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

FORM 8-K

CURRENT REPORT

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

Date of report (Date of earliest event reported): March 4, 2013

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 (the "Company") 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.

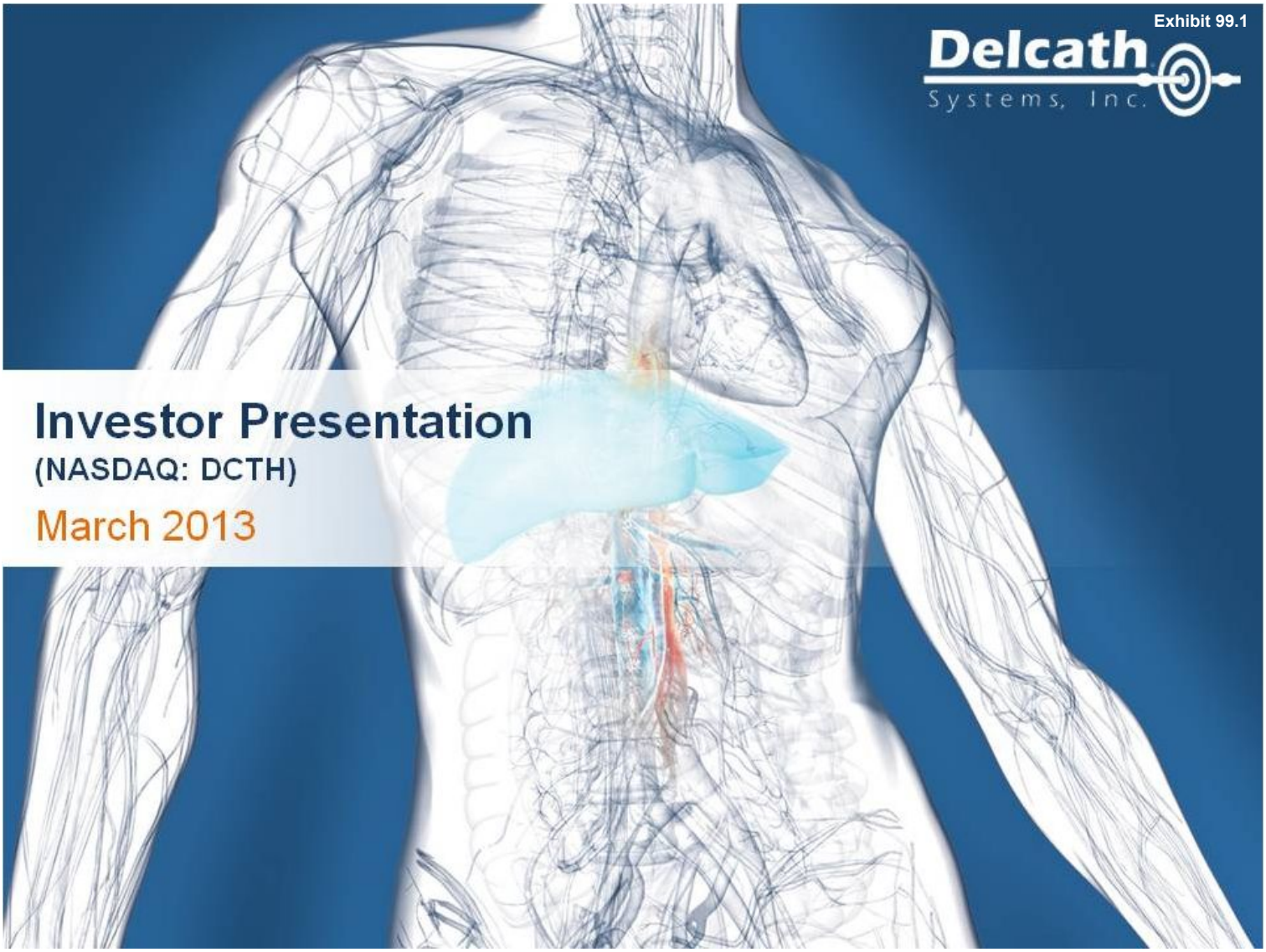
Dated: March 4, 2013

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)

March 2013

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: the outcome of the ODAC meeting, and the impact, if any, of the advisory panel's recommendation on the FDA's decision regarding the Company's new drug application (NDA), uncertainties relating to: 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 ocular melanoma to the liver, adoption, use and resulting sales, if any, for the *Delcath Hepatic Delivery 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 Delivery System in various markets and the potential of the 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 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, the number of cancer centers in Germany and Italy able to successfully negotiate and receive reimbursement for the CHEMOSAT procedure and the amount of reimbursement to be provided, 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 CHEMOSAT Hepatic Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin, approval of the CHEMOSAT Hepatic Delivery System to delver and filter doxorubicin in key Asian markets and adoption, sales, if any, and patient outcomes using the same, the timing, price and use, if any, of the committee equity financing facility with Terrapin, 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.*

Investment Considerations

- Commercial stage company focused on oncology
- Proprietary CHEMOSAT® Hepatic Delivery System allows unique whole organ therapy for the liver
- CHEMOSAT system has demonstrated extension of progression free survival
- Addressing large unmet market need for cancer patients who usually die of liver failure
- Estimated initial market opportunity of ~$2.3 billion in U.S. & EU
- Expanding clinical data expected to broaden clinical use and indications
- On the cusp of realizing the potential:
  - EU - early commercial launch underway; reimbursement in key EU markets expected in Q1/Q2
  - U.S. - NDA under review ; ODAC May 2, PDUFA date June 15, 2013
- Attractive financial model, multiple capital resources available and experienced management team to execute plan

Concentrating the Power of Chemotherapy

Our Product

US Market

- Proposed Trade Name

Melblez Kit™ (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System)

- Proprietary Drug/Device Combination Product Regulated as a drug 505(b)(2) NDA by U.S. FDA
- Proposed indication for the treatment of patients with unresectable ocular melanoma metastatic to the liver
- Melblez Kit comprised of Melblez™ (melphalan hydrochloride for injection) and the Delcath Hepatic Delivery System

