#### 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 1, 2011

#### **DELCATH SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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

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

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

NONE

(Former name or former address, if changed since last report)

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

[] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 5.07. Submission of Matters to a Vote of Security Holders

Delcath Systems, Inc.'s Annual Meeting of Stockholders was held on May 26, 2011. Set forth below are the final voting results for each of the proposals submitted to a vote of the shareholders.

1. The nominees for election as Class II Directors, each for a three year term, were elected based upon the following vote:

Nominees	Votes For	Withheld Authority	<b>Broker Non-Votes</b>
Eamonn P. Hobbs	11,391,700	2,218,253	23,932,315
Douglas G. Watson	11,816,444	1,793,509	23,932,315

2. The proposal to approve, on an advisory basis, the compensation of our named executive officers ("say-on-pay"), was approved based upon the following votes:

Votes For	Votes Against	Abstentions	<b>Broker Non-Votes</b>
10,701,228	2,655,874	253,053	23,992,313

3. The proposal to determine, on an advisory basis, the frequency of future "say-on-pay" votes received the following votes:

Every 1 Year	Every 2 Years	<b>Every 3 Years</b>	Abstain	<b>Broker Non-Votes</b>
7,458,941	350,619	5,598,487	201,709	23,992,313

4. The proposal to ratify the appointment of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2011 was approved based upon the following votes:

Votes For	Votes Against	Abstentions	Broker Non-Votes
35,614,139	1,943,609	64,520	23,992,313

#### Item 7.01. Regulation FD Disclosure.

A copy of Delcath Systems, Inc.'s shareholder meeting presentation slides that the Company presented at the Annual Meeting of Stockholders held on May 26, 2011 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. Shareholder Meeting 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 1, 2011

By: /s/ Peter Graham

Name:Peter GrahamTitle:Executive Vice President, General Counsel

#### EXHIBIT INDEX

Exhibit No.Description99.1Delcath Systems, Inc. Shareholder Meeting Presentation Slides



Concentrating the Power of Chemotherapy ™

# Shareholder's Meeting May 26, 2011

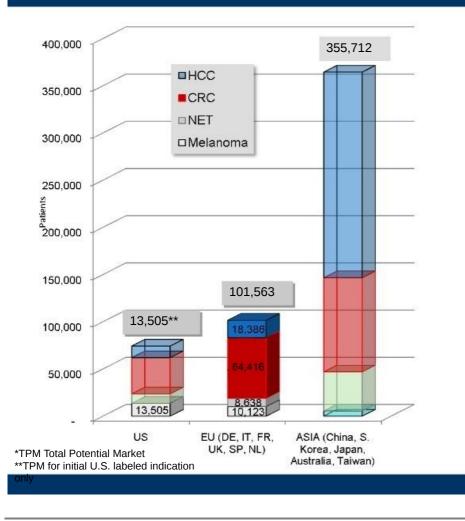
**NASDAQ: DCTH** 

This presentation contains forward-looking statements, within the meaning of federal securities laws, related to future events and future financial performance which include statements about our expectations, beliefs, plans, objectives, intentions, goals, strategies, assumptions and other statements that are not historical facts. Forwardlooking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions, which could cause actual results to differ materially from expected results, performance or achievements expressed or implied by statements made herein. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including; uncertainties relating to the time required to build inventory and establish commercial operations in Europe, adoption, use and resulting sales, if any, for the chemosaturation delivery system in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the system as a treatment for patients with cancer in the liver, availability of melphalan in the EEA, acceptability of the Phase III clinical trial data by the FDA, our ability to address the issues raised in the Refusal to File letter received from the FDA and the timing of our re-submission of our NDA, re-submission and acceptance of the Company's NDA by the FDA, approval of the Company's NDA for the treatment of metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, approval of the current or future chemosaturation system for other indications or the same indication in other foreign markets, actions by the FDA or other foreign regulatory agencies, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, our ability to secure reimbursement for the chemosaturation system, progress of our research and development programs and future clinical trials, uncertainties regarding our ability to obtain financial and other resources for any research, development and commercialization activities, overall economic conditions and other factors described in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K and the Quarterly Reports on Form 10-Q that we file with the Securities and Exchange Commission.

"My wife was a patient at John Wayne Cancer Center under Dr. Mark Faires 2009-2010....out of all the studies and trials that she went through, your treatments were the only ones that actually made a difference for my wife. The tumors in her liver started to shrink.... Your treatments actually made a difference for us, in the sense it was giving us hope, which in the battle of cancer makes a gigantic difference....I believe the treatments your company created have marvelous potential. Even though we have not won the war against cancer, I think that you are winning battles along the way....I know that if it were caught a little sooner, your treatments would have worked even better and possibly helped it from spreading. Thank you for working as hard as you all do and for creating miracles through science.

