - ❑ Radiofrequency ablation (RFA), Microwave, Cryoablation
  - ❑ Hepatic arterial infusion (HAI)
  - ❑ Systemic chemotherapy

Existing Liver Cancer Treatments Have Significant Limitations

Existing Liver Cancer Treatments Have Limitations

Treatment	Advantages	Disadvantages
Systemic	– Non-invasive – Repeatable	– Systemic toxicities – Limited efficacy in liver
Regional (e.g., Isolated Hepatic Perfusion)	– Therapeutic effect – Targeted	– Invasive/limited repeatability – Multiple treatments are required but not possible
Focal (e.g. surgery, radioembolization, chemoembolization, radio frequency ablation)	– Partial removal or treatment of tumors	– Only 10% to 20% resectable – Invasive and/or limited repeatability – Treatment is limited by tumor size, number of lesions and location – “See a tumor, treat a tumor”

Unmet Medical Need Exists for More Effective Liver Cancer Treatments

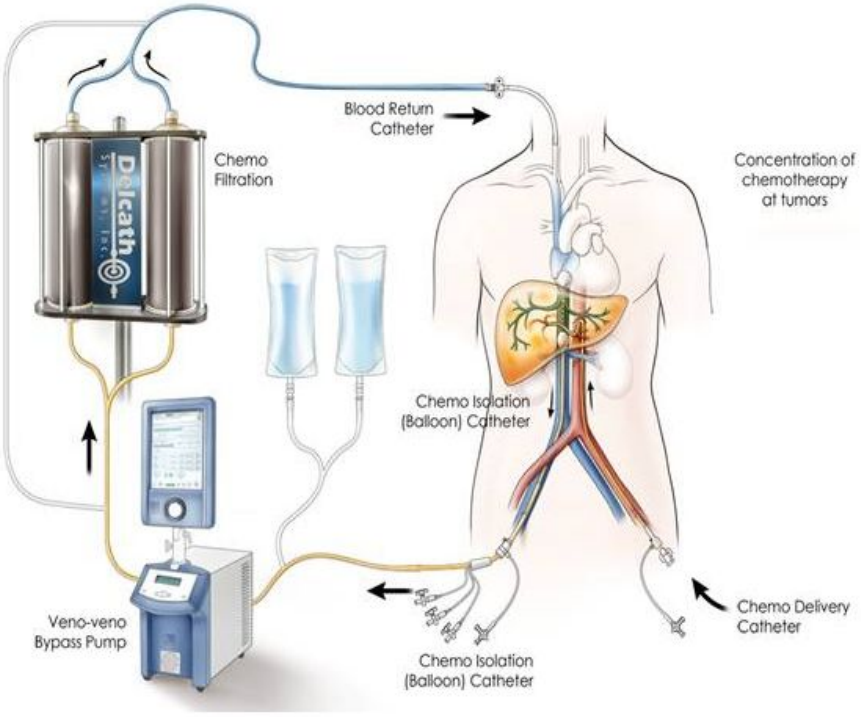
Our Solution

- Our proprietary CHEMOSAT system isolates the liver circulation, delivers an ultra-high concentration of chemotherapy (melphalan) to the liver and filters most of the chemotherapy out of the blood prior to returning it to the patient
- The procedure typically takes approximately two hours to complete and involves a team including the interventional radiologist and perfusionist
- CHEMOSAT (Gen 2) has demonstrated minimal systemic toxicities and impact to blood components in initial commercial use and may complement systemic therapy
- CHEMOSAT has been used on approximately 200 patients to date through clinical development and early commercial launch

Concentrating the Power of Chemotherapy for Disease Control in the Liver

The Delcath CHEMOSAT System

CHEMOSAT®



Chemosaturation

1. ISOLATE
2. SATURATE
3. FILTRATE

Improved disease control in the liver

Treats entire liver (macro and micro)

Controls systemic toxicities

Allows for over 100x effective dose escalation at tumor site

Repeatable & minimally invasive,

Complements systemic therapy

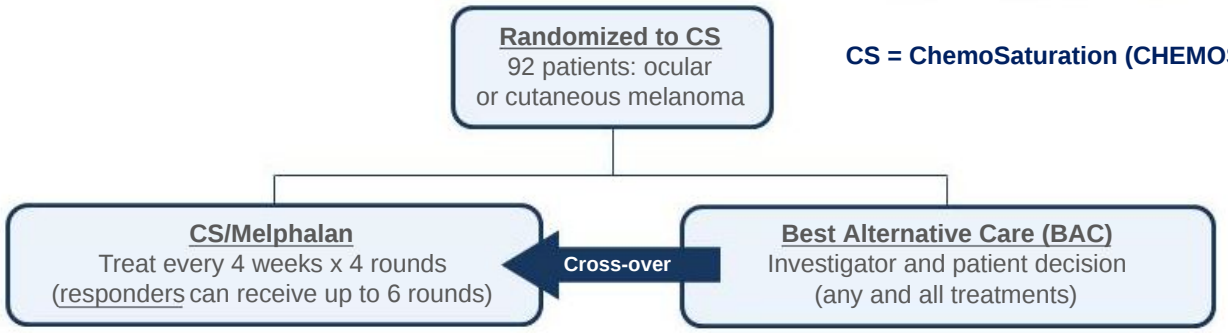
Note: Image not to scale.

Minimally Invasive, Repeatable Liver Procedure That Could Complement Systemic Therapy

The Data

- We conducted a randomized Phase 3 study under a Special Protocol Assessment (“SPA”) using Generation 1 of our chemosaturation system in patients with melanoma (ocular and cutaneous) metastatic to the liver
- Melanoma liver metastases are relatively homogeneous regardless of origin
- Liver metastases are typically the life-limiting aspect of the disease
- Melanoma is notoriously insensitive to systemic chemotherapy and our study was a great demonstration of our technology’s potential in a challenging histology

Phase III Clinical Trial Design



CS = ChemoSaturation (CHEMOSAT)

Primary Trial Endpoint

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

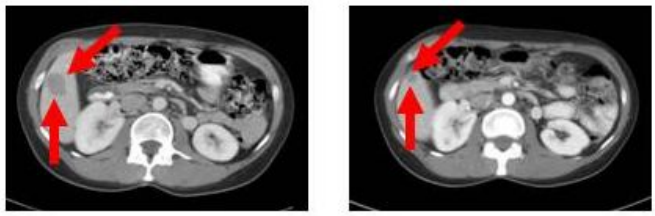
Secondary Trial Endpoints

- **Investigator hPFS**
- **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**

Modeled hPFS for Trial Success:

