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): November 9, 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.

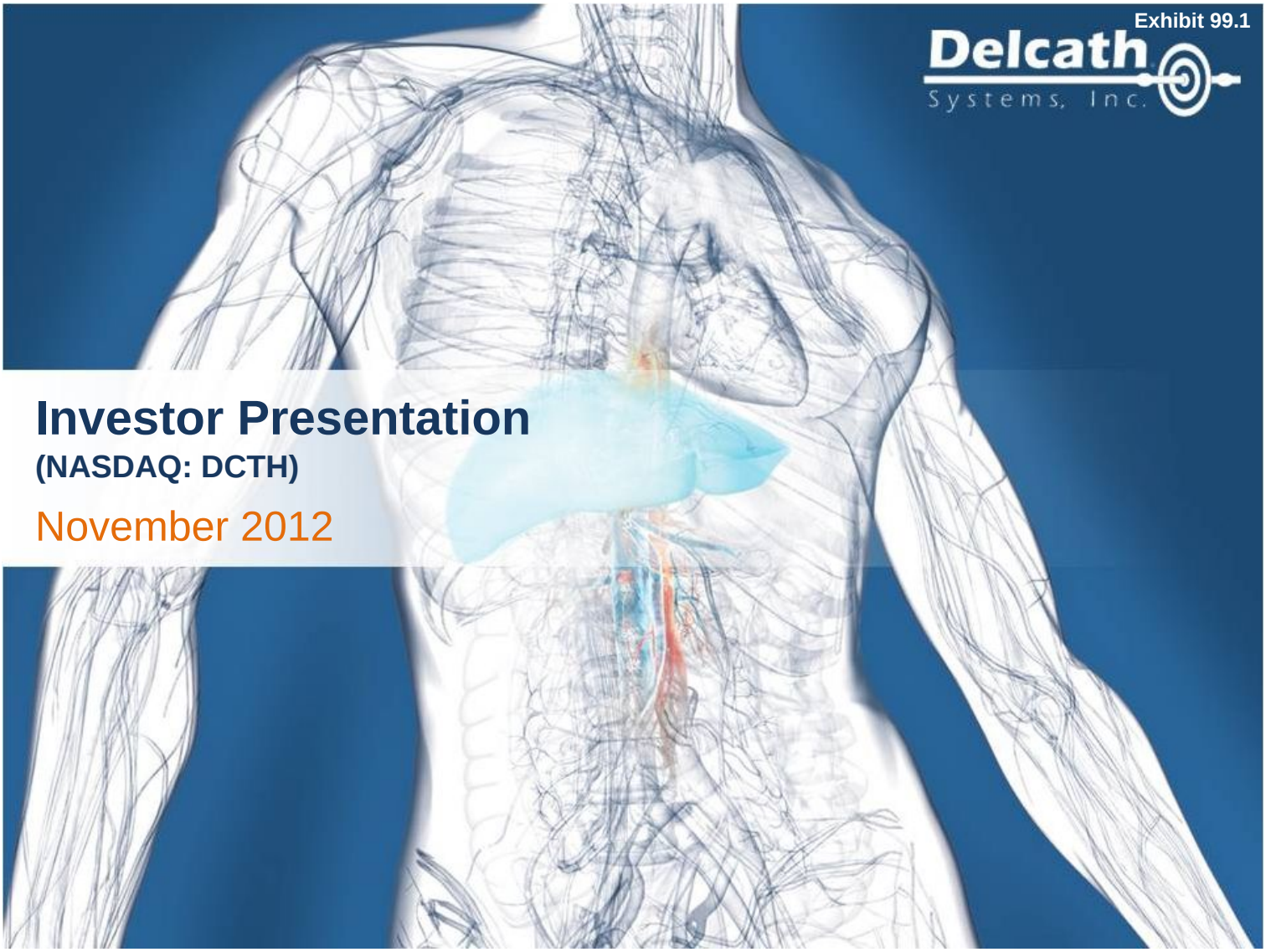
Dated: November 9, 2012

By: /s/ Peter J. Graham
Name: Peter J. 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)

November 2012

Forward-looking Statements

Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This presentation contains forward-looking statements, which 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: our ability to address the contents of the 74 Day letter, timing of completion of the FDA's review of our NDA, the extent to which the FDA may request additional information or data and our ability to provide the same in a timely manner, acceptability of the Phase 1, 2 and 3 clinical trial data by the FDA, FDA approval of the Company's NDA for the treatment of metastatic melanoma to the liver, adoption, use and resulting sales, if any, for the chemosaturation system in the United States, adoption, use and resulting sales, if any, for the Hepatic CHEMOSAT delivery system in the EEA, our ability to successfully commercialize the chemosaturation system in various markets and the potential of the chemosaturation system as a treatment for patients with cancers in the liver, the timing and our ability to successfully enter into strategic partnership and distribution arrangements in foreign markets including Australia and key Asian markets and resulting sales, if any, from the same, patient outcomes using the Generation 2 system, approval of the current or future chemosaturation system for other indications and/or for use with various chemotherapeutic agents, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for the CHEMOSAT system in various markets, submission and publication of the Phase II and III clinical trial data, the timing and results of research and development projects, the timing and results of future clinical trials including the initiation of clinical trials in key Asian markets with the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin, approval of the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin in key Asian markets and adoption and patient outcomes using the same, 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 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. 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, while pursuing opportunities in other regions
  - In Europe, CHEMOSAT with Melphalan is approved and is currently being sold
- 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