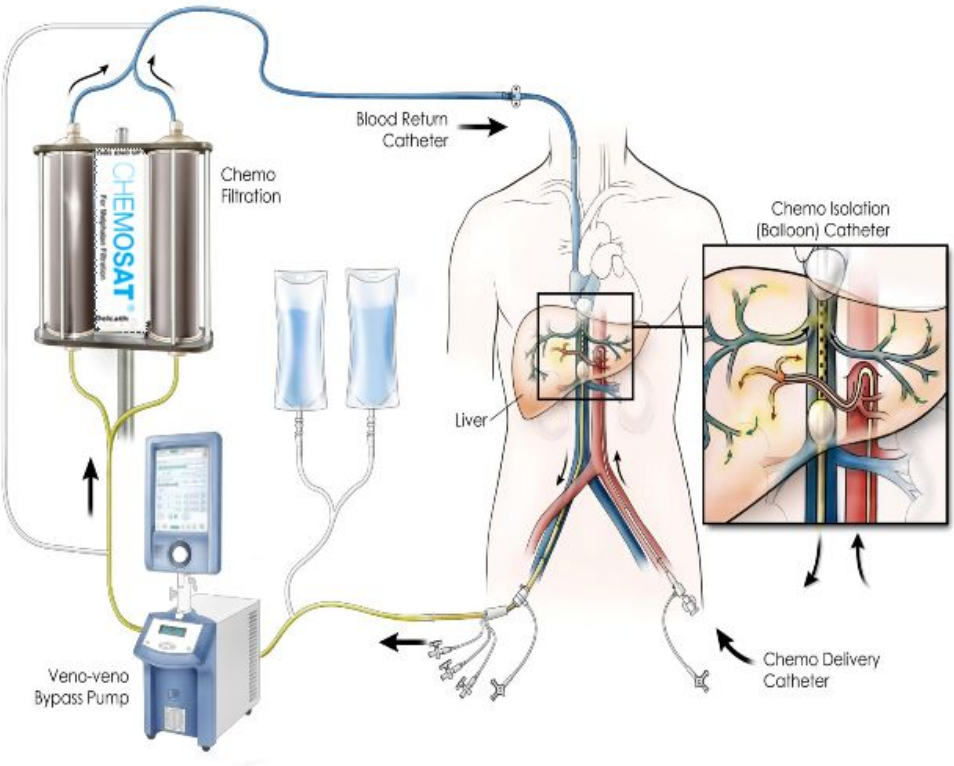
Ex US Markets

- Marketed under the trade name

CHEMOSAT® Hepatic Delivery System

- Regulated as a Class IIb Medical Device
- Indicated for the intra-hepatic of administration of melphalan hydrochloride and subsequent filtration of the venous blood return.
- CHEMOSAT Kit supplied without melphalan

The Delcath Hepatic Delivery System



CHEMOSAT®

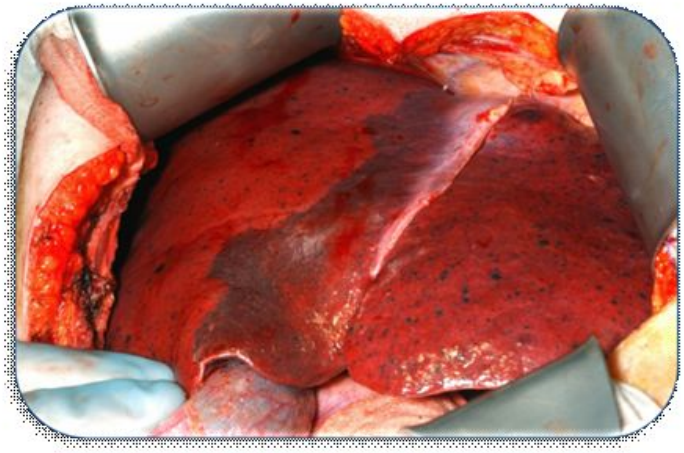
1. ISOLATE
2. SATURATE
3. FILTRATE

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

Minimally Invasive, Repeatable Procedure That Could Complement Systemic Therapy

Melanoma Liver Metastases

- A challenging histology
- Notoriously insensitive to systemic chemotherapy and focal interventions
- CHEMOSAT has demonstrated ability to extend progression free survival



Our Opportunity

- Ability to achieve ultra-high concentrations of chemotherapy provides potential treatment options for a wide variety of cancers in the liver

A Great Demonstration of CHEMOSAT's Potential

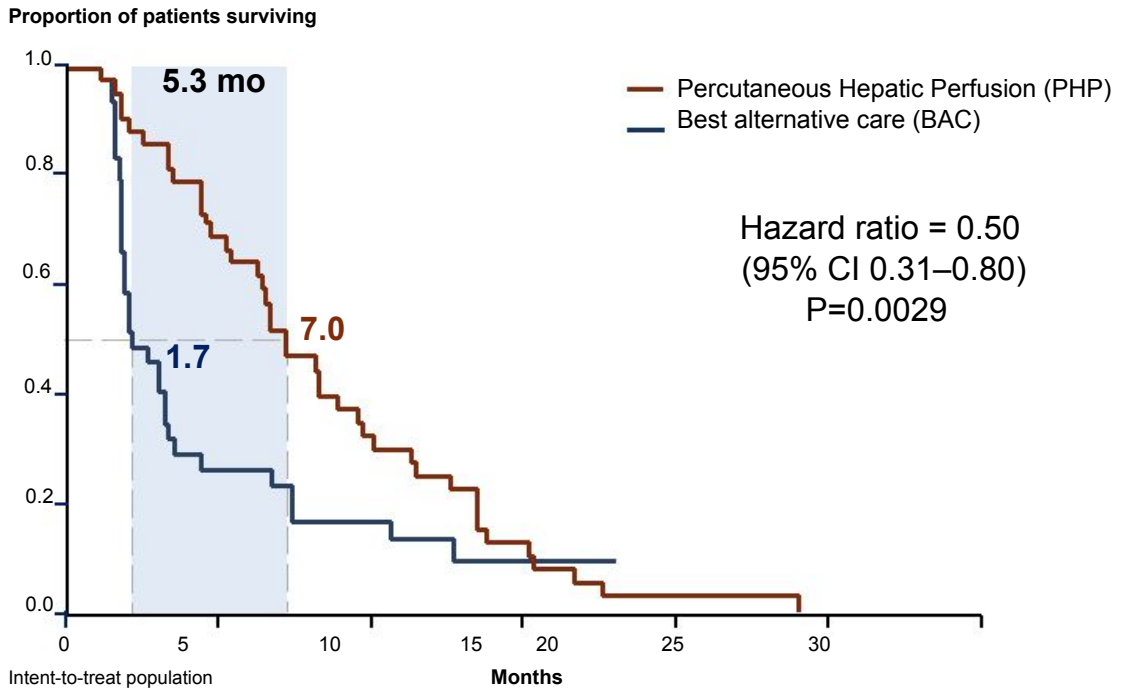
Clinically Differentiated Results

- Phase 1, 2 and 3 trials with percutaneous hepatic perfusion (PHP) produced positive results in multiple histologies
- Melanoma Liver Mets
  - Positive Phase 3 results in hepatic metastatic melanoma
  - n=93 (90% ocular melanoma, 10% cutaneous melanoma)
- Neuroendocrine Tumor (NET) Liver Mets
  - mNET cohort in Phase 2 trial showed encouraging 42% objective response rate (ORR) vs ~10% for approved targeted therapy
  - median overall survival of ~32 months on ITT basis
- Hepatocellular Carcinoma (HCC)
  - Positive signal with high-dose melphalan in HCC cohort of Phase 2 trial (5/8 patients) is encouraging when approved systemic therapies have modest efficacy and challenges with tolerability
- Colorectal Cancer (CRC) Liver Mets
  - Data from surgical Isolated Hepatic Perfusion (IHP) with melphalan indicates strong potential in well-defined patient population with earlier stage CRC yielding ~50-60% median response rate and median OS of 17.4-24.8 mos
- Safety profiles consistent with pivotal US Phase 3 melanoma trial