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

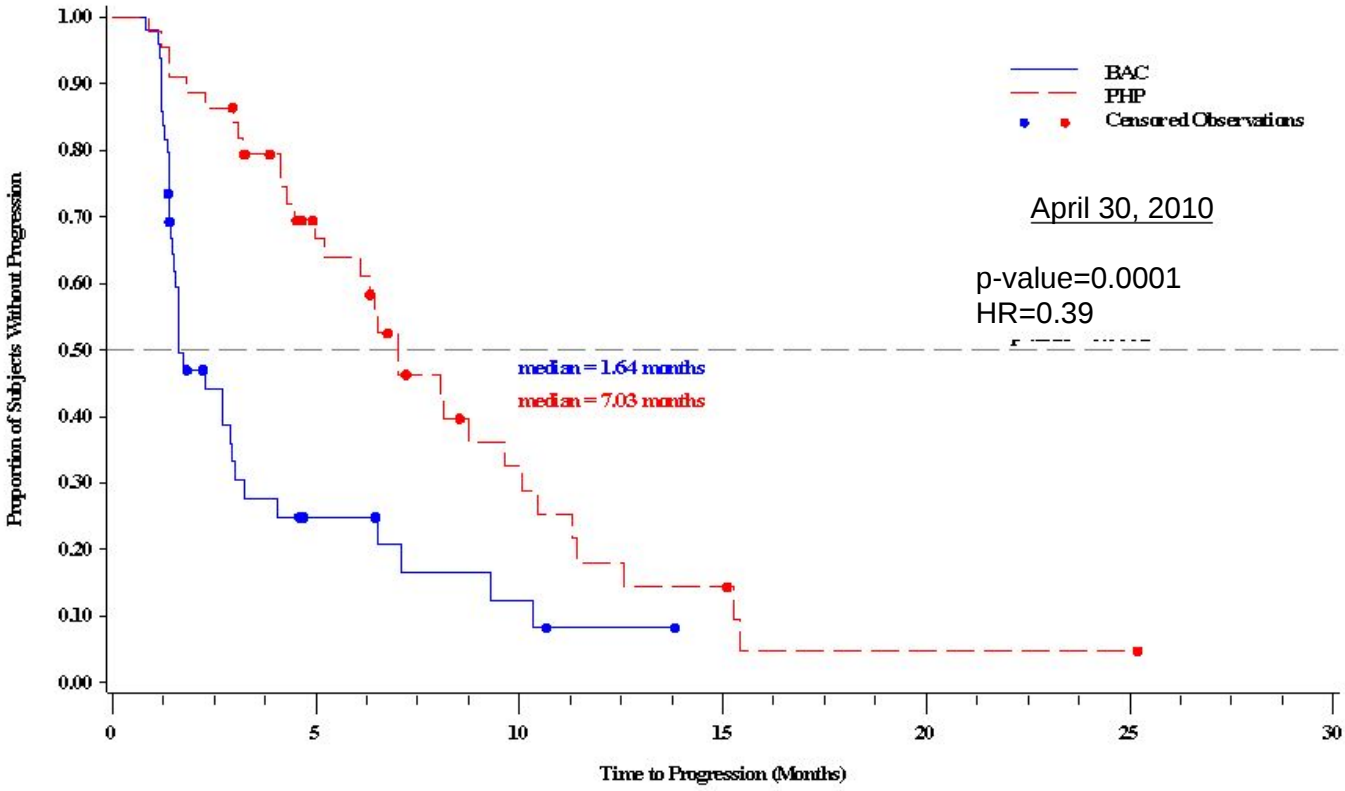
Hepatic Response – Metastatic Melanoma



Pre-CS (Baseline) **Post-CS (22+ Months)**

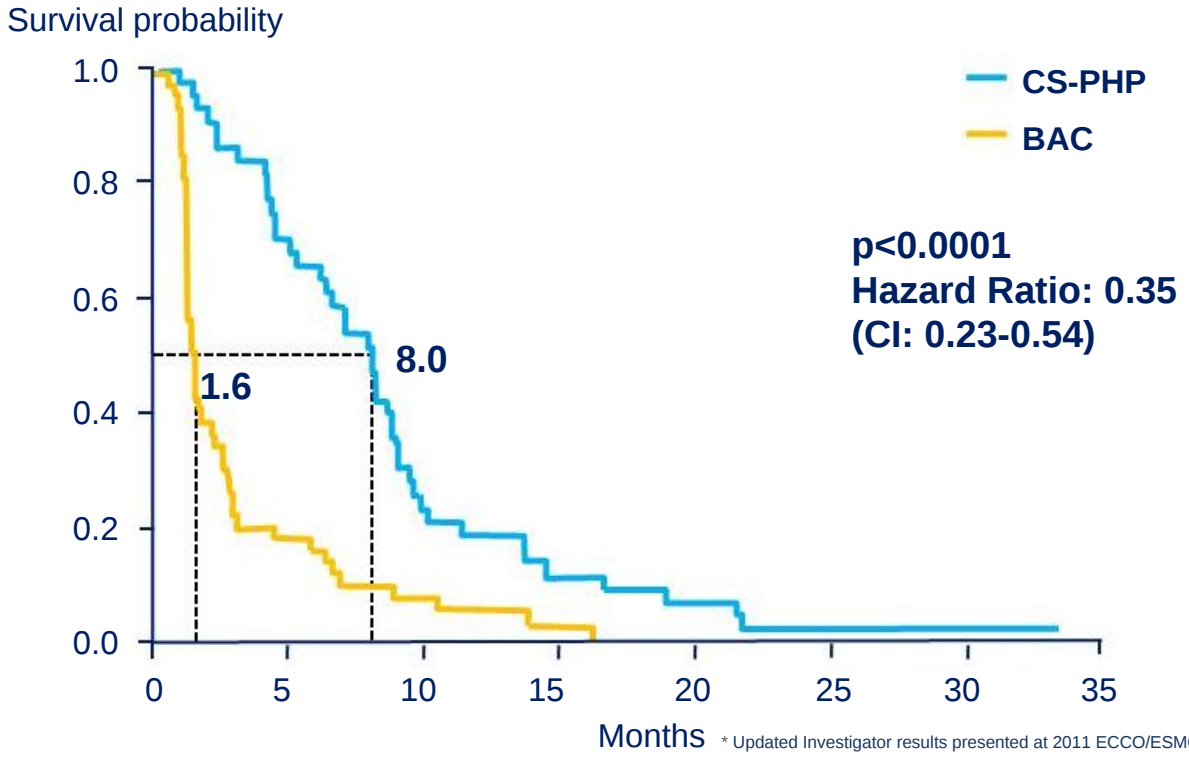
Fully Powered, 93 Patient, Randomized, Multi-Center NCI Led Study

Phase 3 – Primary Endpoint hPFS (ITT – IRC Analysis)



CS-PHP Demonstrated >4x Improvement in Primary Endpoint of hPFS

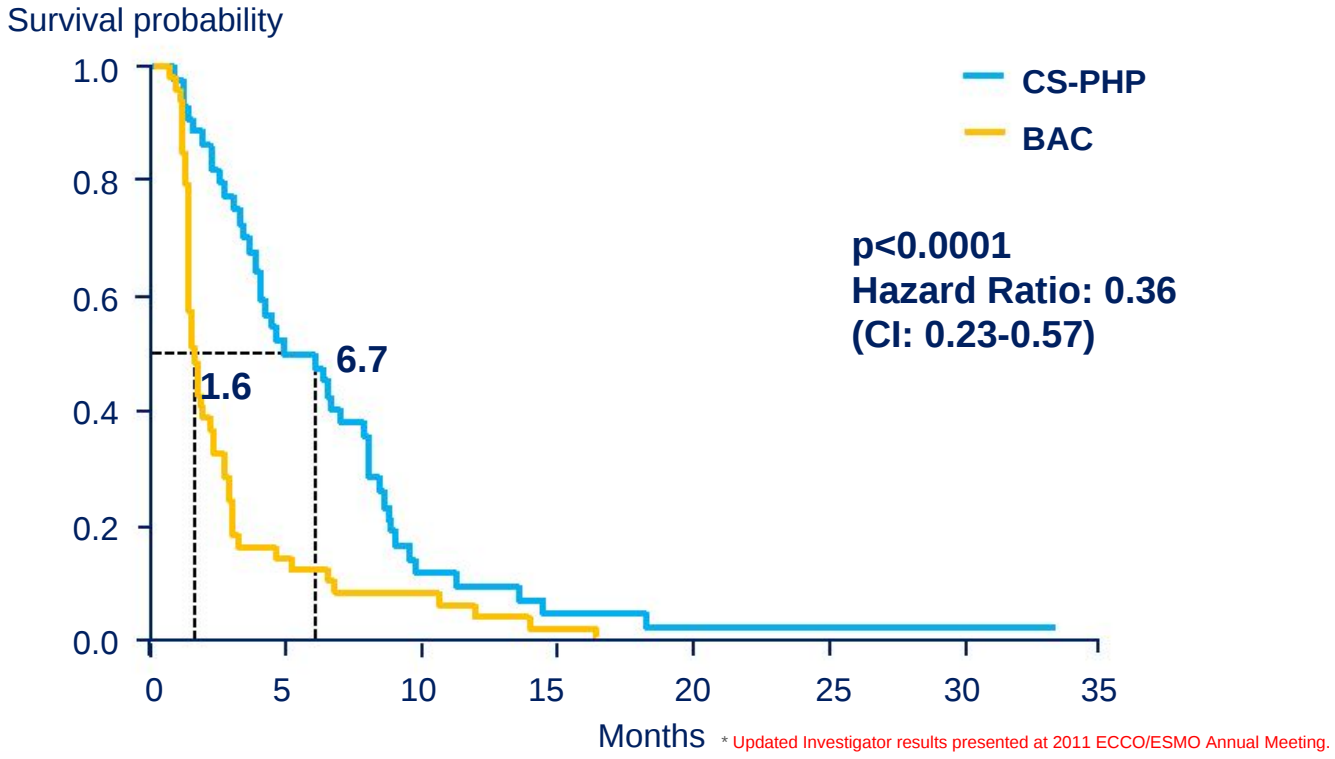
Phase 3 Hepatic Progression Free Survival (ITT -INV*)



* Updated Investigator results presented at 2011 ECCO/ESMO Annual Meeting.