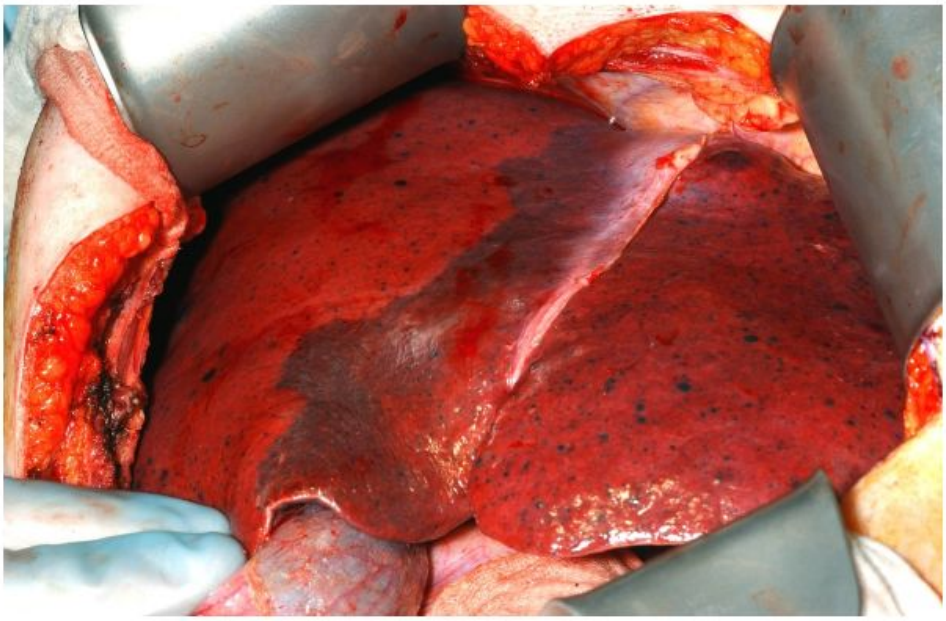
Existing Liver Cancer Treatments Have Significant Limitations

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 – Tumor revascularization – **Cannot treat diffuse disease**

Unmet Medical Need Exists for More Effective Liver Cancer Treatments

Diffuse Hepatic Metastases from Ocular and Cutaneous Melanoma



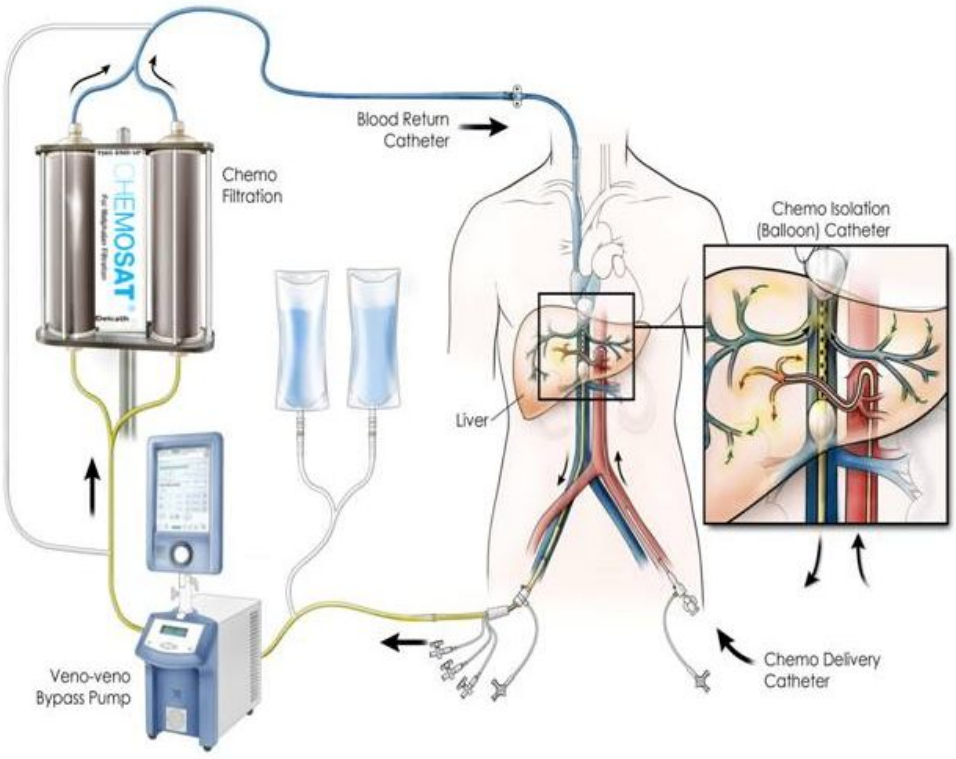
- Diffuse disease in the liver is prevalent
- Effective treatment for patients with liver-limited or dominant cancers remains a clinical challenge
- Whole organ therapy creates a new option for patients in the management of liver dominant disease

Our Solution – Whole Organ-Focus Disease Control

- 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®

1. **ISOLATE**
2. **SATURATE**
3. **FILTRATE**

Chemosaturation

- Improves disease control in the liver
- Treats entire liver (macro and micro)
- Controls systemic toxicities
- Allows for over 100x effective dose escalation at tumor site

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 with melphalan 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

Randomized to CS
93 patients: ocular or cutaneous melanoma

CS = ChemoSaturation (CHEMOSAT)

CS/Melphalan
Treat every 4 weeks x 4 rounds
(responders can receive up to 6 rounds)

Cross-over

Best Alternative Care (BAC)
Investigator and patient decision
(any and all treatments)