Encouraging Initial Results on a Broad Range of Histologies

Positive Phase 3 Results – Primary Endpoint hPFS

Hepatic progression-free survival (IRC)

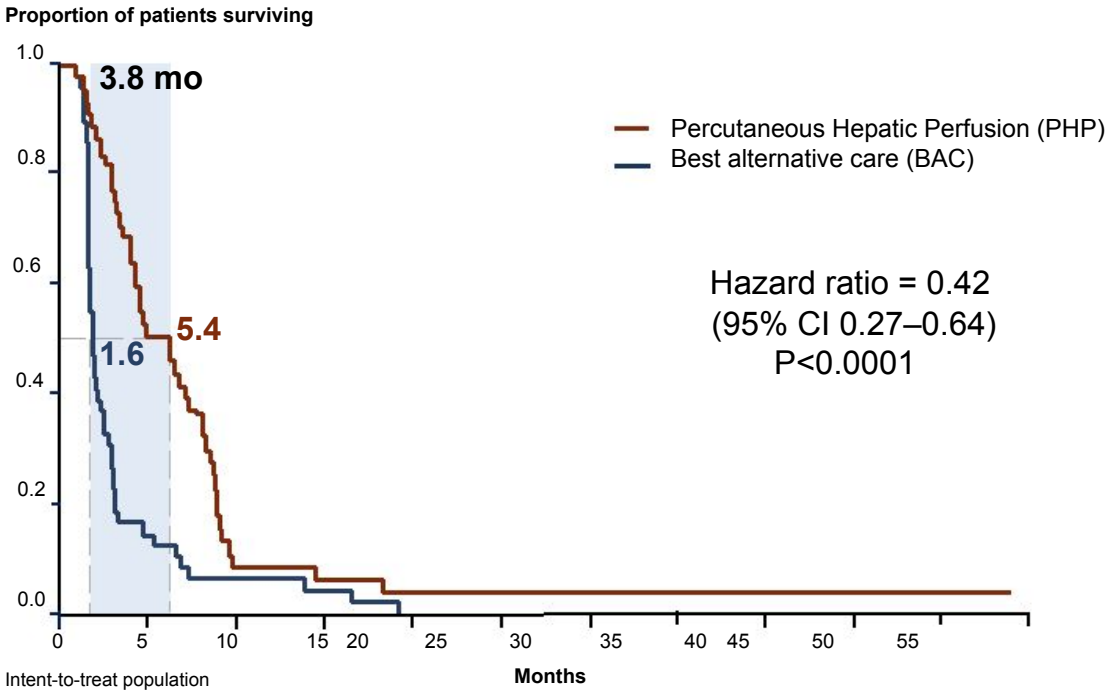


INDEPENDENT REVIEW COMMITTEE (IRC) ASSESSMENT – UPDATED ANALYSIS (4 June 2012)

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

Positive Phase 3 Results – Overall PFS

Overall progression-free survival (investigator)

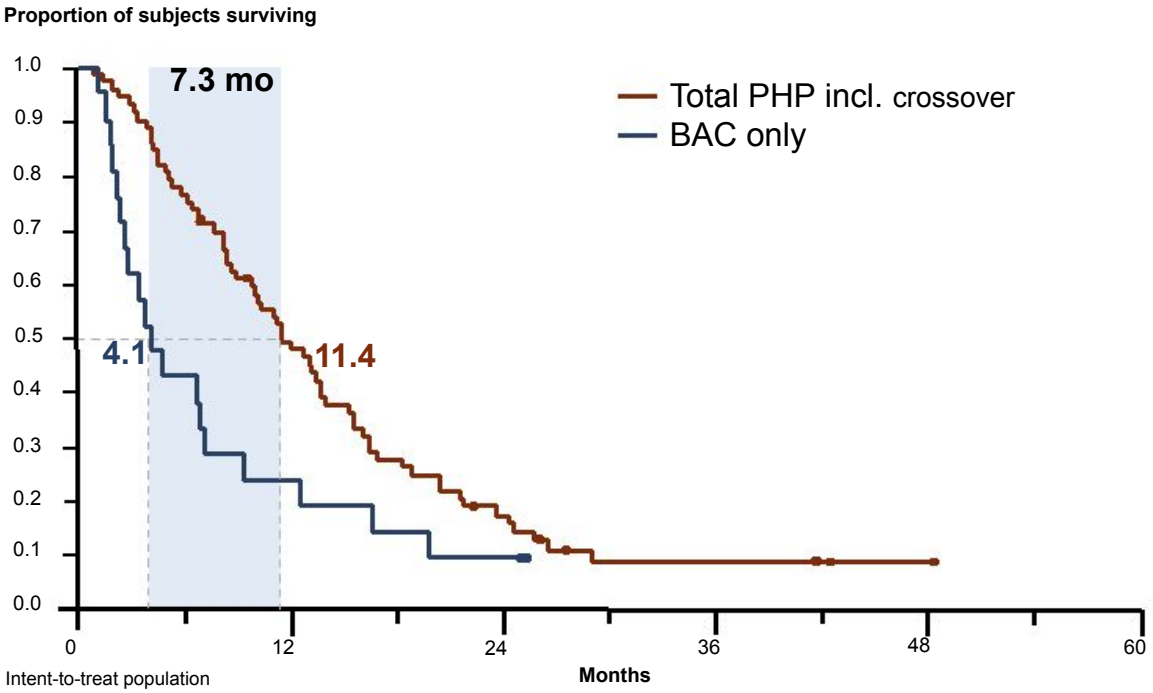


INVESTIGATOR ASSESSMENT – UPDATED ANALYSIS (4 June 2012)

PHP also Demonstrated a Highly Statistically Significant Improvement in Overall PFS

Overall Survival – Exploratory Subset Analysis

TOTAL PHP vs BAC ONLY



Overall Survival Tail For PHP Treated Patients

Phase 2 Multi-Histology NCI Trial – Summary

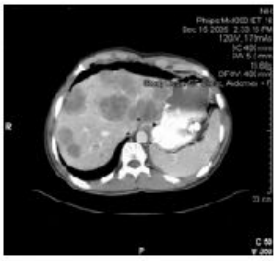
- Strong efficacy signals in mNET
  - 42% objective Response Rate (ORR) vs ~10% for approved targeted therapy
  - 66% patients had hepatic tumor shrinkage and durable disease stabilization
- Positive Signal in primary hepatic malignancies (HCC and Cholangiocarcinoma) in 5 of 8 patients
- Similar safety profiles across tumor types

