

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

FORM 8-K

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

Date of report (Date of earliest event reported): **June 8, 2010**

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16133
(Commission File Number)

06-1245881
(IRS Employer
Identification Number)

810 Seventh Avenue, Suite 3505, New York, New York, 10019
(Address of principal executive offices, including zip code)

(212) 489-2100
(Registrant's telephone number, including area code)

NONE
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01. Regulation FD Disclosure.

On June 8, 2010, Eamonn Hobbs, chief executive officer, made a presentation at the Jefferies 2010 Global Life Sciences Conference in New York City. A copy of the slides that accompanied the presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The information disclosed under this Item 7.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits.

The following exhibit is filed herewith:

(d) Exhibits.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DELCATH SYSTEMS, INC.

Dated: June 8, 2010

By: /s/ David McDonald
Name: David A. McDonald
Title: Chief Financial Officer

EXHIBIT INDEX

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Investor Presentation

June 2010

NASDAQ: DCTH

Forward-looking Statements

This presentation contains forward-looking statements, within the meaning of federal securities laws, related to future events and future financial performance. Many of these statements involve known and unknown risks and uncertainties, which could cause actual results to differ materially from expected results, performance or achievements expressed or implied by statements made herein. These risks are described in the prospectus supplement, the accompanying prospectus, and the other documents incorporated by reference therein that Delcath files with the Securities and Exchange Commission including the 2009 Annual Report on Form 10-K and in Delcath's Quarterly Reports on Form 10-Q. All of Delcath's plans and objectives made in this presentation are based upon management's current expectations, but many such expectations are based upon economic, clinical and regulatory uncertainties, and thus, may differ materially from actual results.

Company Highlights

- § The Delcath Chemosaturation System (PHP) is a proprietary system delivering ultra-high chemotherapy doses to the liver with manageable systemic toxicities
- § Minimally invasive approach to targeted, regional cancer therapy that combines an existing drug and straightforward delivery system
- § **Successful Phase III** trial results reported
- § FDA submission process underway
- § **Platform technology** with potential use in a range of organs for both cancer and infectious disease, including HCV and HBV
- § Large, unmet market opportunity: 2.6 million liver cancer patients worldwide
- § Issued patents, orphan drug designations present competitive advantages
- § Deep and experienced management team

Establishing a New Paradigm in Cancer Therapy

Deep and Experienced Management Team

| Executive | Title | Prior Affiliation(s) | Years of Experience |
|-------------------------------|---|--|----------------------------|
| Eamonn Hobbs | President and CEO | AngioDynamics, E-Z-EM | 29 |
| David McDonald | CFO | AngioDynamics, RBC Capital Markets | 27 |
| Krishna Kandarpa, M.D., Ph.D. | CMO and EVP, R&D | Harvard, MIT, Cornell, UMass | 36 |
| Agustin Gago | EVP, Global Sales & Marketing | AngioDynamics, E-Z-EM | 28 |
| Peter Graham | EVP & General Counsel | Bracco, E-Z-EM | 15 |
| John Purpura | EVP, Regulatory Affairs & Quality Assurance | E-Z-EM, Sanofi-Aventis | 26 |
| Jason Rifkin, J.D. | SVP, Clinical Affairs | Fox Rothschild | 7 |
| Michael Dellario | VP, Global Marketing | AngioDynamics, E-Z-EM, Early Stage Marketing Consultant | 32 |
| Armand Frigon | VP, Operations | Sterigenics, Covidien, BARD | 36 |
| Barbra Keck | VP, Controller | Deloitte & Touche | 8 |

Significant Combination Product Approval and Commercialization Experience

Recent Accomplishments

- § Built new leadership team with in-depth drug and device product and commercialization experience
- § Established manufacturing facility
- § Reported successful Phase III Trial results
- § Increased enrollment momentum in separate Phase II clinical trial
- § Improved visibility in medical community
- § Raised over \$35 million in equity capital
- § Positioned for 2011 commercialization