CS-PHP Demonstrated a 5x Improvement in Primary Endpoint of hPFS

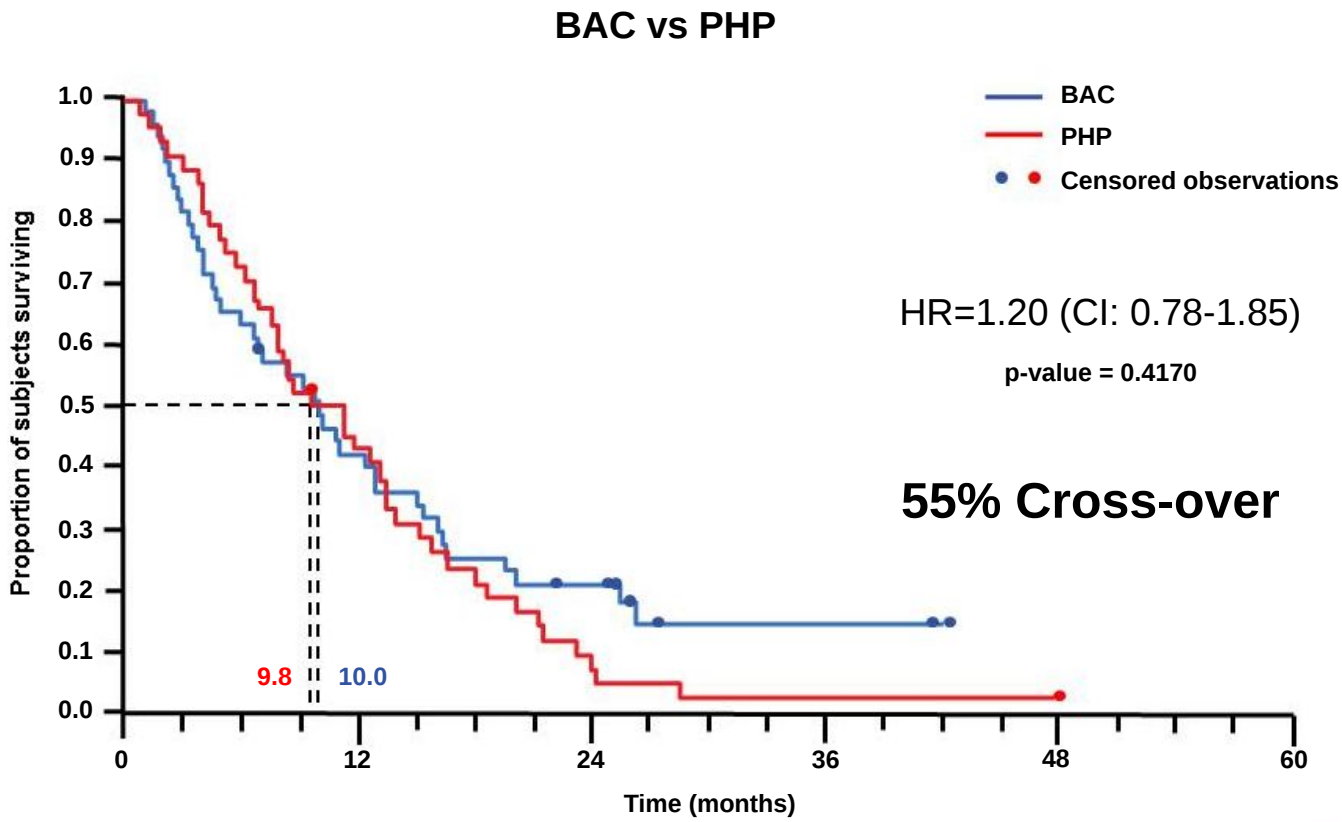
Phase 3 Overall Progression-free Survival (ITT – INV*)



* Updated Investigator results presented at 2011 ECCO/ESMO Annual Meeting.

CS also Demonstrated a Highly Statistically Significant Improvement in Overall PFS

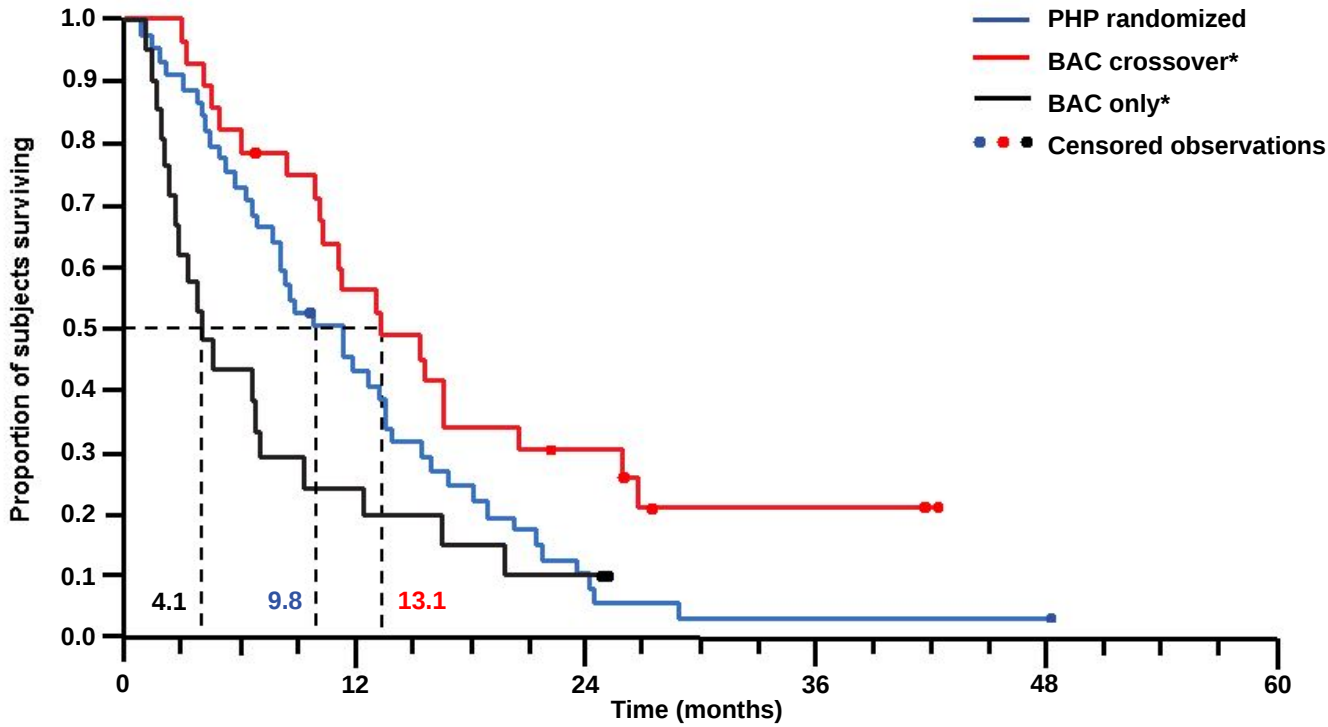
Overall survival (ITT population)



Overall Survival Confounded By Crossover Study Design

Overall survival (ITT population)