Positive Efficacy Signals In Additional Types of Cancer

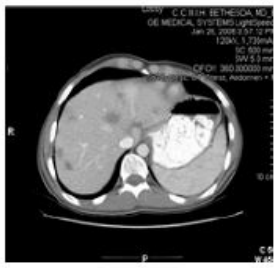
Phase 2 NCI Trial – Metastatic Neuroendocrine Cohort

Phase 2 mNET Tumor Cohort (n=24)*	Number (n)
Tumor Types	
Pancreatic NET	13
Carcinoid tumor	3
Other NET	8
Response	
Partial Response (PR)	10
Stable disease (SD)	6
Progressive disease	3
Not assessed or evaluable	5
Objective Response Rate	**42%**
Median Duration of Hepatic Response	
Partial Response (n-10)	23.5 months
Partial Response/Stable Disease (n=16)	16.8 months
Hepatic Progression Free Survival (IIT n=24)	
Median Hepatic PFS	16.8
Min/Max	2.1, 64.1
Overall Survival After CS	
Median	31.9 months
Min/Max	2.4, 81.1

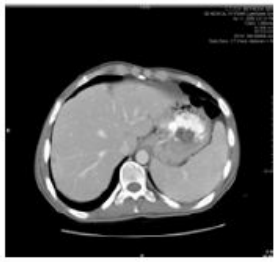
66% disease control



Pre-PHP
(Baseline)



Post-PHP #1
(+6 Weeks)



Post-PHP #2
(+4 Months)

Compelling Clinical Data in Attractive mNET Market

Phase 2 NCI Trial – Hepatobiliary Carcinoma Cohort

- Best hepatic tumor response by modified RECIST assessed by investigators
  - Partial response (PR) 1 patient
  - Stable disease (SD) 4 patients
  - Progressive disease 1 patient
  - Not assessed or evaluable 2 patients
- Median duration of response
  - hPR (N=1) 6.42 months
  - hPR/SD (N=5) 8.12 months
- Hepatic progression free survival (ITT N=8)
  - Median 5.60 months
  - Minimum, Maximum 2.7, 12.2 months
- Overall survival (ITT N=8)
  - Median 9.12 months
  - Minimum, Maximum 3.4, 20.5 months
- HCC is the most common primary cancer of the liver, with approximately 750,000* new cases diagnosed worldwide annually
- Intend to initiate new HCC trials with CHEMOSAT

*Source: GLOBOCAN

Encouraging Positive Signal for Primary Liver Cancer

Phase 2 NCI Trial – mCRC Cohort

- **Substantial clinical evidence of benefit of using ultra-high dose 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 ~50-60% and median OS of 17.4 – 24.8 mos1,2**
- Delcath Phase 2 NCI Trial – mCRC Cohort
  - Challenges enrolling at NCI due to competing FOLFOX & FOLFIRI trials
  - 17 patients treated since 2004
  - 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, Gelderblom H, et al. Ann Oncol. 2008;19:1127-34
2) Alexander, HR, Barlett DL, et al. Ann Surg Oncol, 16:1852-9, 2009

Strong Rationale for Using CHEMOSAT-with-Melphalan to Treat mCRC

Additional Clinical Data Generation

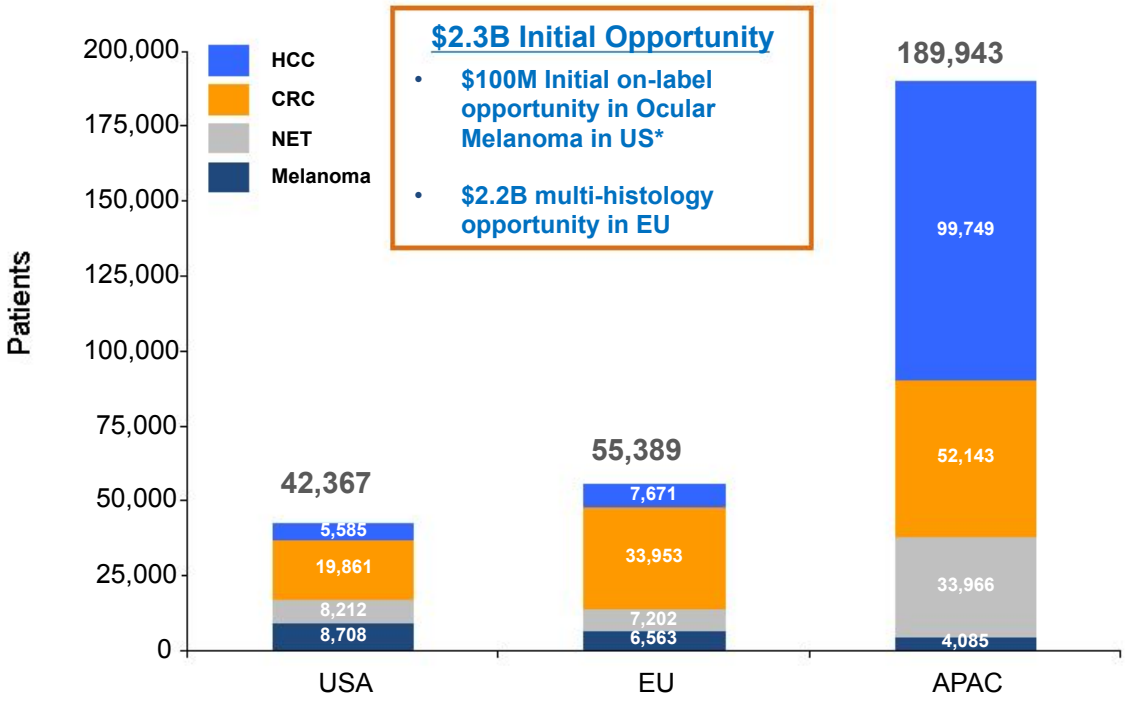
- Goals:
  - Expand US (PHP: MEL) label indications beyond the initial indication we are seeking
  - Generate robust clinical data to support commercialization
- FDA has accepted IND Amendment to include Gen 2 device in Expanded Access Program (EAP), compassionate use (CU), and all future clinical trials
- Initiated EAP to treat first patient in January, 2013
- Activate EU Registry to systematically collect data from commercial experience