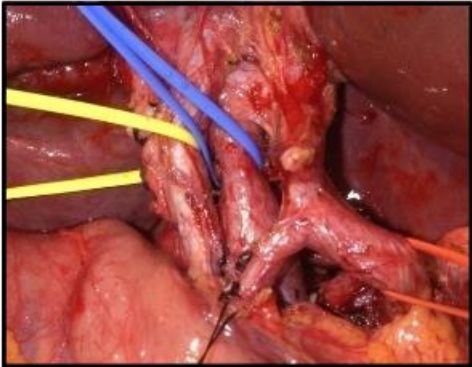
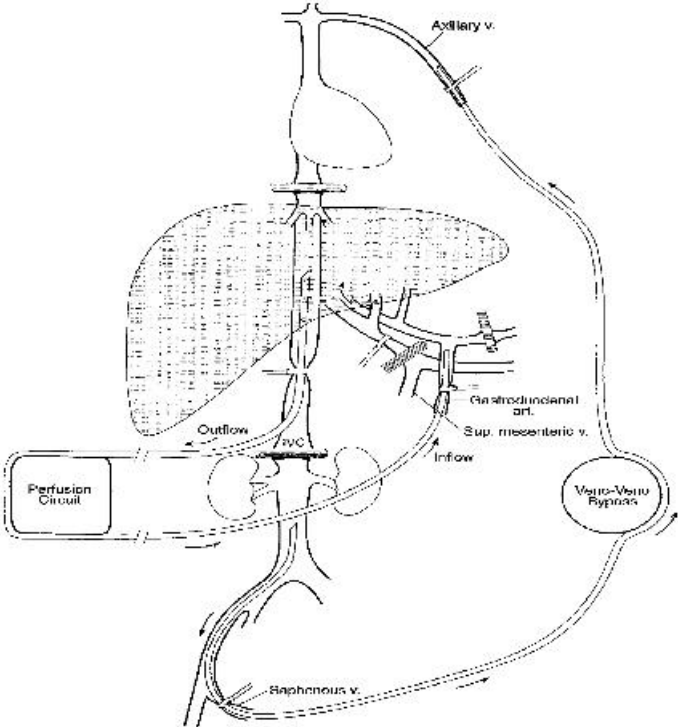
The New Delcath: Executing a Sustainable Growth Strategy

Spectrum of Liver Cancer Treatments

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

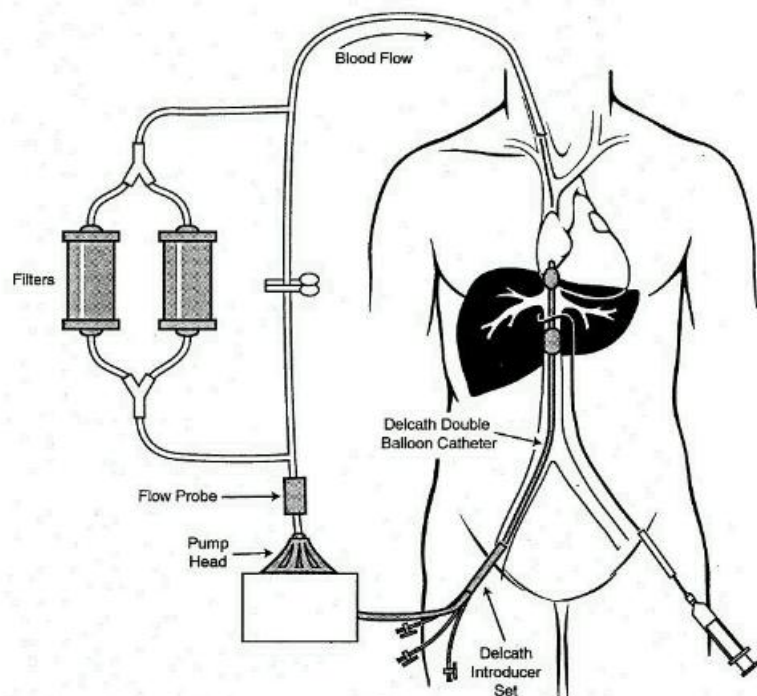
Existing Treatments Involves Significant Limitations

Open Surgical IHP



IHP: Proof of Concept, but High Morbidity and Non-Repeatable

The Delcath Chemosaturation System™



Note: Image not to scale.