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

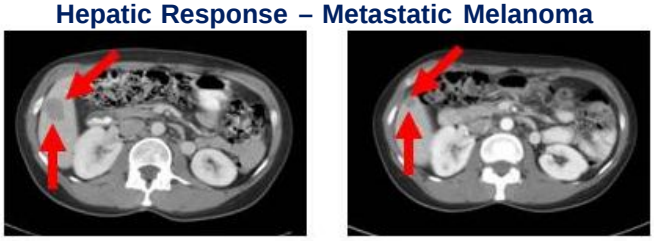
Secondary Trial Endpoints

- **Investigator hPFS**
- **Hepatic objective response rate**
- **Overall objective response rate**
- **Overall Survival – Diluted by Cross Over**
- **SAP calls for analysis of various patient subsets**

Modeled hPFS for Trial Success:

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

Hepatic Response – Metastatic Melanoma

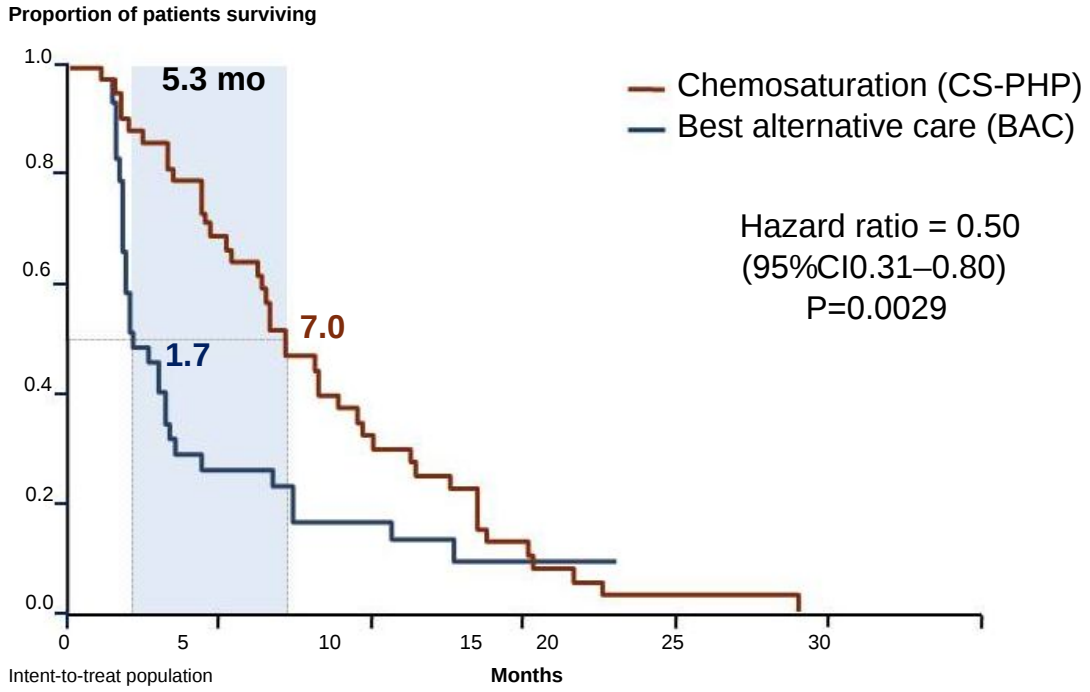


Pre-CS (Baseline) **Post-CS (22+ Months)**

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

Positive Phase III Results – Primary Endpoint hPFS

Hepatic progression-free survival (IRC)

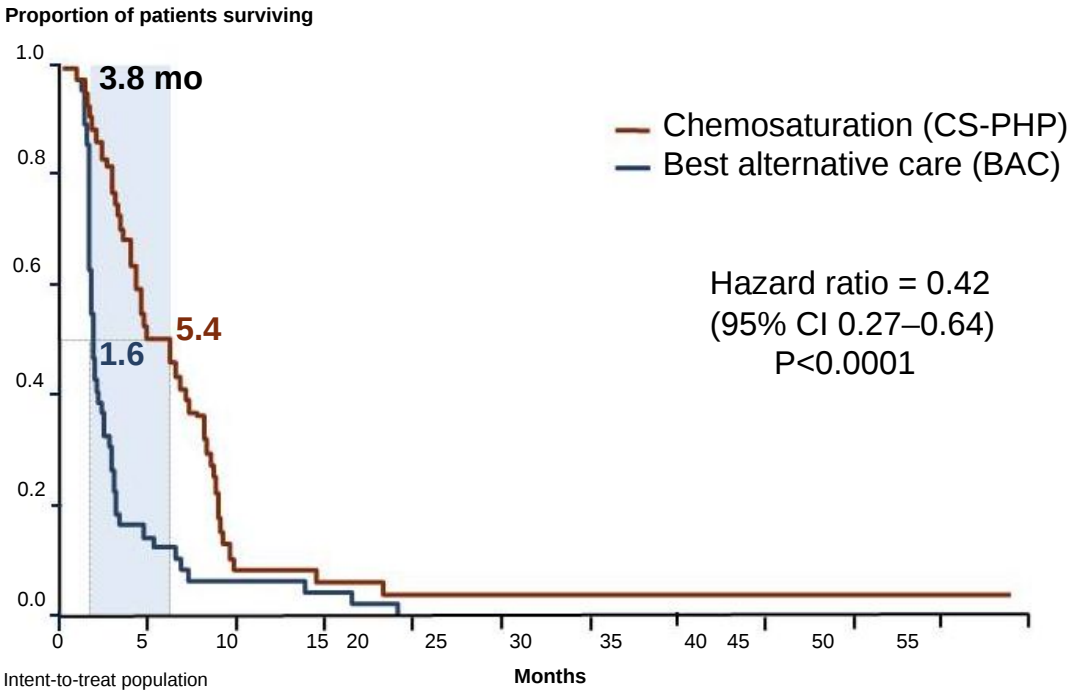


INDEPENDENT REVIEW COMMITTEE (IRC) ASSESSMENT – UPDATED ANALYSIS (4 June 2012)