2013 Clinical Development Plan

- Planned company sponsored trials, subject to agreement with FDA
  - **Hepatocellular carcinoma (HCC)**
    - Global Phase 3 Randomized CHEMOSAT Melphalan vs. best supportive care (BSC) for patients where Sorafenib is inappropriate
      - Primary endpoint: Overall Survival
  - **Advanced colorectal cancer (CRC)** with liver dominant metastasis
    - Global Phase 3 Randomized CHEMOSAT Melphalan vs. best alternative care (BAC)
      - Primary endpoint: Overall Survival
  - **Metastatic Neuroendocrine tumor (NET) with liver dominant disease**
    - Global Phase 3 Randomized CHEMOSAT Melphalan vs. Best Alternative Care (BAC)
      - Primary endpoint: Hepatic PFS
- Planned phase 2 studies including global Investigator-initiated trials (IITs) in multiple indications: HCC, NET, CRC, melanoma

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

CHEMOSAT - Potential Multi-Billion Dollar Global Market

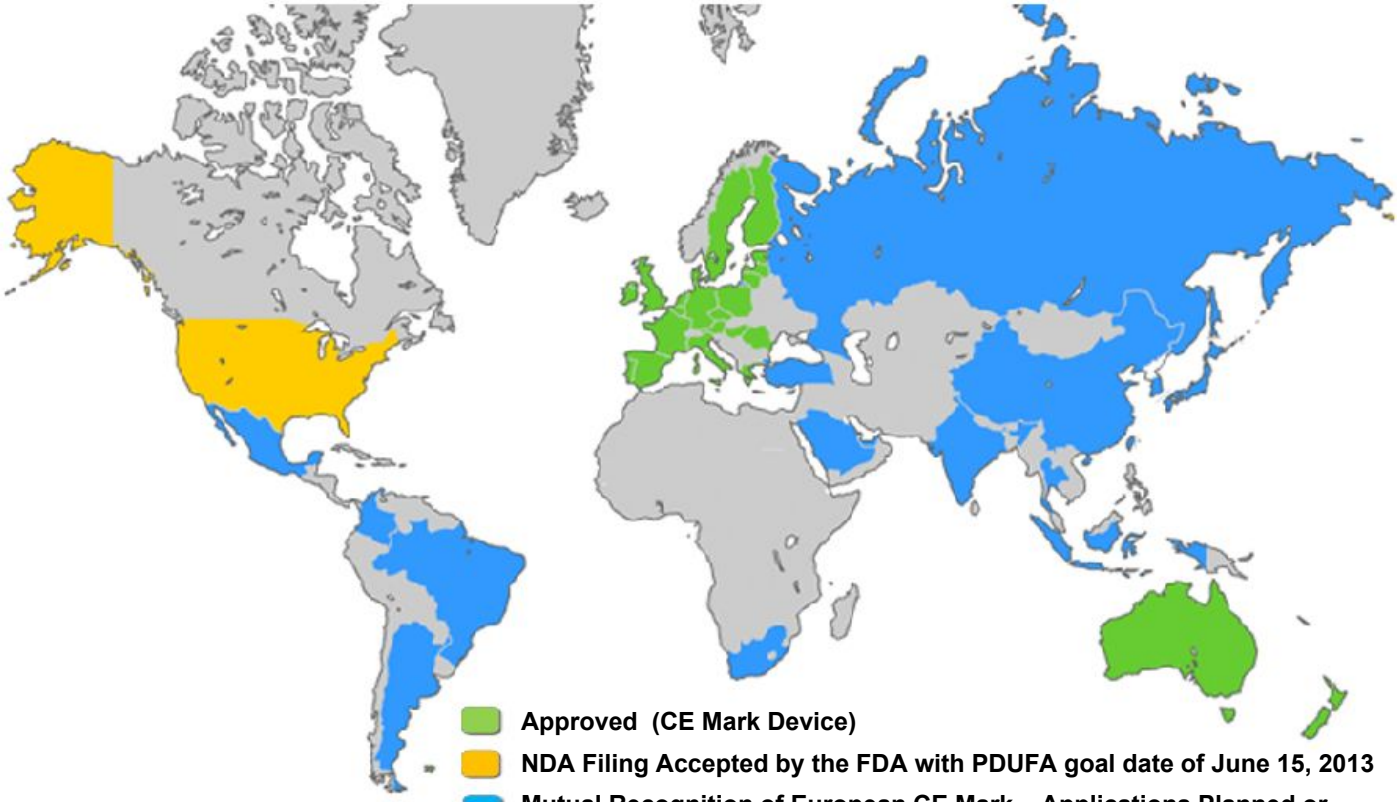


Sources: LEK Consulting, GLOBOCAN, Company estimates.
EU: Initial target countries of Germany, UK, Italy, France, Spain, Netherlands, Ireland.
APAC: Initial target countries of China, Japan, S. Korea, Taiwan, Australia.
Assumes 2.5 treatments per patient.
Assumes EU ASP of $15K; US ASP of $25K; APAC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

* Assumes FDA approval for ocular melanoma metastatic to the liver

$2.3 Billion Initial Market Opportunity with Pharmaceutical-Like Gross Margins

Global Commercialization Status



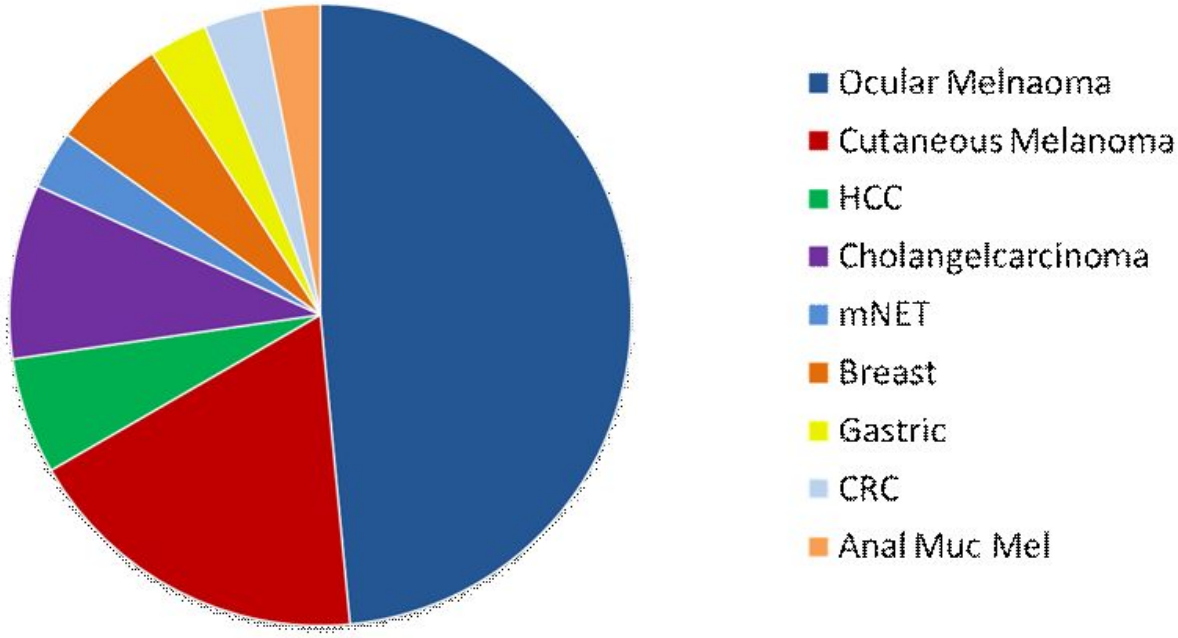
Addressing A Multi-Billion Dollar Global Market