Jonathan Hawkes Received May 16, 2011

### Large Unmet Clinical Need = Large Commercial Opportunity



CE Mark in EU for delivery of melphalan to the liver permits physician use on a broad range of liver cancers

Potential \$3 Billion EU Labeled Market Opportunity\*

Leverage CE Mark for regulatory approvals in Asia, America's (EX US), MEA, and Australia

Potential \$8 Billion Asia/Australia Market Opportunity\*

Seeking initial indication in US for melanoma mets – \$670 million \*\* market Opportunity, with significant potential label expansion opportunity

### **Accomplishments:**

- § Successful Phase 3 trial results reported
- § Completed Phase 2 neuroendocrine metastases trial arm at NCI
- § Negotiated and Signed long term agreement for U.S. melphalan supply
- § Created Company's first strategic plan
- § Established manufacturing facility and achieved ISO 13485 Certification
- § Increased Company bandwidth by staffing R&D, Clinical, Regulatory, Operations and Commercial teams
- § Expanded Company's IP portfolio through development of new trade secret manufacturing processes and other IP development that we expect will lead to new patent filings
- § Achieved European CE Mark device approval for Delcath Hepatic Delivery System with broad labeling
- § Leveraging CE Mark to obtain reciprocal regulatory approvals in Asia, Ex US Americas, MEA, and Australia
- § Established commercialization plans to address the potential \$3.0 billion European labeled market opportunity

### Significant Progress

### **Challenges:**

- § FDA
  - § Current FDA environment is extremely challenging
  - § Combination products are the most challenging of all (both Drug and Device)
  - § Refusal to File (RTF)
- § Lack of necessary "bandwidth" for a Pharma/Device company
- § DCTH Stock "volatility" and overall market conditions make optimizing financings very challenging
- § Delays in securing strategic partner in China (PRC)

**Significant Challenges** 

### **Accomplishments:**

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### Significant Progress

### Summary of Phase 3 Clinical Trial Results

- § Primary endpoint exceeded, p value = 0.001, hazard ratio of .301
  - § Treatment arm shows 5x median hepatic progression free (hPFS) survival compared to control arm
  - § CS/PHP median hPFS of 245 days compared to 49 days for BAC
  - § 86% overall clinical benefit (CR + PR + SD)
- § Secondary endpoints support results
  - § OS Secondary endpoint No difference in Kaplan-Meier curves due to cross over treatment response (298 days compared to 301 days)
- § OS cohort analysis favorable
  - § Median survival of 298 days for treatment arm compared to 124 in non-crossover BAC patients
  - $\S$  14 treatment patients (6 treatment, 8 crossover) and 3 BAC patients still alive at 12/31/2010
- § Safety profile expected and consistent with currently approved labeling for melphalan
  - § Treatment related Deaths: 3/40 patients (7.5%) 3/116 procedures (2.6%)
  - § Neutropenic Sepsis (n=2) 5%, Hepatic Failure (n=1) 2.5% (95% tumor burden)

Trial Outcomes Favorable and Consistent with Special Protocol Assessment

## Phase 1&2 NCI Trials - Neuroendocrine

#### **Neuroendocrine Tumor Trial Results (n=23)\***

-	mber
(n)	
	3
	17
	4
	1
	3
	13
	2
	15
	<b>79</b> %
Duration	
(months)	39
	40
	(n) Duration



**Pre-CS** (Baseline)

Post-CS #1 (+6 Weeks)



Post-CS #2 (+4 Months)

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

#### **Promising Initial Response Rate in Attractive Market**

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### Significant Progress

**Our Mission:** 

Achieve breakthroughs in regional and targeted therapies for primary and metastatic cancers through the use of proprietary and 3<sup>rd</sup> party drugs and minimally invasive drug delivery systems that improve clinical outcomes while creating increasing returns to our shareholders

### To Achieve Our Mission we will seek to...

- § Expand our pipeline of target indications that have compelling clinical and financial cases and will generate strong IP
- § Conduct the pre-clinical, clinical, and regulatory work necessary to achieve approvals for targeted indications in jurisdictions around the world
- § Manufacture, sell and supply the device system into these markets and market the drug where it makes sense to do so
- § Delcath will pursue this mission both with our own resources and in partnership with others