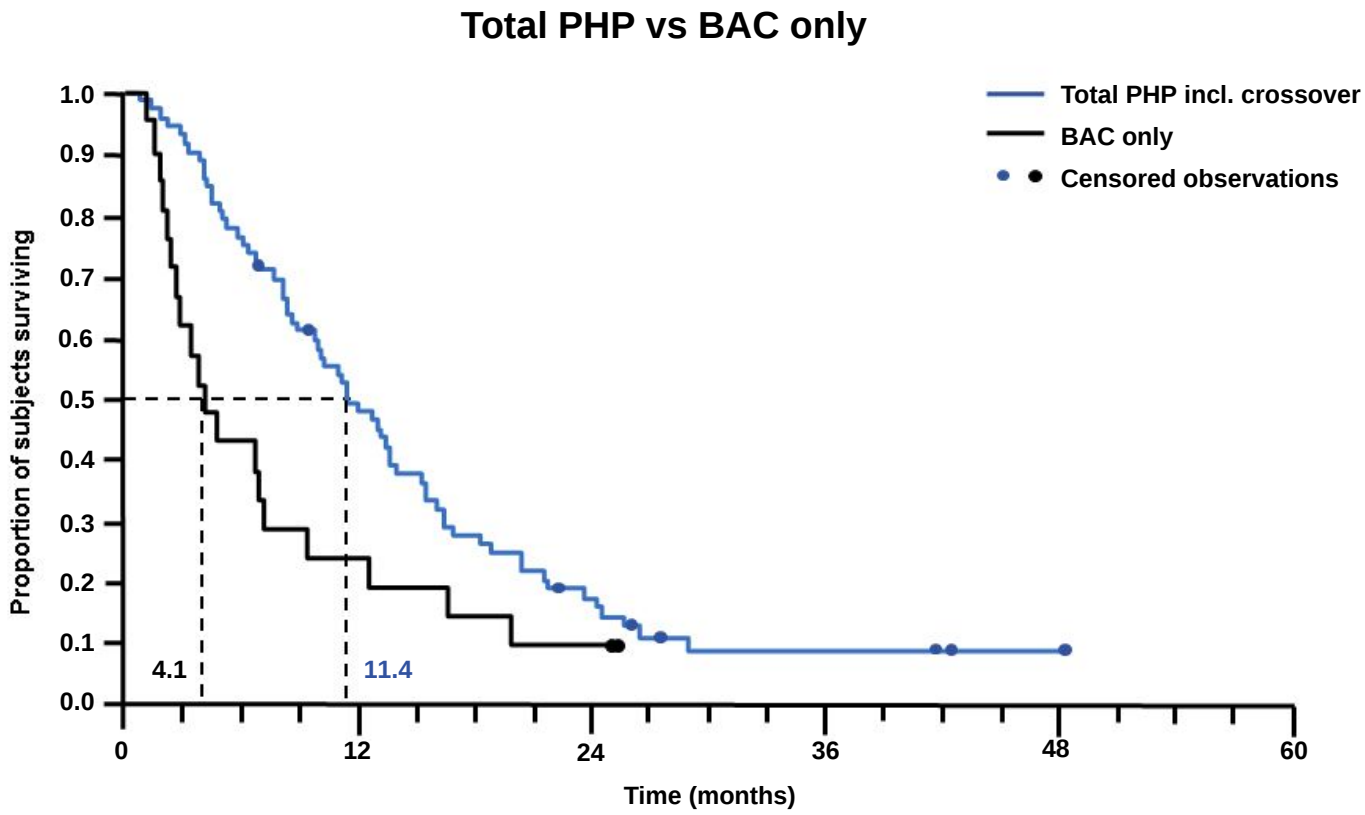
PHP randomized vs PHP crossover vs BAC only



* Similar patient characteristics and demographics between BAC crossover and BAC only

Overall Survival Tail PHP Treated Patients

Overall survival (ITT population)



Overall Survival Tail For Treated Patients

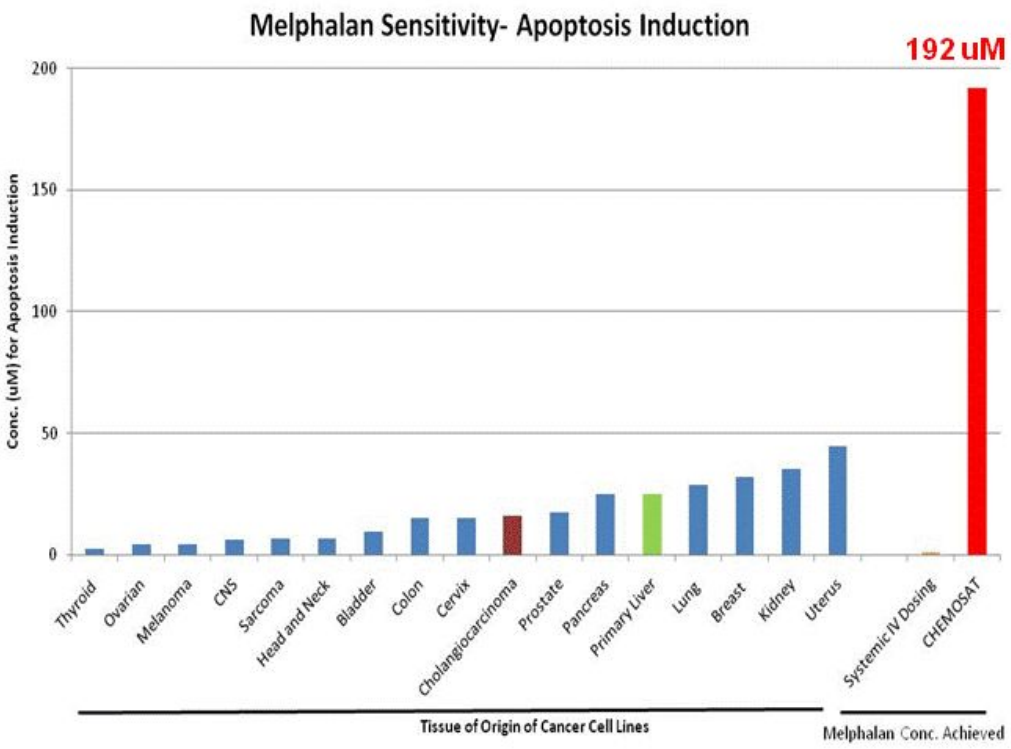
Positive Phase III Results

- Primary endpoint exceeded (hPFS:IRC), p value = 0.0001, hazard ratio of .39 as of 4/2010
  - Treatment arm shows 4.4x median hepatic progression free (hPFS) survival compared to control arm
  - CS/PHP median hPFS of 7.0 months compared to 1.6 months 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 (10.6 months compared to 10.02 months) as of 6/2012
  - CS/PHP median overall PFS of 5.42 months vs. 1.64 months for BAC as of 6/2012
- OS exploratory cohort analysis favorable
  - Median survival of 9.8 months for treatment arm compared to 4.1 months non-crossover BAC patients
  - Median survival of 11.4 months for all patients treated with melphalan, including crossover
  - 8 CS/PHP-treated patients and 2 BAC-treated patients still alive as of 6/2012
- Gen 1 Safety profile – expected and consistent with currently approved labeling for melphalan
  - 30-day deaths on PHP: 3/44 patients (6.8%)
    - 1 Neutropenic Sepsis (2.3%); 1 Hepatic Failure 2.5% (95% tumor burden); 1 gastric perforation
  - 30-day deaths on BAC: 3/49 patients (6.1%)

Trial Outcomes Favorable and Consistent with Special Protocol Assessment

Melphalan Sensitivity: In Vitro Tumor Cell Lines Study

Cancer Origin (Cell lines)	Apoptosis Induction (uM)
Thyroid (2)	2.54
Ovarian (1)	4.31
Melanoma (5)	4.53
CNS (4)	6.40
Sarcoma (5)	6.68
Head and Neck (2)	6.78
Bladder (5)	9.50
Colon (5)	15.12
Cervix (3)	15.16
Cholangiocarcinoma (1)	16.00
Prostate (2)	17.55
Pancreas (4)	25.00
Primary Liver (4)	25.04
Lung (5)	28.60
Breast (5)	31.82
Kidney (5)	35.30
Uterus (1)	44.60