CHEMOSAT: EU Launch Underway

- Marketing in target EU countries - Italy, Germany, France, UK, Ireland, NL, Spain
- Training completed in key centers
  - Eight EU Clinical Sites activated in 2012
- EU clinicians using CHEMOSAT for a broad range of liver metastases
  - Use includes: cutaneous melanoma, ocular melanoma, colorectal cancer (CRC), gastric cancer, breast cancer, neuroendocrine tumor (NET), hepatocellular carcinoma (HCC) and Cholangiocarcinoma
- EU reimbursement in progress
  - Italy – Existing DRG for partial reimbursement identified; supplemental reimbursement applications submitted
  - Germany – Value 4 NUB interim reimbursement granted February 2013
  - UK – Reimbursement anticipated Q2 2013

Expansion of EU Clinical and Commercial Footprint Expected in 2013

CHEMOSAT: Multiple Tumor Types Treated in Europe



- Physicians are recognizing the potential of CHEMOSAT in various tumor types
- CHEMOSAT utilized in Germany, Italy, UK, France, Ireland
- EU Registry To Be Initiated Q2

U.S. NDA Under Review

- Oncology Drug Advisory Committee (ODAC) panel scheduled for May 2, 2013
- PDUFA date: June 15, 2013
- Initial indication: unresectable metastatic ocular melanoma in the liver
  - Provides lowest risk pathway to FDA approval and fastest access
- 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
- Three meetings scheduled with FDA to discuss clinical programs for planned label expansions in each of NET, HCC,CRC

FDA Decision Expected in June

U.S. Commercialization Strategy

- Launch in Q4 2013 assuming approval on PDUFA date of June 15, 2013
- Initial commercial focus on centers that are active in the EAP or participated in the Phase 3 clinical trial
- Utilize active EAP hospitals as Centers of Excellence for training and support of new centers
- Intend to seek specific CPT reimbursement code for the Melblez Kit procedure, based upon value proposition relative to other cancer therapies
- Educate Medical Oncologists via Medical Science Liaison (MSL)
- Direct strategy to sell to hospital based Interventional Radiologists and Surgeons

Participating EAP Centers Provide Immediate Commercial Footprint

Barriers to Entry

- **Patent Protection**
  - 6 U.S. patents in force and 6 U.S. patent applications pending
  - 9 foreign patents in force (with patent validity in 25 countries) and 14 foreign patent applications pending
  - Primary US 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 proprietary 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

Financial Summary

Cash & Cash Equivalents:	**$23.7 million at December 31, 2012 (unaudited)**
ATM Program	**$21.5 million remaining as of December 31, 2012**
Committed Equity Financing Facility (CEFF)	**Up to $32.8 million as of December 31, 2012**
Working Capital Line of Credit:	**$20 million credit facility**
Debt:	**None**
Cash Spend:	**Approx. $10 million in 4Q 2012 (unaudited)** **Projected 2013 quarterly cash spend $9-$12 million**
Shares Outstanding:	**76.8 million (87.2 million fully diluted[1]) as of December 31, 2012**

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

Multiple Capital Resources Available to Execute Plan

Management: A Track Record of Success

Executive	Title	Prior Affiliation(s)	Years of Experience
Eamonn Hobbs	President and CEO	AngioDynamics, E-Z-EM	32
Graham Miao, Ph.D.	EVP & CFO	D&B, Pagoda Pharma, Schering-Plough, Pharmacia, JP Morgan	23
Krishna Kandarpa, M.D., Ph.D.	CSO and EVP, R&D	Harvard, MIT(HST), Cornell, UMass	33
Agustin Gago	EVP, Global Sales	AngioDynamics, E-Z-EM	31
Jennifer Simpson, Ph.D.	EVP, Global Marketing	Eli Lilly (ImClone), Johnson & Johnson (Ortho Biotech)	23
Peter Graham, J.D.	EVP, General Counsel & Global Human Resources	Bracco, E-Z-EM	18
David McDonald	EVP, Business Development	AngioDynamics, RBC Capital Markets	30
John Purpura	EVP, Regulatory Affairs & Quality Assurance	E-Z-EM, Sanofi-Aventis	29
Harold Mapes	EVP, Global Operations	AngioDynamics, Mallinckrodt	27
Gloria Lee, M.D., PH.D.	EVP, Clinical & Medical Affairs	Hoffmann-La Roche, Syndax Pharmaceuticals, Inc.	21
Bill Appling	SVP Medical Device R&D	AngioDynamics	27
Dan Johnston, Ph.D.	VP, Pharmaceutical R&D	Pfizer, Wyeth	12

2012 Accomplishments

- First patients treated with CHEMOSAT Melphalan in Europe in January
- Obtained CE Mark for Gen 2 CHEMOSAT Melphalan filter in April
- Executed contract for MSL services in EU in 1Q 2012 (Quintiles was selected to support EU launch of CHEMOSAT)
- Secured agreements with 14 leading cancer centers in EU
- 8 EU Clinical Sites Activated for commercial use
- US NDA submitted in August 2012
- US NDA accepted with PDUFA date of June 15, 2013
- Obtained CE Mark for CHEMOSAT Doxorubicin in October
- Interim reimbursement established in Italy in December

Considerable Achievements Built the Foundation For Commercial Success

2013 Anticipated Milestones

- ✓ First patient enrolled in EAP - Q1 2013
- ✓ Obtained NUB Value 4 interim reimbursement in Germany – Q12013
- Obtain interim reimbursement in UK – Q2 2013
- Submission for publications of Phase 3 data and mNET arm of Phase 2 data in Q1 2013
- Initiate EU Registry - Q1 2013
- ODAC Panel Meeting May 2, 2013
- Receive NDA approval for Melblez Kit by PDUFA date of June 15, 2013
- First commercial sale in APLA – Q2 2013
- Commence Company's first investigator initiated trial (IIT) – Q2 2013
- First patient enrolled in Company sponsored trial (CST) to expand indications – Q4 2013
- US commercial launch of Melblez Kit – Q4 2013
- First patient enrolled in Taiwan HCC pivotal trial – Q4 2013
- Execute strategic partnership for China