CS-PHP Demonstrated 4x or 5.3 months Improvement in Primary Endpoint of hPFS

Positive Phase III Results – Overall PFS

Overall progression-free survival (investigator)

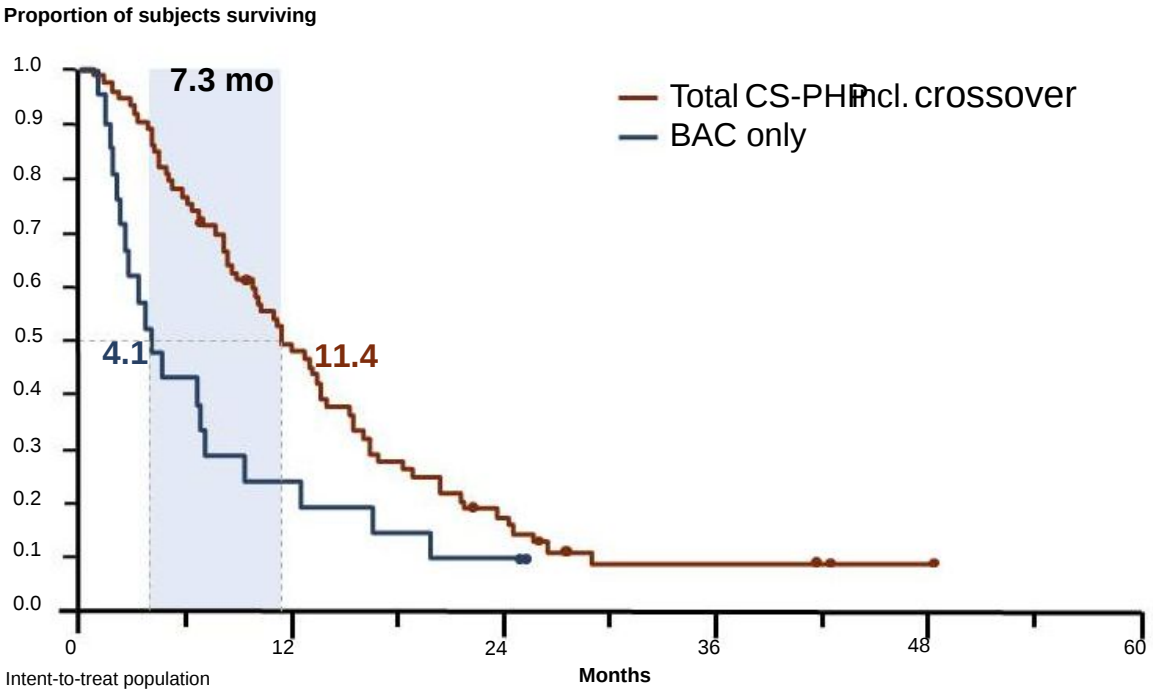


INVESTIGATOR ASSESSMENT UPDATED ANALYSIS (4 June 2012)

CS-PHP also Demonstrated a Highly Statistically Significant Improvement in Overall PFS

Overall Survival – Exploratory Subset Analysis

TOTOL CS-PHP vs BAC ONLY



Overall Survival Tail For CS-PHP Treated Patients

Positive Phase III Results

- Primary endpoint (hPFS by IRC) exceeded, p value = 0.0029, hazard ratio of 0.50 as of June, 2012
  - CS/PHP median hepatic progression free survival (hPFS) was 4-fold of control, or 5.3 months improvement
  - CS/PHP achieved a median hPFS of 7.0 months vs 1.7 months for BAC control
  - 75% overall clinical benefit (CR + PR + SD)
- Secondary endpoints consistent with primary endpoints
  - CS/PHP achieved a median overall PFS of 5.4 months vs. 1.6 months for BAC
  - OS – No difference demonstrated due to heavy crossover from BAC to CS/PHP
  - Median OS 10.6 months vs. 10.0 months for CS/PHP and BAC respectively
- OS exploratory analyses supportive of key observations
  - Median overall survival of 11.4 months for all patients treated with melphalan, including crossover
  - BAC patients did not cross-over to CS/PHP had a median survival of 4.1 months
  - 7 CS/PHP-treated and 3 BAC-only patients still alive as of 6/2012
- Gen 1 Safety profile – 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