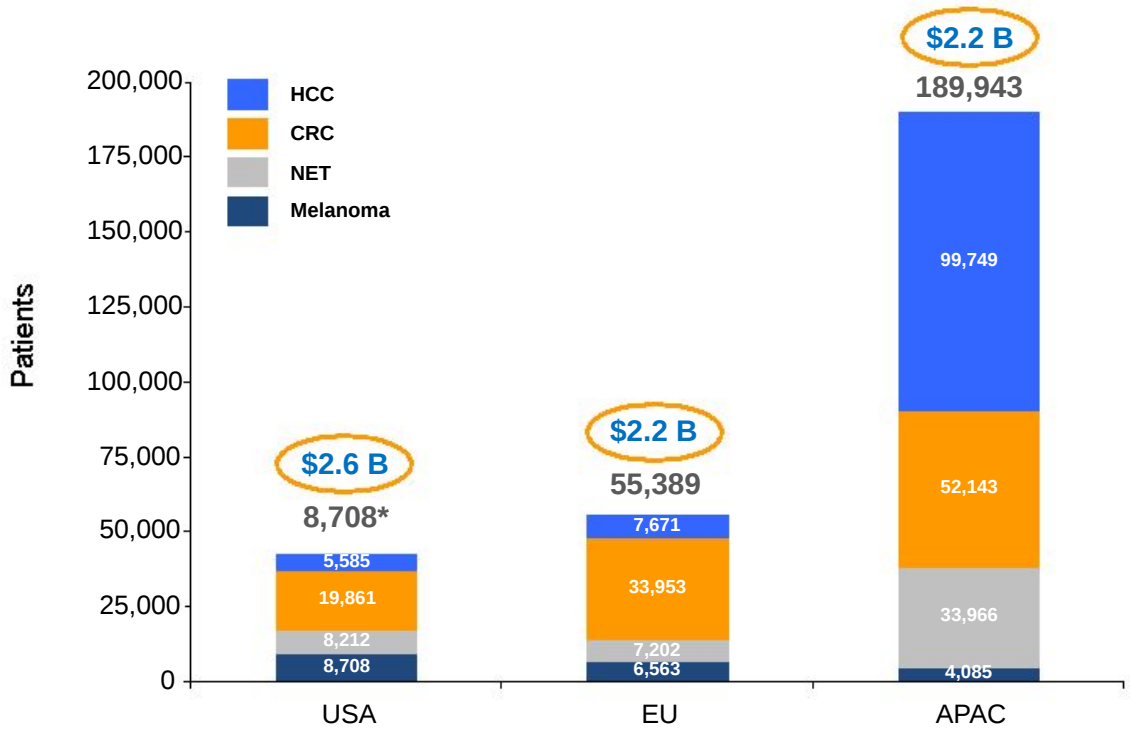


We Believe CHEMOSAT Will Be Effective On a Wide Variety of Cancer Histologies

Our Opportunity

- At the concentrations of melphalan we are achieving in the liver, we believe CHEMOSAT will be effective on a wide variety of histologies
- We believe that physicians are recognizing the broad applicability of CHEMOSAT, based on early experience and their interest in testing our technology with melphalan in a variety of tumor histologies
- CE Mark approved broad indication
- Large global market opportunity with pharmaceutical-like gross margin ~ 80%

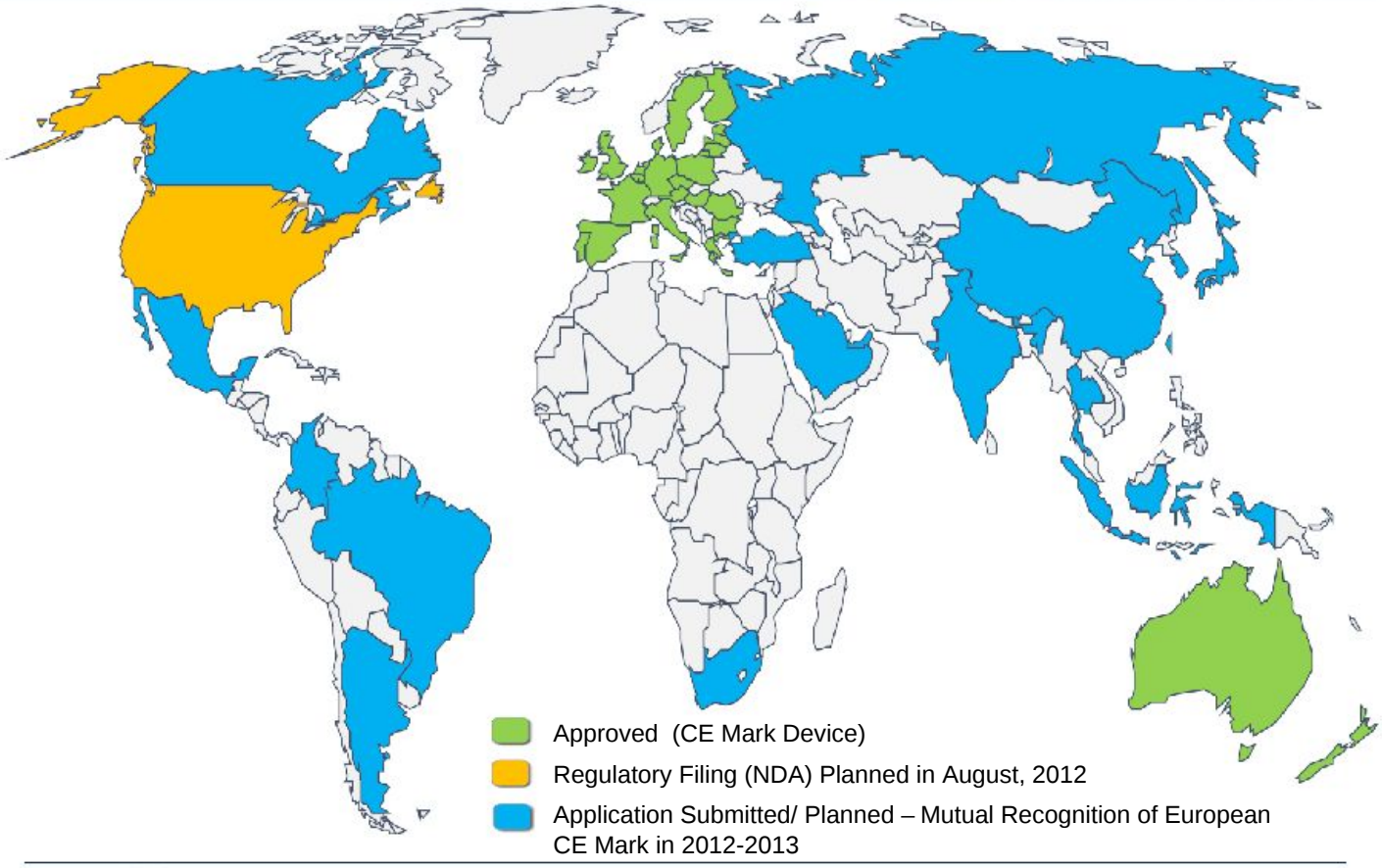
CHEMOSAT - Potential Multi-Billion Dollar Market



Sources: LEK Consulting, GLOBOCAN, Company estimates.
*TPM for initial U.S. labeled indication only.
EU: Initial target countries of Germany, UK, Italy, France, Spain, Netherlands, Ireland.
APAC: Initial target countries of China, Japan, S. Korea, Taiwan, Australia.
Assumes 2.5 treatments per patient.
Assumes EU ASP of $15K; US ASP of $25K; APAC ASP of $5K.