A Busy Year Focused on US Approval, Clinical Data and Commercial Adoption

A Compelling Investment Opportunity

- Commercial stage company focused on oncology
- Proprietary CHEMOSAT Hepatic Delivery System allows unique whole organ therapy for the liver
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- Addressing large unmet market need for cancer patients who usually die of liver failure
- Estimated initial market opportunity of ~$2.3 billion in U.S. & EU
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- On the cusp of realizing the potential:
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  - U.S. - NDA under review; ODAC May 2, PDUFA date June 15, 2013
- Attractive financial model, multiple capital resources available and experienced management team to execute plan

Concentrating the Power of Chemotherapy

Concentrating the Power of Chemotherapy™

Appendices

Appendix 1

LIVER CANCER TREATMENT OPTIONS

The Problem

- Metastatic disease to the liver, brain or lungs is often the life-limiting location of solid tumors
  - Often life-limiting or leads to withdrawal of systemic treatments in favor of palliative care
- Effective treatment for patients with liver-limited or dominant cancers remains a clinical challenge
  - Can be diffuse
  - Often not responsive to chemotherapy and radiation therapy
- Whole organ therapy creates a new option for patients in the management of liver dominant disease

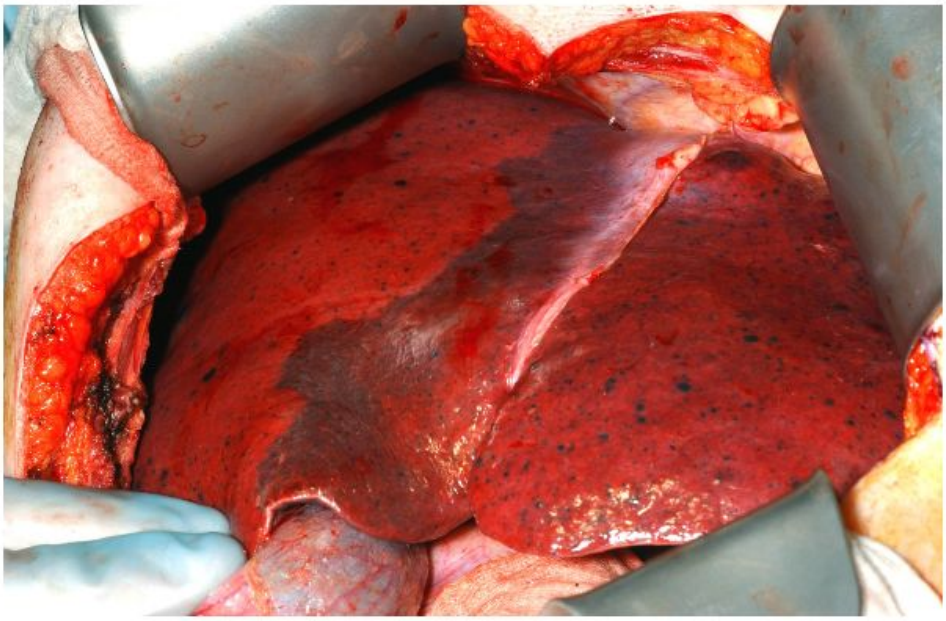
Existing Liver Cancer Treatments Have Significant Limitations

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 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

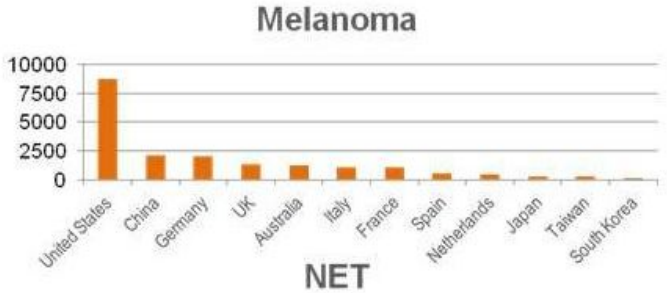
- Our proprietary CHEMOSAT System isolates the liver circulation, delivers an ultra-high concentration of chemotherapy (melphalan) to the liver and filters most of the chemotherapy out of the blood prior to returning it to the patient
- The procedure typically takes approximately two hours to complete 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

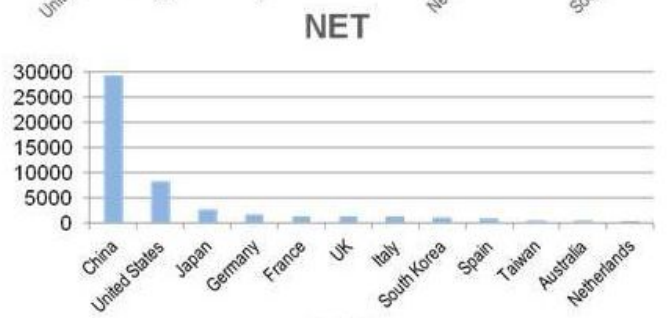
Concentrating the Power of Chemotherapy for Disease Control in the Liver

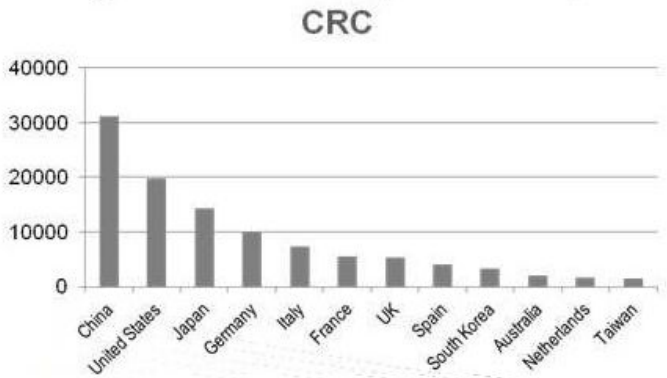
Appendix 2

MARKET OPPORTUNITY BY DISEASE & TARGET COUNTRIES

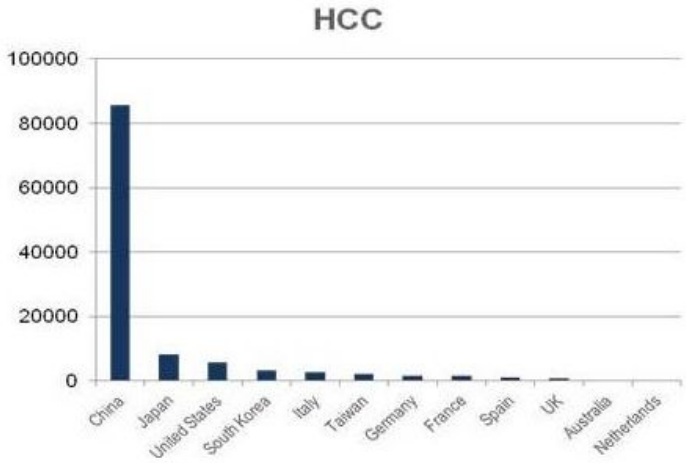
Market Opportunity by Disease (patients)