The Evidence for Melphalan

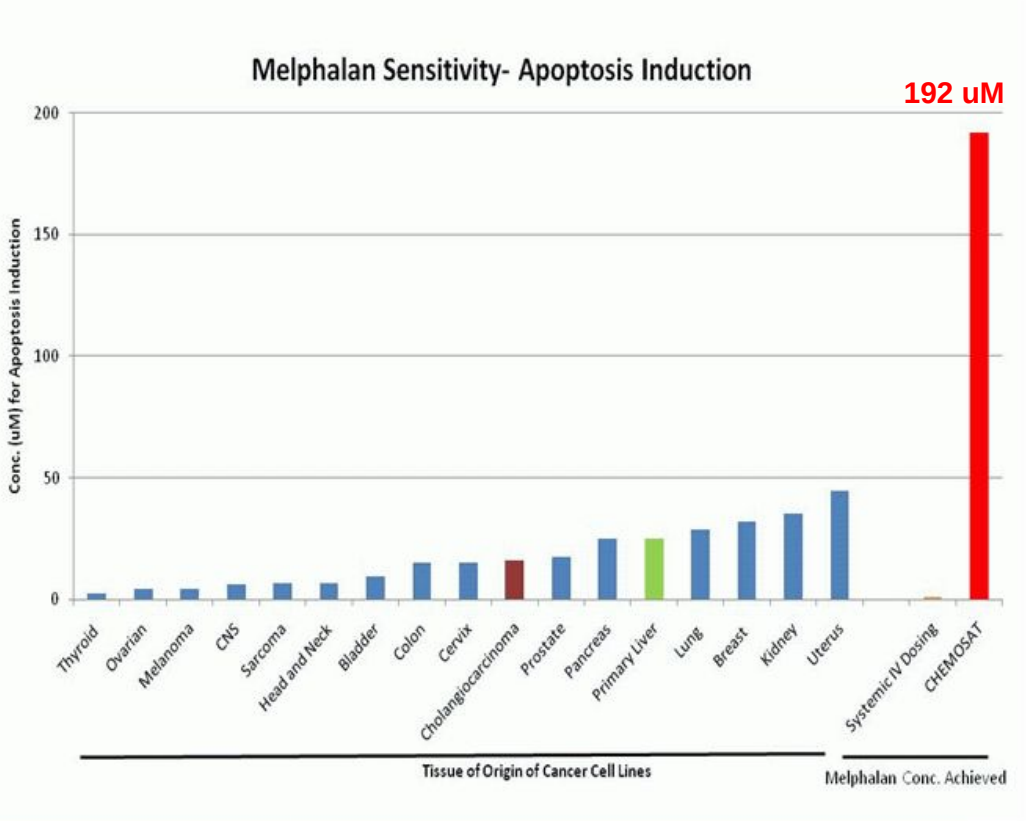
- Melphalan, an established chemotherapy agent, is proven active at high doses with broad antitumor activity

Authors	Technique	N	Tumor	Drug(s)	ORR, %	Median OS, months
Grover et al. 2004	IHP	13	NET	Melphalan ± TNF	50	48
Noter et al. 2004	IHP	8	Ocular melanoma	Melphalan	50	10
Alexander et al. 2000	IHP	22	Ocular melanoma	Melphalan ± TNF	62	11
Alexander et al. 2003	IHP	29	Ocular melanoma	Melphalan	62	12
Alexander et al. 2009	IHP	120	Colorectal	Melphalan ± TNF, TNF	61	17
van Iersel et al. 2008	IHP	154	Colorectal	Melphalan	50	25
van Iersel et al. 2010	IHP	99	Colorectal	Melphalan	–	25
Verhoef et al. 2008	PHP	24	Various	Melphalan	62	–

1. Grover AC, et al. Surgery 2004;136:1176-82
2. Noter SL, et al. Melanoma Res 2004;14:67-72
3. Alexander HR Jr, et al. Clin Cancer Res 2000;6:3062-70
4. Alexander HR Jr, et al. Clin Cancer Res 2003;9:6343-9
5. Alexander HR Jr, et al. Ann Surg Oncol 2009;16:1852-9
6. Van Iersel LB, et al. Ann Oncol 2008;19:1127-34
7. Van Iersel LB, et al. Ann Oncol 2010;21:1662-7
8. Verhoef C, et al. Ann Surg Oncol 15:1367-74