$7 Billion Annual Global Opportunity with Pharmaceutical-Like Gross Margins

Global Commercialization Status



On The Cusp of Addressing A Multi-Billion Dollar Global Market in Next Two Years

European Commercialization Strategy

Strategy:

- Focus efforts in 7 Target Countries (EU 5 + Netherlands & Ireland)
- 8-10 leading EU cancer centers as initial training centers
- Validate business model and demonstrate scalability
- Push and Pull marketing and selling strategy

Tactics & Execution:

- Educate medical oncologists via contract organization
- Sell to hospital-based interventional radiologists, surgeons and C-suite decision makers with combination of direct sales and distributors
- Hospitals procure melphalan from third parties and physicians use at their discretion
- Establish European patient education & awareness programs (PR, website)
- Leverage existing new technology reimbursement channels, while pursuing permanent procedure reimbursement
- Clinical trials to generate additional data for CRC and HCC to support revenue ramp up

Currently In Initial Training and Marketing Phase

Patient Referral Path

Patient

Diagnosis of Cancer

Primary Care

Medical Oncologist

Offers systemic therapy

Identification of **liver involvement** with no improvement from systemic therapy

Surgical Oncologist

Offers resection or other focal therapy

CHEMOSAT®

Chemosaturation

Interventional Radiologist

Offers chemosaturation procedure

When **liver disease is controlled,** patients return to the Medical Oncologist for additional systemic therapy

CHEMOSAT Training and Marketing Commenced in Europe

- Entered training and marketing agreements with leading cancer centers in Europe
  - Milan, Italy – European Institute of Oncology (IEO)
  - Frankfurt, Germany – Johann Wolfgang Goethe-Universität (JWG)
  - Kiel, Germany – Universitätsklinikum Schleswig-Holstein
  - Villejuif, France – Cancer Institute Gustave Roussy (IGR)
  - Barcelona, Spain – El Hospital Quiron
  - Naples, Italy – Instituto Nazionale Tumori Fondazione "G. Pascale"
  - Amsterdam, The Netherlands – Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital
  - Erlangen, Germany – University Hospital of Erlangen
  - Pamplona, Spain – Clinica Universidad de Navarra
  - Bordeaux, France – Hôpital Saint-André
  - Galway, Ireland – University Hospital Galway
  - Leiden, The Netherlands – Leiden University Medical Center
  - Southampton, United Kingdom – Southampton University Hospital
- Training completed and patients treated at IEO, Italy; JWG University Hospital, Frankfurt, Germany; IGR, France; UHG, Ireland
  - Liver metastases from cutaneous melanoma, ocular melanoma, gastric cancer, breast cancer, and cholangiocarcinoma
- Selected Quintiles to support EU launch with medical science liaisons (MSL)

Continue Training and Marketing Centers Roll-Out

European Reimbursement Considerations

- No centralized pan-European medical device reimbursement body – reimbursement mechanisms vary greatly at national and regional levels across our target markets
- Working with reimbursement specialists to develop a plan in each of our key markets for both interim and long term reimbursement
- Interim reimbursement plans expected to begin coming online during fourth quarter:
  - Currently, initial procedures are being covered by private payment and research funding
  - Apply for funding under existing New Technology Payment programs
    - Italy – Regional Applications being submitted
    - Germany - interim reimbursement process is being actively sponsored and driven by the German Radiology Society
    - United Kingdom - key centers in the area of cutaneous and ocular melanoma have applied for interim funding

Reimbursement Mechanisms in Place to Support Commercial Launch

International Strategy beyond EU and US

- Leverage CE Mark to obtain reciprocal regulatory approvals for CHEMOSAT System in other international markets
- International regulatory submissions status:
  - Application submitted and expected approvals in
    - Australia - 2012 (Gen 1 approved) (Gen 2 expected in Aug)
    - Hong Kong - 2012 (Gen 2 expected in Dec.)
    - Canada - 2012 (Gen 2 expected in Dec.)
    - S. Korea - 2012 (Gen 2 expected in Dec.)
    - Singapore - 2013
    - Brazil - 2014
    - Israel - 2014
  - Intend to submit applications
    - Argentina
    - Mexico
    - Russia
    - India
    - Japan
    - China and Taiwan
- Utilize 3rd party melphalan and doxorubicin available to physicians

Combination of Strategic Partnerships and Specialty Distributors

U.S. FDA Regulatory Status

- Pre-NDA submission meeting with FDA conducted in January 2012
  - Satisfied with FDA response
  - Addressed RTF related issues
    - Manufacturing plant inspection timing
    - Product and sterilization validation
    - Additional statistical analysis clarification
    - Additional safety data
- Completed data entry and monitoring
  - Completed data migration to new FDA compliant CDISC database
  - Created new Case Report Form (CRF)
- We locked database on May 25, 2012
- Will include Gen 2 Filter as part of the Chemistry, Manufacturing and Control module
- Plan to file NDA submission in August 2012
- Initiated dialogue with FDA to discuss optimal approval path for Gen 2
- Amended IND and Expanded Access Program (EAP) and Gen 2 was accepted by the FDA for use in EAP, compassionate care and clinical trials in the US

U.S. Commercialization Strategy

- Initial focus on leading cancer centers and referring community hospitals
- Educate Medical Oncologists via Medical Science Liaison (MSL)
- Direct strategy to sell to Interventional Radiologists and Surgeons: 12 sales 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
- Intend to seek chemosaturation specific codes based upon value proposition relative to other cancer therapies

Direct Sales Channels Supplemented with Contract MSLs

Clinical Development Program

- Goal:
  - Expand indications for HCC and mCRC with US registration trials
  - Generate robust clinical data to support commercialization
- IND Amendment accepted by the FDA to include Gen 2 in Expanded Access Program (EAP), compassionate use and all future clinical trials
  - Plan to initiate EAP for metastatic melanoma in September 2012
- Initiate EU Registry in Q4 2012- Collect specific standardized data from commercial use of CHEMOSAT in Europe
- Planned Clinical Trials (first patient enrolled in 2013)
  - HCC
    - Global Phase 2 randomized 1L CHEMOSAT Melphalan vs. Sorafenib
    - US registration – Global Phase 3 Randomized 2L CHEMOSAT Melphalan vs. BSC for Sorafenib Failure
    - Asia Phase 3 Randomized 2L CHEMOSAT Doxorubicin vs. BSC for Sorafenib Failure
  - mCRC
    - Global Phase 2 Signal Seeking/Safety 2L CHEMOSAT Melphalan
    - US Registration – Global Phase 3 Randomized 2L CHEMOSAT Melphalan vs. Approved Alternatives

Establish CHEMOSAT as the Standard of Care (SOC) for Disease Control in the Liver

2012 Milestones

- First patients have been treated with CHEMOSAT Melphalan in Europe - Done
- Execute contract for MSL services in EU – 1Q 2012 (Quintiles was selected to support EU launch of CHEMOSAT) - Done
- Secure agreements with 8-10 leading cancer centers in EU - Done
- Obtain CE Mark for Gen 2 CHEMOSAT Melphalan - Done
- US NDA submission in August 2012
- Submission for publications of Phase III data and mNET arm of Phase II data – 2H 2012
- First patients enrolled in EAP – 2H 2012
- Obtain approval of CE Mark for CHEMOSAT Doxorubicin – 2H 2012
- Potential Asia strategic partnership – dedicated BD with China a top priority
- Initiate EU Registry in Q4 2012

Financial Update

Cash & Cash Equivalents:	**$29.3 million at June 30, 2012**
Financing:	**$21.1 million (net) raised in a follow-on equity offering in May 2012**
ATM Program	**$31.0 million remaining as of July 31, 2012**
Working Capital Line of Credit:	**$20.0 million credit facility**
Debt:	**None**
Cash Spend:	**$14.2 million in 2Q2012**
Shares Outstanding:	**65.7 million (79.4 million fully diluted[1])**
Institutional Ownership:	**20%**
Market Capitalization:	**$113 million as of July 31, 2012**
Avg. Daily Volume (3 mo.):	**1,100,000**

1) Fully diluted includes an additional 4.7 million options and 9 million warrants