Advantages of Chemosaturation

§ ISOLATION

§ Treats entire liver

§ SATURATION

§ Allows for ~ 100x effective dose escalation of drug agents at tumor site

§ FILTRATION

§ Controls systemic toxicities

Converts Traumatic Open Surgery to Minimally Invasive, Repeatable Procedure

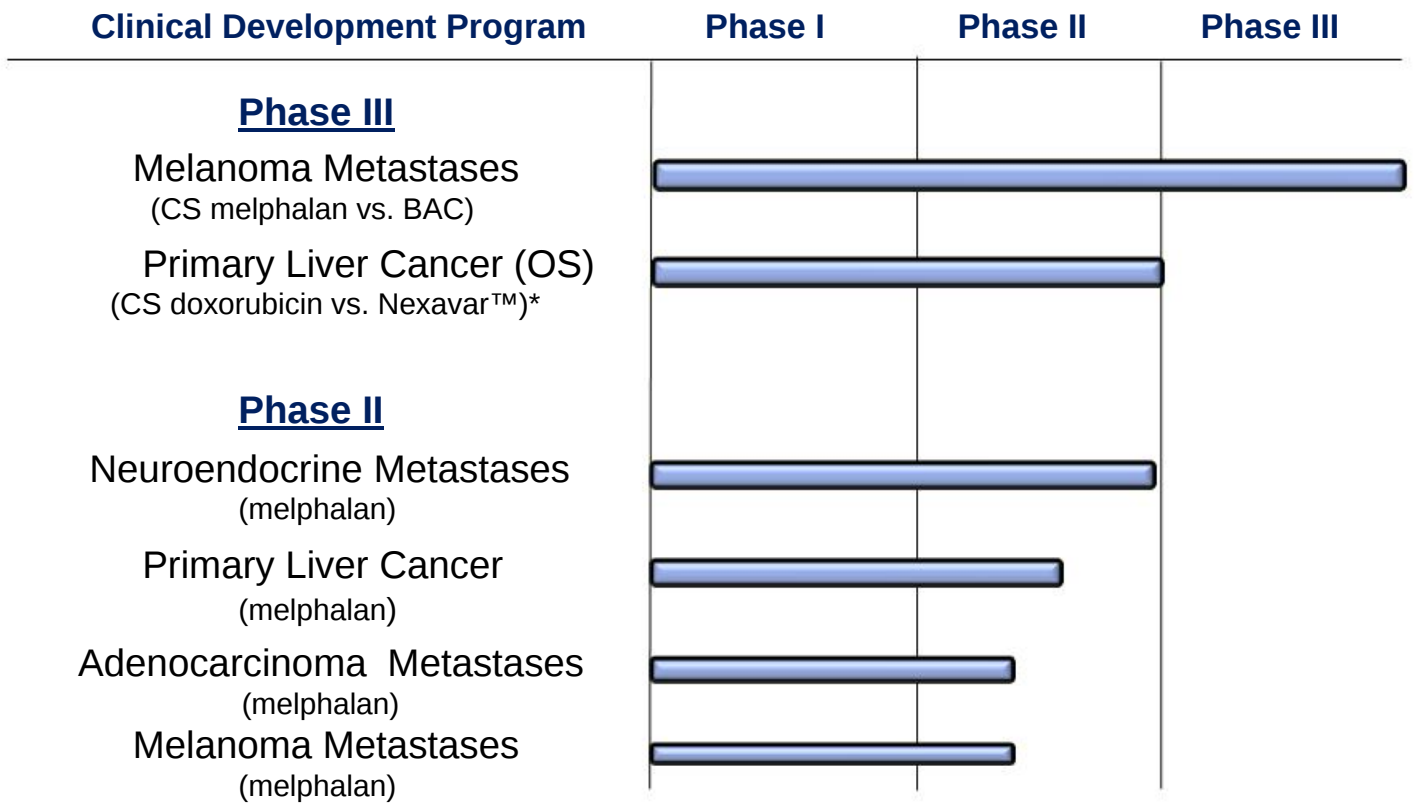
Melphalan

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

- § Well understood, dose dependant, tumor preferential, alkylating cytotoxic agent that demonstrates no hepatic toxicity
- § Manageable systemic toxicities associated with Neutropenia and Cytopenia
- § Drug dosing over **10x higher** than FDA-approved dose via systemic IV chemotherapy
- § Dose delivered to tumor is approx. **100x higher** than that of systemic IV chemotherapy

The Drug of Choice in Liver Cancer Therapy

Currently Approved Clinical Trials



* Approved under prior IDE, but inactive.