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

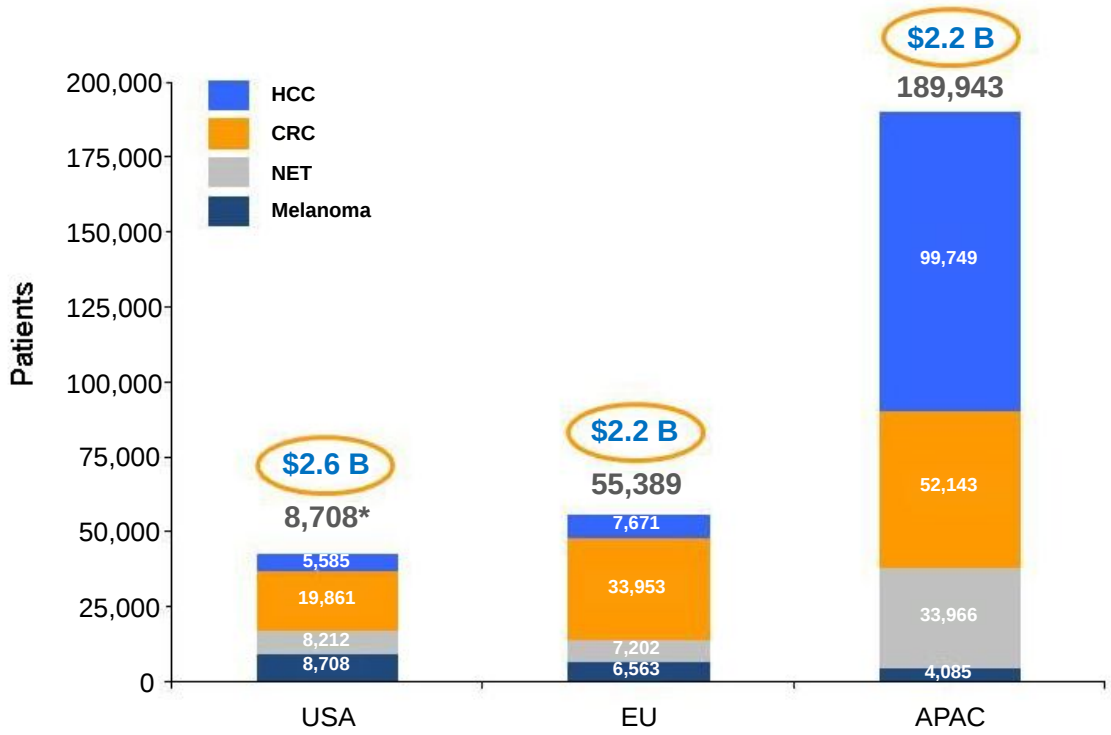


We Believe CHEMOSAT Will Be Effective On a Wide Range of Solid Tumors

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%

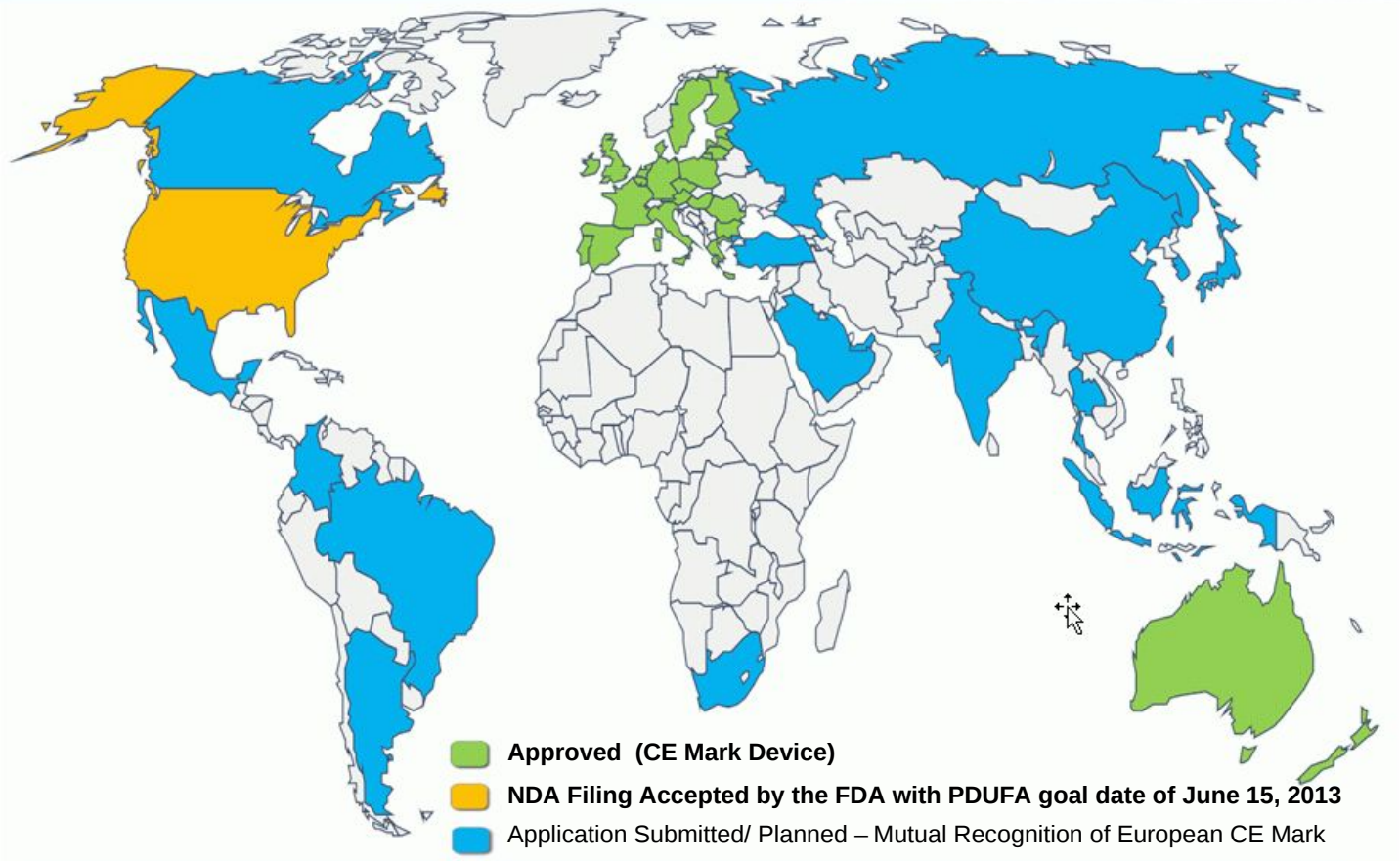
CHEMOSAT - Potential Multi-Billion Dollar Market



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



Addressing A Multi-Billion Dollar Global Market

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 and surgical oncologists via contract organization
- Sell to hospital-based oncologists, interventional radiologists, surgeons and C-suite decision makers with combination of direct sales and distributors
- Focus on medical and surgical oncologists at referral centers
- Hospitals procure melphalan from third parties and physicians use at their discretion
- Establish European patient education and awareness programs (PR, website)
- Leverage interim reimbursement channels, while pursuing permanent procedure reimbursement
- Focused clinical trial program to generate additional data and build clinical experience across multiple centers for various tumor types (e.g. HCC, NET and CRC)