### **Accomplishments:**

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### Significant Progress

# Manufacturing Facility



### **Accomplishments:**

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### Significant Progress

### **Deep and Experienced Management Team**

Executive	Title	Prior	Years of Experience
Eamonn	President and CEO	Affiliation(s) AngioDynamics,	30
e e e e e e e e e e e e e e e e e e e	CFO	FigibBynamics, RBC Capital	28
McDonald Krishna Kandarpa, M.D.,	CMO and EVP, R&D	Markets Harvard, MIT, Cornell, UMass	37
ନ୍ସିuStin Gago	EVP, Global Sales & Marketing	AngioDynamics, E-Z-EM	29
Peter	EVP & General	Bracco,	16
Graham, J.D. John Purpura	EVP, Regulatory Affairs & Quality Assurance	E-Z-EM Z-	27
Bill Appling	SVP Medical	EMgioDynamics Sahofi- Aventis	25
Bernie Tyrrell	Device S&B N. American Sales & Marketing	Epicept, Otsuka,	33
Dan Johnston, Ph.	VP, Pharma R&D	Astra Prizer, Wyeth Zeneca, Johnson	10
Parold Mapes	EVP Operations	AngioDynamics, Golvidion, Eli Lillly	25

### Significant Combination Product Approval and Commercialization Experience

### **Board of Directors**



Harold Koplewicz, M.D. Chairman Child Mind Institute, NYU



Chair Comp Committee Cortex



Douglas G. Watson Chair - N&G Committee Pittencrieff Glen Assoc



Director OSI Pharmaceuticals

**Significant Additions** 



Laura Philips, PhD Chair Audit Committee WellGen



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### Significant Progress

#### **Patent Protection**

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

#### **Trade Secret Protection**

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

#### **FDA Protection**

- § Orphan Drug Designation granted for melphalan in the treatment of ocular melanoma, cutaneous melanoma and metastatic neuroendocrine tumors, as well as for doxorubicin in the treatment of HCC
  - § Provides 7 years of marketing exclusivity post FDA approval
- § Additional Orphan Drug applications to be filed for other drugs and indications, including melphalan for HCC and CRC

#### Working to Expand Intellectual Property

### **Accomplishments:**

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### Significant Progress

## **Cleared to Market our Device**

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

Large European Market Opportunity Concentrated in Six Countries

### **Accomplishments:**

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### Significant Progress

# Challenges...

### #1 - FDA

- § Overall Climate
- § Combination (both drug & device) product is the most challenging
- § RTF

Goal: Submit NDA by end of year

# Why did we get an RTF?

- § On February 22, 2011, received Refusal to File (RTF) letter from the FDA
  - § Manufacturing plant inspection timing
  - § Product and sterilization validation
  - § Additional statistical analysis clarification
  - § Additional safety data
  - § RTF stated that safety information provided in NDA was insufficient to allow FDA to accept our application and ultimately review the risk/benefit profile of the chemosaturation system
  - § FDA & SPA approved CRF's did not collect all hospitalization data in the patient records in an effective manner
  - § Follow-up meeting with FDA held in April 2011 to review proposed plan of action which includes:
  - § Collection of all available safety information in new CRF for all 186 patients in the Phase I, II and III clinical trials

#### Goal: Resubmit NDA by end of 2011

### #2 - Lack of internal "bandwidth"

Solution:

Recruit top Pharma and Device industry talent

Improved core competencies and expanded organizational infrastructure

### **#3 - Optimized financings**

Volatility of DCTH stock and overall market conditions make optimizing equity financings very challenging

Solution: Continue to explore all financing alternatives including debt

### **#4 - China Strategic Partnership**

- § Strategic partners in China had strong preference for a doxorubicin CHEMOSAT system since melphalan for injection is not yet approved in China (PRC)
- § Reluctant to make significant monetary commitments until compelling HCC data is available
- § De-novo regulatory pathway very uncertain...strong preference to leverage predicate approval, i.e. CE Mark or FDA
- Solution: Intend to revisit discussions with potential partners in China based on leveraging CE Mark and melphalan availability, and continue development of doxorubicin ChemoSAT system

# **Charting a Path Forward**

- **§ EU Commercialization Plans**
- **§** Product Development
  - **§** Generation 2 Product Roll Out and Implications
    - § HE Filter
    - § Improved isolation/aspiration catheters
    - § Improved clinician interface features
  - **§** Additional Clinical Data Development Plans
- § Asia, Ex US Americas, MEA, Australia regulatory approvals (based on CE Mark) and commercial roll out plans
- **§ NDA Resubmission Plans**
- **§ US Commercial Roll Out Plans**

## **2011 European Commercialization**

Establish EU Operations (2011) Train Centers of Excellence and Test Market (2011-2012)

Commercial Launch (2012)

**Objective:** Broad Commercial Adoption

### Major Assumptions:

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

Strategy and Tactics to Address All Key Constituents

## **2011 European Commercialization**

Establish EU Operations (2011) Train Centers of Excellence and Test Market (2011-2012)

Commercial Launch (2012)