Phase I Trial - Proof of Concept (2005)

Phase I Ocular Melanoma Patients

§ 11 evaluable patients

| Response | Number (n) | Percent (%) | Duration (months) |
|--------------------------------|------------|--------------|----------------------|
| Progressive Disease | 2 | 18.2% | |
| Stable Disease | 3 | 27.3 | 14+, 9, 7 |
| Partial Response | 4 | 36.4 | 17, 15, 7+, 7 |
| Complete Response | 2 | 18.2 | 12, 11 |
| Objective Response Rate | 6 | 54.5% | |
| Overall Clinical Benefit | 9 | 81.8 | |

Safety data - Phase I Trial (all patients)

§ Maximum Dose - 3.5 mg/kg

- Grade IV toxicities observed

§ **Optimal Dose - 3.0 mg/kg**

- Manageable hematological toxicities - Neutropenia & Cytopenia

Tolerability Data

§ **Side effect profile approximates standard melphalan (0.25 mg/kg)**

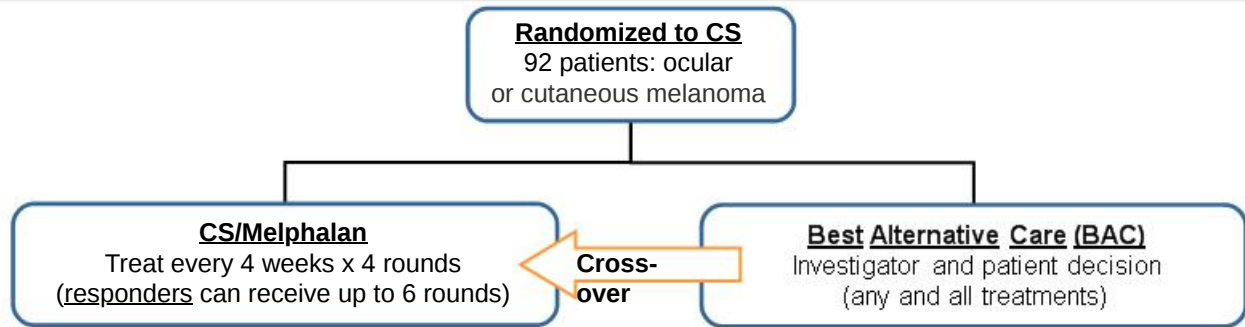
Encouraging Early Clinical Data

Phase III Clinical Trial Highlights

- § NCI-led pivotal study
- § Granted Fast Track review designation
- § **Special Protocol Assessment (SPA)** with FDA to support NDA (505(b)(2)) regulatory pathway (**SPA reviewed and validated by outside counsel**)
- § Randomized, 92 patient multi-center trial (93 enrolled)
- § Top line data released April 21, 2010
- § Complete trial investigators data set presented at ASCO on June 5, 2010 (**blinded independent core lab top line data released April 21, 2010**)

93-Patient Randomized, Non-blinded, Multi-center, NCI-Led Study

Phase III Clinical Trial Design



Primary Trial Endpoint

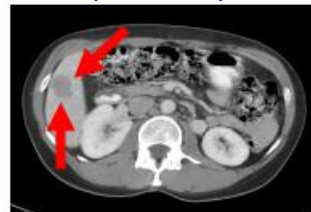
- § Statistically significant difference in Hepatic Progression Free Survival ("hPFS"): $p < 0.05$
- § Over 80% of Oncologic drugs approved by FDA 2005 - 2007 on endpoints other than overall survival*

Modeled hPFS for Trial Success:

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

Secondary Trial Endpoints

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



Pre-CS (Baseline)



Post-CS (22+ Months)

Fully Powered with Well-defined and FDA Accepted Endpoints

Phase III Clinical Trial Results (ASCO)

- § Trial results **exceed primary endpoint expectations**; p value = 0.001
- § Treatment arm shows **5x** median hPFS compared to control arm
- § CS/PHP median hPFS of 245 days compared to 49 days for BAC
- § **Hazard Ratio = .301**
- § **Patients failed prior therapies (radiation, chemo, immuno, image guided local)**
- § 90% Ocular, 10% Cutaneous - **No difference in response**
- § **Overall PFS 186 vs. 46 days for BAC**
- § **34% response rate** for CS/PHP compared to 2% for BAC
- § **52% stable disease** for CS/PHP compared to 27% for BAC
- § **86% overall clinical benefit (CR + PR + SD)**

We are pleased with the Trial Results

Phase III Clinical Trial Results (ASCO)