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; Southampton, UK, St Andre, France
  - Liver metastases from cutaneous melanoma, ocular melanoma, gastric cancer, breast cancer, neuroendocrine tumor (NET), hepatocellular carcinoma (HCC) 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 execute 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
- Italy – Secured a pathway for reimbursement using an existing Diagnosis Related Group code (DRG) for use with CHEMOSAT. We will continue to seek additional supplemental new technology payments, and potentially pursue a new higher reimbursing DRG for CHEMOSAT
  - A limited number of procedures are currently being covered by private payment and research funding
  - Apply for funding under existing New Technology Payment programs
    - Italy – First Regional Application submitted for supplemental (in addition to DRG) new technology payments.
    - Germany - Interim reimbursement process is being actively sponsored and driven by the German Radiology Society – 12 NUB applications filed
    - United Kingdom – Our lead centers are seeking to gain PCT (Primary Care Trust) approval. This would allow us to perform CHEMOSAT procedures in 3 to 4 key centers in the UK

Reimbursement Program Now In Execution Phase

International Strategy beyond EU and US

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

Combination of Strategic Partnerships and Specialty Distributors

U.S. FDA Regulatory Status

- NDA accepted and under active FDA review since submission in mid August, 2012
- We are working closely with the FDA during the review process
- PDUFA goal date of June 15, 2013 assigned by the FDA
- FDA advised Oncology Drug Advisory Committee (ODAC) panel to be expected
- NDA filing included:
  - Comprehensive set of additional data in a new FDA compliant CDISC database
  - Gen 2 filter as part of the Chemistry, Manufacturing and Control (CMC) module
- We have also amended IND and Expanded Access Program (EAP) and Gen 2 has been accepted by the FDA for use in EAP, compassionate use and prospective clinical trials in the US

U.S. Commercialization Strategy

- Initial focus on centers that participated in the phase III clinical trial
- Educate Medical Oncologists via Medical Science Liaison (MSL)
- Direct strategy to sell to Interventional Radiologists and Oncologists
  - Approximately 12 sales territories ultimately expanding to as many as 60 territories as revenues ramp
- Utilize top centers from Phase III trial as Centers of Excellence for training and support
- Intend to seek chemosaturation specific CPT reimbursement code, based upon value proposition relative to other cancer therapies

Direct Sales Channels with MSL Clinical Support

Clinical Development Program

- Goal:
  - Expand US (CS-PHP: MEL) label indications to include HCC and mCRC
  - Generate robust clinical data to support commercialization
- FDA has accepted IND Amendment to include Gen 2 device in Expanded Access Program (EAP), compassionate use (CU), and all future clinical trials
  - Intend to initiate EAP for metastatic melanoma by Q412
- Initiate EU Registry to systematically collect relevant data from commercial experience
- New Clinical Trials (first patient enrolled in 2013)
  - mCRC
    - Global Phase 3 Randomized **2L** CHEMOSAT Melphalan vs. Approved Alternatives
  - HCC
    - Global Phase 3 Randomized **2L** CHEMOSAT Melphalan vs. BSC for Sorafenib Failure
    - Asia Regional Phase 3 Randomized **2L** CHEMOSAT Doxorubicin vs. BSC for Sorafenib Failure
- Multiple Phase 2 studies under evaluation: HCC, NET, mBreast, Pancreatic
- Support investigator-initiated trials (IITs)

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

CHEMOSAT System for Doxorubicin – CE Mark

- Satisfied all of the requirements to affix the CE Mark to Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin in October, 2012
  - Provides a pathway for regulatory approval in China and S. Korea
- Provides basis for partnership opportunities in China and S. Korea where doxorubicin has a broad label
- 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*
- Plan to use CHEMOSAT Doxorubicin in Asia Phase III *2L* HCC trials

Addressing the Large HCC Market Opportunity in China

2012 Milestones

- First patients have been treated with CHEMOSAT Melphalan in Europe - Done
- Execute contract for MSL services in EU in 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 - Done
- US NDA acceptance with standard review in October 2012 - Done
- Obtain CE Mark for CHEMOSAT Doxorubicin in 2H 2012 - Done
- Submission for publications of Phase III data and mNET arm of Phase II data in Q4 2012
- First patients enrolled in EAP in Q4 2012
- Initiate EU Registry in Q4 2012
- Potential Asia strategic partnership – dedicated BD with China a top priority

Financial Update

Cash & Cash Equivalents:	**$28.3 million at September 30, 2012**
Financing:	**$21.1 million (net) raised in a follow-on equity offering in May 2012**
ATM Program	**$24.5 million remaining as of September 30, 2012**
Working Capital Line of Credit:	**$20.0 million credit facility**
Debt:	**None**
Cash Spend:	**$14.6 million in 3Q2012**
Shares Outstanding:	**73.4 million (83.8 million fully diluted[1])**
Institutional Ownership:	**13%**
Market Capitalization:	**$120 million as of September 30, 2012**
Avg. Daily Volume (3 mo.):	**1,000,000**

1) Fully diluted includes an additional 4.8 million options and 5.6 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.	CSO 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 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