Team

Executive	Title	Prior Affiliation(s)	Years of Experience
Eamonn Hobbs	President and CEO	AngioDynamics, E-Z-EM	31
Graham Miao, Ph.D.	EVP & CFO	D&B, Pagoda Pharma, Schering-Plough, Pharmacia, JP Morgan	22
Krishna Kandarpa, M.D., Ph.D.	CMO and EVP, R&D	Harvard, MIT(HST), Cornell, UMass	32
Agustin Gago	EVP, Global Sales	AngioDynamics, E-Z-EM	30
Jennifer Simpson, Ph.D.	EVP, Global Marketing	Eli Lilly (ImClone), Johnson & Johnson (Ortho Biotech)	22
Peter Graham, J.D.	EVP, General Counsel & Global Human Resources	Bracco, E-Z-EM	17
David McDonald	EVP, Business Development	AngioDynamics, RBC Capital Markets	29
John Purpura	EVP, Regulatory Affairs & Quality Assurance	E-Z-EM, Sanofi-Aventis	28
Harold Mapes	EVP, Global Operations	AngioDynamics, Mallinkrodt	26
J. Chris Houchins	SVP, Clinical and Medical Affairs	Arno, Schering-Plough, Pfizer, Pharmacia, GD Searle	21
Gloria Lee, M.D., PH.D.	SVP, Global Clinical Development	Hoffmann-La Roche, Syndax Pharmaceuticals, Inc.	20
Bill Appling	SVP Medical Device R&D	AngioDynamics	26
Dan Johnston, Ph.D.	VP, Pharmaceutical R&D	Pfizer, Wyeth	11

Appendices

Appendix I

Intellectual Property

Intellectual Property

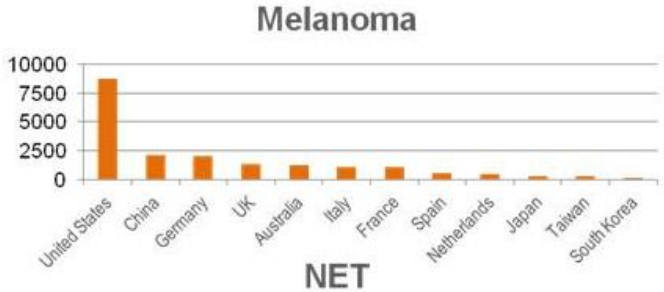
- Patent Protection
  - 5 U.S. patents in force and 5 U.S. patent applications pending
  - 6 foreign patents in force (with patent validity in 22 countries) and 15 foreign patent applications pending
  - Primary device patent set to expire August 2016
  - Up to 5 years of patent extension post FDA approval
- Trade Secret Protection
  - Developed improved 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

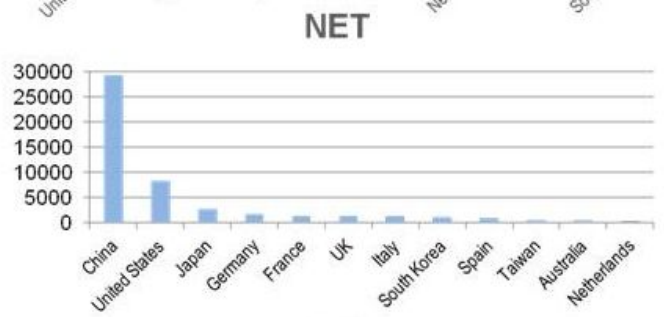
Multiple Levels of Protection

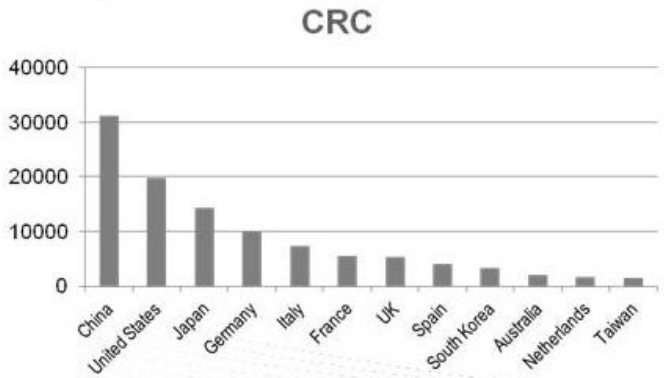
Appendix II

CHEMOSAT Market Opportunity by Disease and Target Counties

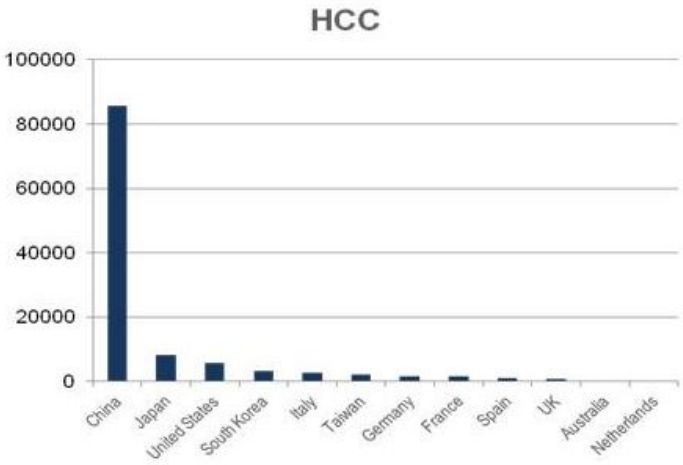
Market Opportunity by Disease (patients)







- **Europe – Largest near-term opportunity**
- **CRC – Largest opportunity worldwide**
- **Melanoma – Largest opportunity is in US**
- **China - Largest opportunity for HCC**



Market Opportunity defined as Total Potential Market (TPM) for CHEMOSAT®

1.Primary cancer incidence
2.Adjusted for predominant disease in the liver (primary or metastatic cancer)
3.Adjusted for addressable patients via Delcath CHEMOSAT®

Europe Market by Disease – Device Only

	Germany (Direct)	UK (Direct)	France (Indirect)	Italy (Indirect)	Spain (Indirect)	Netherlands (Direct)	Ireland (Direct)	Total Potential (patients)	Potential Market ($ MM)[1,2,3]
Total Potential Market #Patients									
Ocular Melanoma	404	297	295	285	197	79	19	1,576	$ 62
Cutaneous Melanoma	1,625	994	753	801	360	379	73	4,987	$ 206
CRC	9,902	5,300	5,475	7,281	4,016	1,644	335	33,953	$1,339
HCC (Primary)	1,637	720	1,514	2,597	1,087	82	35	7,671	$277
NET	1,783	1,336	1,353	1,299	974	360	98	7,202	$ 281
TOTAL	**15,351**	**8,647**	**9,389**	**12,263**	**6,634**	**2,545**	**560**	**55,389**	**$ 2,166**

Sources: LEK Consulting, GLOBOCAN, Company estimates.
1) Assumes 2.5 treatments per patient.
2) Assumes ASP of ~$15K USD.
3) Assumes mix of direct sales and distributors.

Europe Presents Significant Potential Market Opportunity

US Market by Disease – Device and Drug Combination

Liver Metastasis	Potential Market # Patients	Potential Market # Procedures	Potential Market ($MM)[1,2]
Ocular Melanoma	1,685	4,213	$ 105
Cutaneous Melanoma	7,023	17,557	$ 439
TOTAL MELANOMA (Initial Expected Label)	**8,708**	**21,770**	**$ 544**
CRC	19,861	49,653	$ 1,241
HCC (Primary)	5,586	13,964	$ 349
NET	8,212	20,530	$ 513
OTHER TOTAL (Potential Label Expansion)	**33,659**	**84,147**	**$ 2,104**
TOTAL	**42,367**	**105,917**	**$ 2,648**

Sources: LEK Consulting, GLOBOCAN, Company estimates.
1) Assume 2.5 treatments per patient.
2) Estimated ASP of $25K.

APAC Market by Disease

	China (Device)	S. Korea (Device)	Japan (Device)	Taiwan (Device)	Australia (Device)	Total Potential (patients)	Potential Market ($MM)[1,2]
Total Potential Market #Patients							
HCC (Primary)	**85,780**	**3,258**	**8,296**	**2,152**	**263**	**99,749**	**$ 1,156**
Other							
CRC	31,127	3,245	14,298	1,441	2,031	**52,143**	**$ 642**
NET	29,197	1,048	2,759	500	462	**33,966**	**$ 393**
Ocular Melanoma	1,765	66	175	31	96	**2,134**	**$ 25**
Cutaneous Melanoma	382	43	136	246	1,144	**1,951**	**$ 23**
OTHER TOTAL	**62,472**	**4,403**	**17,368**	**2,218**	**3,733**	**90,194**	**$ 1,083**
TOTAL	**148,104**	**7,661**	**25,665**	**4,370**	**3,996**	**189,943**	**$ 2,239**

Sources: LEK Consulting, GLOBOCAN, Company estimates.
1) Assume 2.5 treatments per patient.
2) Estimated ASP of ~$5K.