- § **Majority of BAC patients crossed over and obtained similar response from treatment**
- § **OS Secondary endpoint - No difference (due to cross over treatment response)**
- § **OS cohort analysis - all positive trends**
 - § Median survival of 298 days for treatment arm compared to 124 in non-crossover BAC patients
 - § Median survival of 398 days for BAC Cross Over patients vs. 124 non-crossover BAC patients
- § **Safety profile as expected** - in line with current FDA approved labeling for IV administration of Melphalan and Phase I CS/PHP study results
 - § Treatment related Deaths:
 - § 3/40 patients (7.5%) 3/116 procedures (2.6%)
 - § Neutropenic Sepsis (n=2) 5%, Hepatic Failure (n=1) 2.5% (95% tumor burden)
 - § Current approved labeling for Melphalan - 3% to 10% mortality rate.
 - § Instituting REMS (Risk Evaluation & Mitigation Strategy) to address proper management associated with safe use.

We are very pleased with the Trial Results

Phase III Trial Review

- § **Conducted under valid SPA**
- § **PFS primary endpoint often used for FDA approval* (OS used < 20%)**
- § **Primary endpoint exceeded**
- § **Secondary endpoints supports results**
- § **OS cohort analysis - favorable**
- § **Safety profile - expected and in accordance with currently approved labeling for melphalan**

**"Review of Oncology and Hematology Drug Product Approvals at the US Food and Drug Administration Between July 2005 and December 2007", Sridhara, Johnson, Justice, Keegan, Chakravarty, Pazdur; Journal of the National Cancer Institute; January 29, 2010

Very Successful Trial

Phase III Trial “Questions”

- § Do we have a valid SPA?
 - § FDA letter dated February 9, 2006 - SPA deemed acceptable
 - § SPA reviewed and deemed valid in written opinion of outside, independent counsel
- § “No statistically significant overall survival benefit demonstrated”?
 - § Trial design required by FDA provided for OS secondary endpoint with a cross over provision which yielded expected results
 - § SAP calls for analysis of OS trends in patient cohorts - all positive
- § Is hPFS as a primary endpoint enough for potential FDA approval?
 - § YES - PFS primary endpoint very often used for FDA approval*
 - § SPA requires hPFS as the primary endpoint
 - § YES

Phase III trial achieved all of its pre-determined goals

Phase III Trial “Questions”

- § Primary endpoint exceeded?
 - § YES
- § Secondary endpoints supportive?
 - § YES
- § Safety profile?
 - § Expected and in accordance with currently approved melphalan
- § What indication will FDA potentially approve?
 - § March 9th Pre-NDA meeting with FDA - Phase III and other data presented and deemed acceptable by FDA for NDA application for the indication “Treatment of metastatic melanoma to the liver, ocular or cutaneous”
 - § No treatment result differences between ocular and cutaneous.
 - § No requirement under SPA for enrollment minimum of either ocular or cutaneous melanoma.

Phase III trial achieved all of its pre-determined goals

Leading Clinical Sites & Investigators

National Cancer Institute (Bethesda, MD) — Marybeth S. Hughes, M.D., FACS

University of Pittsburgh Medical Center (Pittsburgh, PA) — James F. Pingpank, Jr., M.D., FACS

University of Maryland Medical Center (Baltimore, MD) — H. Richard Alexander, Jr., M.D., FACS

Moffitt Cancer Center (Tampa, FL) — Jonathan S. Zager, M.D., FACS

§ **John Wayne Cancer Institute (Santa Monica, CA)** — Mark Faries, M.D., FACS

§ **University of Texas Medical Branch (Galveston, TX)** — Orhan S. Ozkan, M.D.

§ **Swedish Medical Center (Denver, CO)** — Charles Nutting, D.O., FSIR

§ **St. Luke's Cancer Center (Bethlehem, PA)** — Sanjiv S. Agarwala, M.D.