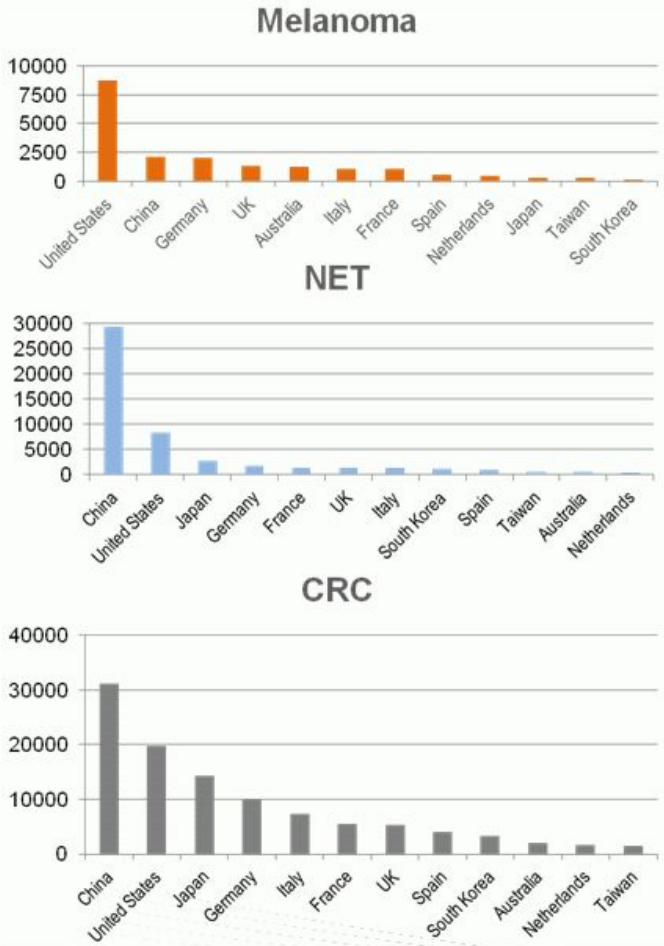
- Patent Protection
  - 5 U.S. patents in force and 6 U.S. patent applications pending
  - 6 foreign patents in force (with patent validity in 22 countries) and 15 foreign patent applications pending
  - Primary device patent set to expire August 2016
  - Up to 5 years of patent extension post FDA approval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

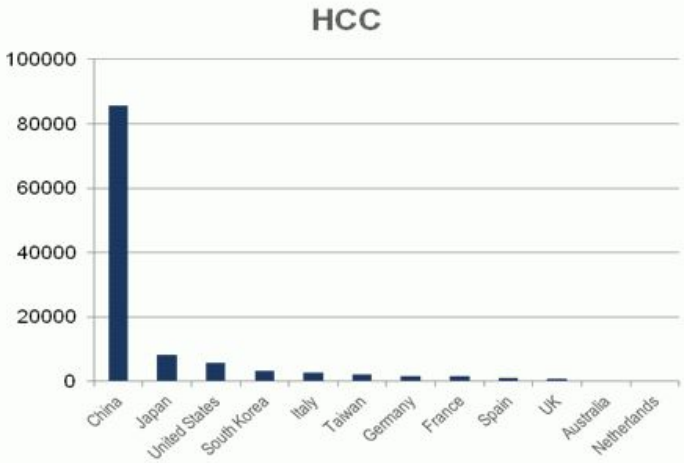
Appendix II

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

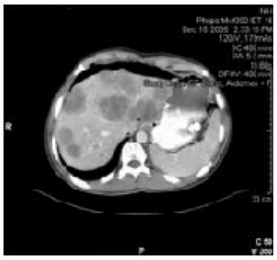
Type	Dosing (mg/kg)
Multiple Myeloma (label)	0.25
Chemoembolization	0.62
Surgical Isolated Hepatic Perfusion (IHP)	1.50
Myeloablation	2.50-3.50
Chemosaturation (PHP)	**3.00**

- 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

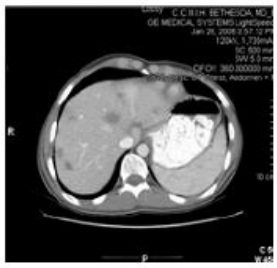
An Established Drug for Liver Cancer Therapy

Phase II NCI Trial – Metastatic Neuroendocrine Cohort

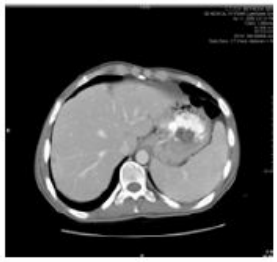
Phase II mNET Tumor Cohort (n=24)*	
	Number (n)
Primary Tumor Histology	
Carcinoid	4
Pancreatic Islet Cell	20
Response	
Not Evaluable (Toxicity, Incomplete Treatment, Orthotopic Liver Transplantation)	4
Progressive Disease	2
Minor Response / Stable Disease	4
Partial Response (30.0% - 99.0% Tumor Reduction)	**13**
Complete Response (No Evidence of Disease)	**1**
Objective Tumor Response	**14**
Objective Tumor Response Rate	***58%***
	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 – Hepatobilliary carcinoma

- 11 patients with tumors of hepatobiliary origin: 5 HCC, 2 intrahepatic and 3 extrahepatic cholangiocarcinoma,1 mixed histology
- CHEMOSAT treatment showed encouraging anti-tumor activities in hepatocellular carcinoma (HCC)
  - 1 Confirmed partial response lasting 7 months
  - 2 stable disease lasting 8 months, 6 months respectively
- Safety profile – consistent with pivotal US Phase III melanoma trial
- HCC is the most common primary cancer of the liver, with approximately 750,000* new cases diagnosed worldwide annually
- 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

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 • Classified as 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 Taiwan and Japan • CHEMOSAT Doxorubicin in China and South Korea • 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

Appendix VI

European Regulatory Update

European Regulatory Update

- Retained new Notified Body
- Device reclassified from class III to class IIB, permitting self-certification in accordance with the same established quality management system
  - The primary difference between Class III and Class IIb is that for Class IIb medical devices the Notified Body is not required to carry out an examination of the product's design dossier as part of its conformity assessment
  - The Company must continue to comply with the essential requirements of the EU Medical Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body
  - The conformity assessment procedure for Class IIb medical devices requires the manufacturer to lodge an application for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body
  - The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body's assessment is favorable it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE mark to the medical devices covered by the assessment
  - Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer.

Concentrating the Power of Chemotherapy™