APAC Target Markets Represent Over $2 Billion Potential Market Opportunity

Appendix III

CHEMOSAT Melphalan Phase I and II

Melphalan Dosing & Background

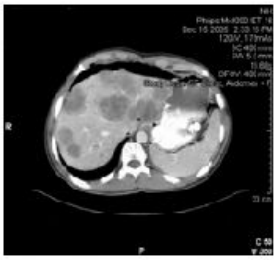
Type	Dosing (mg/kg)
Multiple Myeloma (label)	0.25
Chemoembolization	0.62
Surgical Isolated Hepatic Perfusion (IHP)	1.50
Myeloablation	2.50-3.50
Chemosaturation (PHP)	**3.00**

- Well understood, dose dependant, tumor preferential, alkylating cytotoxic agent that demonstrates little to no hepatic toxicity
- Manageable systemic toxicities associated with Neutropenia and Thrombocytopenia
- Drug dosing **12x higher** than FDA-approved dose via systemic IV chemotherapy
- Dose delivered to tumor is over **100x higher** than that of systemic IV chemotherapy

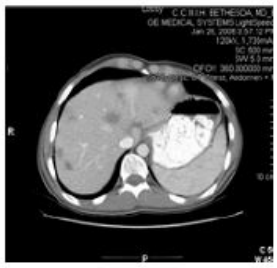
An Established Drug for Liver Cancer Therapy

Phase II NCI Trial – Metastatic Neuroendocrine Cohort

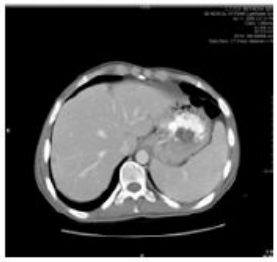
Phase II mNET Tumor Cohort (n=24)*	
	Number (n)
Primary Tumor Histology	
Carcinoid	4
Pancreatic Islet Cell	20
Response	
Not Evaluable (Toxicity, Incomplete Treatment, Orthotopic Liver Transplantation)	4
Progressive Disease	2
Minor Response / Stable Disease	4
Partial Response (30.0% - 99.0% Tumor Reduction)	**13**
Complete Response (No Evidence of Disease)	**1**
Objective Tumor Response	**14**
Objective Tumor Response Rate	***70%***
	Duration (months)
Median Hepatic PFS	15.5
Overall Survival After CS	30.4



Pre-CS
(Baseline)



Post-CS #1
(+6 Weeks)



Post-CS #2
(+4 Months)

*Presentation at ECCO/ESMO 2011 annual meeting.

Compelling Clinical Data in Attractive mNET Market

Phase II NCI Trial – HCC Cohort

- Hepatocellular carcinoma (HCC) is the most common primary cancer of the liver, with approximately 749,000* new cases diagnosed worldwide annually
- Nine patients with tumors of hepatobiliary origin: five HCC patients and four cholangiocarcinoma patients
- Both groups received CHEMOSAT procedures and had positive efficacy signals
- The responses were especially encouraging in the HCC group and consisted of confirmed partial response or durable stable disease
- Safety profile – expected and consistent with pivotal US Phase III melanoma trial
- Intend to invest in new HCC trials with CHEMOSAT

*Source: GLOBOCAN

Encouraging Initial Positive Signal for Primary Liver Cancer

Phase II NCI Trial – mCRC Cohort

- Substantial clinical evidence of benefit of using melphalan to treat mCRC via isolated hepatic perfusion (IHP) procedure
  - Over 800 patients treated in 15 studies since 1998
  - Patients treated only once
  - Median response rate of 47% (range 29%-76%)[1]
- Delcath Phase II NCI Chemosaturation Trial – mCRC Cohort
  - Challenges enrolling at NCI
  - 16 patients treated since 2004
  - Inconclusive efficacy due to advanced disease status (generally 5th or 6th line)
  - Safety profile – expected and consistent with pivotal FDA Phase III melanoma trial
- Intend to invest in new mCRC trials with CHEMOSAT Melphalan

1) van Iersel LB, Koopman M, Van D, V, et al. Ann Oncol. 2010;21:1662-7.

Strong Rationale for Using CHEMOSAT with Melphalan to Treat mCRC

Appendix IV

Published Phase I/II Studies of Doxorubicin with PHP (percutaneous hepatic perfusion) for HCC

CHEMOSAT Doxorubicin Development

- Multiple published Phase I/II studies from MD Anderson Cancer Center and Yale with percutaneous hepatic perfusion (PHP) and Kobe University using doxorubicin show promising response rates for HCC*
- Status:
  - First pass removal efficiency 95% in initial in vitro studies
  - Utilize new trade secret manufacturing process
  - Intend to file and seek CE Mark approval in 2H 2012
  - Plan to use CHEMOSAT Doxorubicin in Asia Phase III *2L* HCC trials
- Expected Benefits:
  - Multiple treatments
  - Reduced systemic toxicity for improved safety profile
  - Concomitant therapy (complements systemic therapies)

Addressing the Large HCC Market Opportunity in China

Phase I/II Studies of PHP-Doxorubicin For HCC

No. of pts	No. of PHP/ pt	Disease stage (tumor diameter)	Treatment	Median survival (mo)	Response Rates	Reference
HCC (n=79) CHM (n=23)	1–4 1–2	IV A: n=66 IV B: n=13 All multiple bilobar Extrahepatic disease in 52%	Doxorubicin 60 –150 mg/m ^{2} Cisplatin 50–150 mg/m ^{2} Mitomycin C 50–200 mg/m ^{2}	16 13	HCC pts RR 64.5% 5-year survival 20.3%	Kobe [1] Phase I/II
HCC (n=11)	1–3	Mean 9.5 cm	Doxorubicin 60 –120 mg/m ^{2}	6.5 13 (responders) 2 (non-responders)	RR 20%	MDACC [2] Phase I
HCC (n=5) CHM (n=8) Other (n=8)	2–4	Extrahepatic disease in 17%	Doxorubicin 50 –120 mg/m ^{2} 5-FU 1000–5000 mg/m ^{2}	NR	RR 22%	Yale [3] Phase I
HCC (n=7) Other (n=11)	1–10	NR	Doxorubicin 90 –120 mg/m ^{2}	23 (responders) 8 (non-responders)	RR 58%	Yale [4] Phase I

1) Ku Y et al. Chir Gastroenterol 2003;19:370–376.
2) Curley SA et al. Ann Surg Oncol 1994;1:389–99.
3) Ravikumar TS et al. J Clin Oncol 1994;12:2723–36.
4) Hwu WJ et al. Oncol Res 1999;11:529–37.

Delivered Safely in Multiple Studies with Promising Response Rates

Appendix V

Product Development Pipeline

Product Development Pipeline

	Initial Opportunity	Near Term (< 5 years)	Intermediate Term (> 5 years)
EU	• All liver cancers – melphalan • Class III medical device • 3rd party melphalan • Gen 2 melphalan CE Mark	• Doxorubicin system CE Mark • mCRC and HCC clinical trials	• CHEMOSAT for additional drugs • CHEMOSAT for other organs (lung and brain)
ASIA	• CHEMOSAT Melphalan in Australia and Hong Kong • 3rd party melphalan	• CHEMOSAT Melphalan in South Korea, Japan • CHEMOSAT Doxorubicin in China and Taiwan • 3rd party doxorubicin	• CHEMOSAT for additional drugs • CHEMOSAT for other organs (lung and brain)
US	• Melanoma liver mets • Proprietary drug-melphalan & CHEMOSAT	• mCRC and HCC indications	• CHEMOSAT for additional drugs • CHEMOSAT for other organs (lung and brain)

Development Aligned to Address Significant Market Opportunity

Concentrating the Power of Chemotherapy ™