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 12, 2010

DELCATH SYSTEMS, INC.
(Exact Name of Registrant as Specified in Charter)

DELAWARE	001-16133	06-1245881
(State of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

600 FIFTH AVENUE, 23RD FLOOR NEW YORK, NEW YORK	10020
(Address of Principal Executive Offices)	(Zip Code)

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

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:

[ ] Written communication 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.

On March 12, 2010, Delcath Systems, Inc. (the "Company") issued a press release regarding a previously noticed quarterly update conference call held on Friday, March 12, 2010. A taped replay of the conference call is available until March 19, 2010. This replay can be accessed by dialing 800-406-7325 for domestic callers and 303-590-3030 for international callers, both using pass code 4228987#. An archived webcast is available on the Company's website, www.delcath.com.

A copy of the press release dated March 12, 2010 regarding the conference call and the transcript of the conference call are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits. The following exhibits are furnished with this report on Form 8-K:

Exhibit Number	Description of Exhibit
99.1	Press Release of Delcath Systems, Inc. dated March 12, 2010
99.2	Transcript of March 12, 2010 Conference Call

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.

Date: March 16, 2010

DELCATH SYSTEMS, INC.

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

EXHIBIT 99.1

Data Release from Phase III Metastatic Melanoma Trial Still Expected in April
FDA Submission Timeline Remains on Schedule

NEW YORK, March 12 -- Delcath Systems, Inc. (Nasdaq: DCTH), which is testing its proprietary treatment system for primary and metastatic cancers to the liver, today provided an update on recent corporate developments.

Recent Highlights

- Reached sufficient number of events in the Company's Phase III metastatic melanoma trial to allow initiation of data analysis, which is expected to be completed in April;
- During the recent pre-NDA meeting with the FDA, and pursuant to the Company's Fast Track Status, the FDA confirmed the rolling submission filing strategy;
- Signed the first research, distribution, sales and marketing agreement for the Delcath PHP System™ with Chi-Fu Trading Co., Ltd. in Taiwan;
- Allowed by the FDA to initiate an Expanded Use Protocol for patients with ocular and cutaneous melanoma metastatic to the liver;
- Initiated expansion of the Company's Scientific Advisory Board with the appointment of Professor Riccardo Lencioni, founder of the International Liver Cancer Association;
- Significantly strengthened financial position via $32.6 million offering;
- Cash and cash equivalents at February 26, 2010 was approximately $32.5 million;
- The Company sponsored a Symposium on the Delcath PHP System during the Sciety of Surgical Oncology annual meeting in St. Louis, MO, March 3-7, 2010;
- Delcath's PHP System is scheduled to be included in the following presentations in March and April:
  - The Seventh International Symposium on Melanoma and Other Cutaneous Malignancies, New York, New York, March 12-13;
  - The Society of Interventional Radiology 35th Annual Scientific Meeting, Tampa, Florida, March 13-18;
  - The 9th World Congress of the International Hepato-Pancreato-Biliary Association, Buenos Aires, Argentina, April 18-22; and
  - The Second European Conference on Interventional Oncology, Florence, Italy, April 21-24;
  - The AmSECT 48th International Conference, Reno, NV, April 28-May 1

"Since mid-November, our team has focused on executing our strategies to gain regulatory approval to market the Delcath PHP System both in the U.S. and in Europe, expand the potential benefits of the Delcath PHP System to patients worldwide and build increasing returns to our shareholders," said Eamonn P. Hobbs, President & CEO. "Overall, we have made significant progress towards our goals and expect to begin the New Drug Application (NDA) process for FDA approval as soon as practically possible."

"The next operational milestone for our company is the April completion of data analysis from our Phase III trial," said Mr. Hobbs. "The trial's data analysis involves the initial review by the principal clinical investigators at each enrolling center, an additional review by the Company's retained Clinical Research Organization, and a final review of medical images for verification of results conducted by an independent core lab before final statistical results are compiled by an independent biostatistical group. We remain highly confident that the trial's data will meet the trial's primary endpoint, and our confidence was recently further buoyed by the FDA's acknowledgement of an expanded access program," added Mr. Hobbs. "Operationally, we are on track to have an inspectable Quality System at our Queensbury manufacturing fa cility by April, which is a key step in the positioning of the Company for commercialization."