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



Market Opportunity defined as Total Potential Market (TPM) for Melblez Kit/CHEMOSAT

1. Primary cancer incidence
2. Adjusted for predominant disease in the liver (primary or metastatic cancer)
3. Adjusted for addressable patients via Melblez Kit/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
CRC	19,861	49,653	$ 1,241
HCC (Primary)	5,586	13,964	$ 349
NET	8,212	20,530	$ 513
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 3

HIGH-DOSE MELPHALAN HISTORY AND RATIONALE

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 Dosing & Background

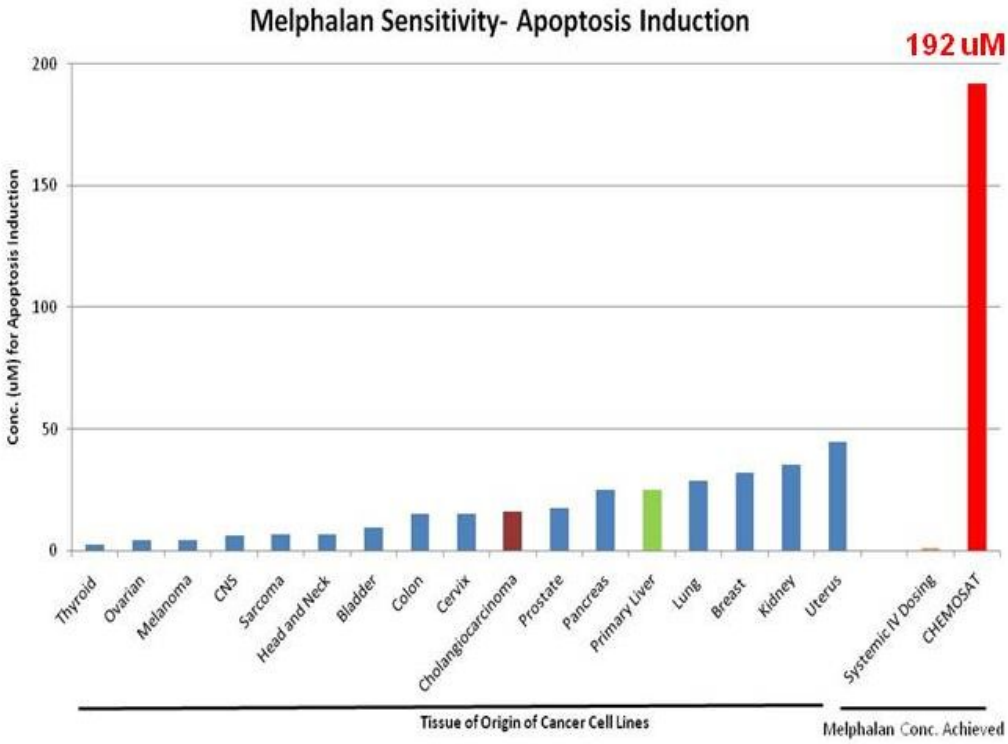
Type	Dosing (mg/kg)
Multiple Myeloma (label)	0.25
Chemoembolization	0.62
Surgical Isolated Hepatic Perfusion (IHP)	1.50
Myeloablation	2.50-3.50
Percutaneous Hepatic Perfusion (**PHP)**	**3.00**

- Well understood, dose dependent, 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

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 Our Technology Will Be Effective On a Wide Range of Solid Tumors

Appendix 4

PHASE 3 TRIAL

Phase III Clinical Trial Design

Randomized to PHP
93 patients: ocular or cutaneous melanoma

PHP = Meblez Kit/CHEMOSAT

PHP/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

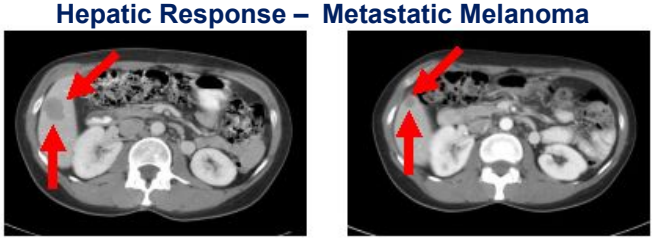
Secondary Trial Endpoints

- **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-PHP (Baseline) **Post-PHP (22+ Months)**

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

Positive Phase 3 Results

- Primary endpoint (hPFS by IRC) exceeded, p value = 0.0029, hazard ratio of 0.50 as of June, 2012
  - PHP median hepatic progression free survival (hPFS) was 4-fold of control, or 5.3 months improvement
  - 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 PHP
  - Median OS 10.6 months vs. 10.0 months for 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 PHP had a median survival of 4.1 months
  - 6 PHP-treated and 2 BAC-only patients still alive as of 2/2013
- 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

Appendix 5

PUBLISHED PHASE 1 / 2 STUDIES OF DOXORUBICIN WITH PHP

Phase 1 & 2 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 6

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, New Zealand, 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	• Orphan Drug - Ocular Melanoma liver mets • Proprietary drug-melphalan & Melblez Kit	• mNET, mCRC and HCC indications	• Proprietary drug/delivery system for additional drugs • Proprietary drug/delivery system for other organs (lung and brain)

Development Aligned to Address Significant Market Opportunity

CHEMOSAT Delivery 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 for multiple tumor types
- 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 Delivery System for Doxorubicin in Asia Phase III *2L* HCC trials

Addressing the Large HCC Market Opportunity in China

Appendix 7

NON US/EU REGULATORY UPDATE

International Strategy beyond EU and US

- Leverage CE Mark to obtain reciprocal regulatory approvals for CHEMOSAT Systems in other international markets
  - Obtained approval for Gen 2 CHEMOSAT Delivery System for Melphalan in Australia
- International regulatory submissions status:
  - Application submitted and expected approvals in
    - Hong Kong - 2013
    - 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

Appendix 8

CHEMOSAT CENTERS

CHEMOSAT Centers 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 (St Andre)**
  - **Galway, Ireland – University Hospital Galway (UHG)**
  - Leiden, The Netherlands – Leiden University Medical Center
  - **Southampton, United Kingdom – Southampton University Hospital (SUH)**
  - **Göttingen, Germany - University Medical Center Göttingen (UMG)**
  - **Varese, Italy – Varese University Hospital (VUH)**
  - Heidelberg, Germany - National Center Tumor Diseases
- Training completed and patients treated at IEO, JWG, IGR, St Andre, UHG, SUH, UMG, VUH
  - Liver metastases from cutaneous melanoma, ocular melanoma, gastric cancer, breast cancer, neuroendocrine tumor (NET), hepatocellular carcinoma (HCC) and Cholangiocarcinoma