§ **Albany Medical Center (Albany, NY)** — Gary P. Siskin, M.D., FSIR

§ **Morristown Memorial Hospital (Morristown, NJ)** — Eric D. Whitman, M.D., FACS

10-Center Trial Run by Leading Cancer Surgeons and Medical Oncologists

Phase I/II NCI Trials - Neuroendocrine

Neuroendocrine Tumor Trial Results (n=23)*

| | Number (n) |
|--|------------|
| Primary Tumor Histology | |
| Carcinoid | 3 |
| Pancreatic Islet Cell | 17 |
| Response | |
| Not Evaluable (Toxicity, Incomplete Treatment, Orthotopic Liver Transplantation) | 4 |
| Progressive Disease | 1 |
| Minor Response / Stable Disease | 3 |
| Partial Response (30.0% - 99.0% Tumor Reduction) | 13 |
| Complete Response (No Evidence of Disease) | 2 |
| Objective Tumor Response | 15 |
| <i>Objective Tumor Response Rate</i> | <i>79%</i> |
| Duration (months) | |
| Median Hepatic PFS | 39 |
| Overall Survival After CS | 40 |



Pre-CS
(Baseline)

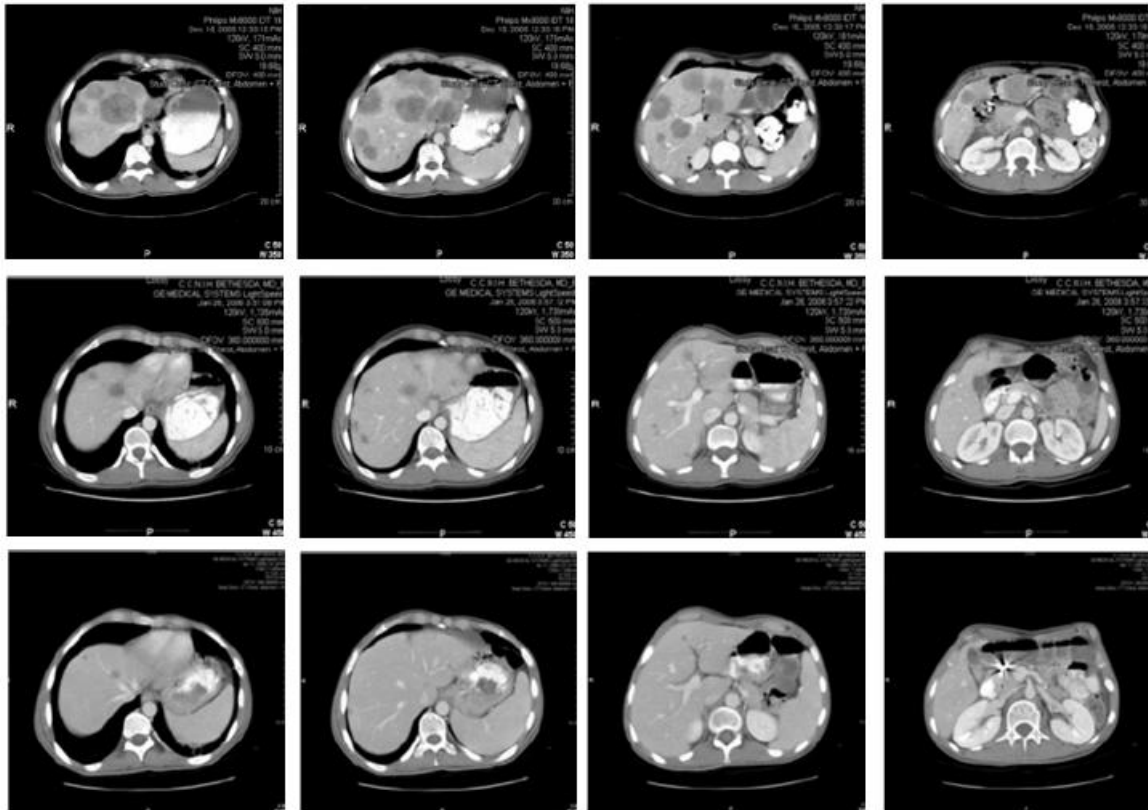
Post-CS #1
(+6 Weeks)

Post-CS #2
(+4 Months)

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

Promising Response Rate in Potentially Large Market

Phase I/II NCI Trials - Neuroendocrine



**Pre-CS
(Baseline)**

**Post-CS
Treatment #1
(+6 Weeks)**

**Post-CS
Treatment #2
(+4 Months)**

Intellectual Property

Patent Protection

- § 7 issued U.S. patents, 9 foreign counterparts granted and 5 pending
- § Primary device patent set to expire August 2016
- § Portfolio protection extends through 2023
- § Post FDA approval up to 5 years of patent extension available