#### Tactics & Execution:

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

### Strategy and Tactics to Address All Key Constituents

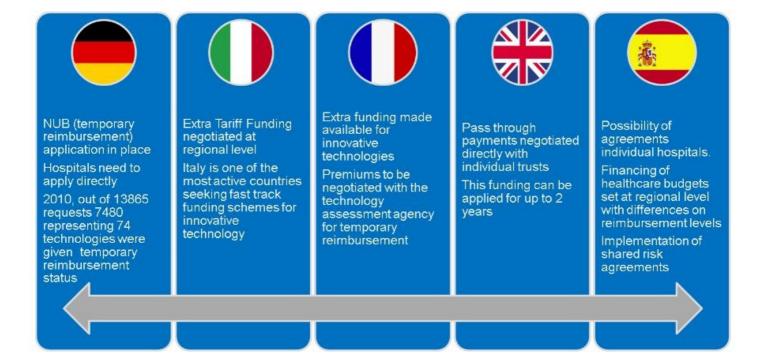
### **European Device Marketing Considerations**

### **Reimbursement:**

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

#### Pathway in Primary EEA Markets

# **Immediate Reimbursement Pathway**



#### **Immediate Pathway in Primary EEA Markets**

### Melphalan:

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

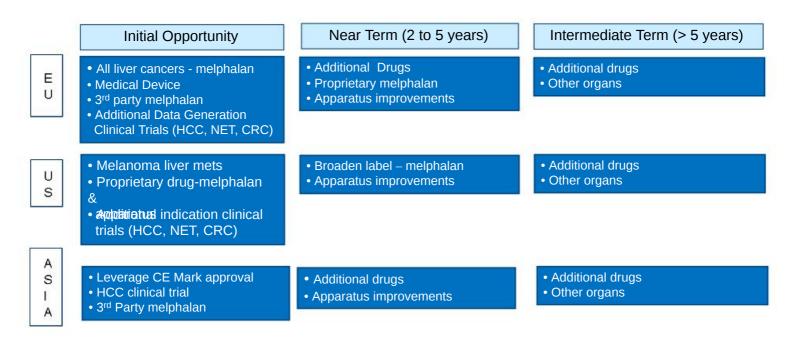
Melphalan is Readily Available to Physicians in the EEA

### **Clinical Data:**

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

**Expand On Our Clinical Data** 

## **Product Development Pipeline**



#### **Robust Development Program**

## High Efficiency (HE) Filter Media Development

### STATUS:

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

### **EXPECTED BENEFITS:**

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

HE Filter Significantly Enhances Procedure and Market Opportunity

# **Gen 2 - HE Hemofiltration Cartridge**





**Dual Filter Housing with Integrated Pole Mount** 

## **Clinical Data Development Goals**

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

## **Anticipated Publication Schedule**

### Phase 3 MEL:

- § Journal submission: Q4 2011 (tied to NDA resubmission safety data)
- § Podium Presentation:
  - § ESMO Stockholm, September 2011
  - § CIRSE Munich, September 2011

### Phase 2 NET:

- § Journal Submission: Q3 2011
- § Podium Presentations
  - § ESMO Stockholm, September 2011
  - § CIRSE Munich, September 2011
  - § IHPBA Adelaide, September 2011

**Leveraging Publications and Presentations** 

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

### **Strategic Partners and Specialty Distributor Model**

- § Initial focus on leading cancer centers and referring community hospitals
- § Market to Medical Oncologists via CSO
- § Direct Strategy to sell to Interventional Radiologists and Surgeons: 12 Sales & Medical Science Liaison territories ultimately expanding to as many as 60 territories as revenues ramp
- § 5 Clinical Specialists initially to support site initiation and training
- § Utilize top centers from Phase III trial as Centers of Excellence for training and support

### **Direct Sales Model in the United States**

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

Physician:

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

Hospital:

- Apply for new ICD-9/10 procedure code to capture full procedure of hepatic isolation and chemosaturation
- § Request new DRG based on costs above those of existing DRGs and clinical dissimilarity to other hepatic procedures in current DRGs

**Pursuing New Specific Codes For Chemosaturation Procedure** 

### **Financial & Operating Overview**

- Follow On Offerings: Raised ~ \$70 million since November 2009
  Burn Rate: Approximately \$2.6 million per month
  Cash: ~ \$39 million at March 31, 2011
  Debt: None
- § Shares Out:

43.1 million (49.8 million fully diluted\*)

### **Capital Structure Strengthened Significantly in 2010**

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

## In conclusion...

- § The last 12 months have seen much progress
- **§** We've faced challenges and are meeting them
- § We're preparing to address a \$3 billion European market opportunity
- § We are initiating efforts to expand clinical data with Gen 2 HE Filter System
- **§** We're committed to building shareholder value