FDA Protection

- § Orphan Drug Designation granted for melphalan in the treatment of ocular melanoma, cutaneous melanoma and metastatic neuroendocrine tumors, as well as for doxorubicin in the treatment of HCC
- § Additional Orphan Drug applications to be filed for other drugs and indications, including HCC and CRC

Multiple Levels of Protection

Initial U.S. Liver Cancer Market Potential

| Disease | U.S. Incidence | Predominant Liver Mets | Potential Market* |
|--------------------------|----------------|------------------------|-------------------------|
| Cutaneous Melanoma | 68,720 | 20% | \$ 687,200,000 |
| Ocular Melanoma | 2,350 | 75% | 88,125,000 |
| Hepatocellular Carcinoma | 22,620 | NA | 1,131,000,000 |
| Neuroendocrine | 19,872 | 50% | 496,800,000 |
| Colorectal | 146,970 | 60% | 4,409,100,000 |
| TOTAL | | | \$ 6,812,225,000 |

- § On label annual market estimated over \$775 Million **in U.S. alone**
- § Less than 10% of global liver cancer cases in U.S.
- § Less than 10% of liver cancer patients qualify for surgery, currently the “gold standard” treatment option,
- § 90% of liver cancer patients have few, if any viable treatment options
- § Majority of all end stage cancer patients die of liver failure

* Assumes 2.5 PHP treatments per patient at an ASP of \$20,000.

\$6.8 Billion Maximum Potential U.S. Market for Above Five Diseases

Commercialization “Questions”

- § **Not an IV or pill...will clinicians embrace CS procedure?**
 - § **Liver cancer patients have typically failed all Medical Oncology treatments and are sent to the Surgeon for management. Surgeons can only resect 10%, so patients currently have few, if any options. Surgeons, Oncologists and Interventional Radiologists have expressed excitement at the prospects of CS as a new procedure for their patients with unresectable liver mets.**
- § **Will clinicians use system “off label”?**
 - § **Although we would never promote off label use, clinicians have stated that they will utilize CS for CR, HCC, NET, patients once it is approved for Melanoma Liver Mets as there are few, if any viable options for those patients**
- § **How will the procedure be reimbursed?**
 - § **Still a work in progress**
 - § **Coverage has been approved by a private payer for compassionate use of CS for sarcoma mets to the liver**

Three-Pronged Business Strategy

Commercialization

- § Gain regulatory approval
 - Goal: receive CE approval by mid 2011
 - Goal: receive FDA approval by mid 2011
- § Build out direct specialty sales force for U.S.
- § Direct and Distribution partners OUS

Pursue Asian Strategic Alliances

- § Invest and develop markets for China, Korea and Japan
- § Chi-Fu Trading Company Ltd. signed 2/9/2010 for Taiwan

Establish U.S. and EU Pharma Alliances

- § Co-develop and fund additional indications for Delcath Chemosaturation System™

Invest In and Develop a World Class Oncology Company

Partnering Opportunities

- § **HCC — survival trial** - CS doxorubicin vs. sorafenib
- § **HCC — survival trial** - CS melphalan vs. sorafenib
- § **Neuroendocrine Liver Mets — hPFS trial** with melphalan
- § **Colorectal Liver Mets — hPFS trial** CS melphalan vs. BAC
- § **Colorectal Liver Mets — hPFS trial** CS irinotecan/oxaliplatin vs. BAC
- § **HCV and HBV** — initiate testing of high dose interferon/anti-virals in Asia
- § **Develop Systems for Other Organs** — lung, brain, pelvis, limbs, others

Strategic Alliances Will Help Drive Development in Additional Indications

Financials

Financial Summary

Financial & Operating Overview

| | |
|-----------------------------------|--|
| § Follow On Offering: | Raised ~ \$35 million in 2009 |
| § Burn Rate: | Approximately \$1.8 million/month |
| § Cash: | ~\$29.6 million at May 31, 2010 |
| § Debt: | None |
| § Shares Out: | 37.3 million (43.9 million fully diluted*) |
| § Institutional Ownership: | ~ 28% at December 31, 2009 |
| § Market Capitalization: | ~ \$580 million as of May 31, 2010 |

Capital Structure Strengthened Significantly in 2009

* Fully diluted includes an additional 3.55 million options at \$4.40, 2.79 million warrants at \$3.53, and 257,910 unvested restricted shares.

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