"Our only recent adjustment to our plan has been a revision in our filing schedule to obtain CE Mark in Europe. We recently confirmed that the Delcath PHP System will be treated as a Class III device in Europe, requiring additional validation testing and documentation. We anticipate filing for this approval by the end of the year, or approximately six months later than originally envisioned. Once complete, these data will also be used to complete the CMC module of our rolling NDA submission in the U.S. All other approval timelines are expected to remain on track," said Mr. Hobbs.

"We continue to actively negotiate strategic partnership transactions similar in structure to the agreement recently reached with Chi-Fu Trading Co. for the Taiwan market. Our goal is to execute additional partnerships that will serve both strategic and financial needs. These partnerships will provide distribution and expanded clinical indications in key Asian markets as well as strengthen our capital position. Given that the timing of such agreements is unpredictable,

we will continue to review other financing options to assure that the company maintains flexibility and is adequately capitalized to execute on the opportunities ahead of us as we move toward commercialization," concluded Mr. Hobbs.

About Delcath Systems, Inc.
Delcath Systems, Inc. is a medical technology company specializing in cancer treatment. The Company is testing a proprietary, patented drug delivery system for the treatment of primary and metastatic liver cancers. Delcath's novel drug delivery platform is testing the delivery of ultra-high doses of anti-cancer agents to the liver while controlling the systemic exposure of those agents. In addition to its fully enrolled Phase III metastatic melanoma study, the Company is currently conducting trials to treat other liver cancers. The Company maintains a broad intellectual property portfolio on a worldwide basis including the U.S., Europe, Asia and Canada. For more information, please visit the Company's website at www.delcath.com.

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This news release 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 successfully complete Phase III clinical trials and secure regulatory approval of our current or future drug-delivery system 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. Yo u 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.

Delcath Systems, Inc.
Balance Sheets as of December 31, 2009 and 2008

	December 31, 2009	December 31, 2008
Assets		
Current assets		
Cash and cash equivalents	$ 35,486,319	$ 6,939,233
Investments - certificates of deposit	-	3,847,904
Investments - treasury bills	-	200,710
Prepaid expenses and other assets	799,416	353,346
Total current assets	36,285,735	11,341,193
Property, plant and equipment		
Furniture and fixtures	36,800	23,170
Computers and equipment	78,063	21,030
Leasehold improvements	431,425	-
	546,288	44,200
Less: accumulated depreciation	(24,982)	(26,711)
Property, plant and equipment, net	521,306	17,489
Total assets	$ 36,807,041	$ 11,358,682
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 1,841,480	$ 703,489
Derivative instrument liability	11,207,214	448,318
Total current liabilities	13,048,694	1,151,807
Commitments and contingencies	-	-
Stockholders' equity		
Preferred stock, $.01 par value, 10,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $.01 par value; 70,000,000 shares authorized; 36,223,097 and 25,383,354 shares issued and 36,194,997 and 25,355,254 outstanding at December 31, 2009 and December 31, 2008, respectively	362,231	253,834
Additional paid-in capital	92,835,174	57,343,507
Deficit accumulated during development stage	(69,371,755)	(47,315,163)
Treasury stock, at cost: 28,100 shares at December 31, 2009 and December 31, 2008	(51,103)	(51,103)
Accumulated other comprehensive loss	(16,200)	(24,200)
Total stockholders' equity	23,758,347	10,206,875
Total liabilities and stockholders' equity	$ 36,807,041	$ 11,358,682

Delcath Systems, Inc.
Income Statements as of December 31, 2009 and 2008

	Quarter ended December 31, 2009	Quarter ended December 31, 2008	Year ended December 31, 2009	Year ended December 31, 2008
Costs and expenses:				
General and administrative expenses	$ 1,771,374	$ 977,815	$ 3,898,705	$ 2,687,688
Research and development costs	3,653,658	1,645,345	9,637,050	5,378,335
Total costs and expenses	5,425,032	2,623,160	13,535,755	8,066,023
Operating loss	(5,425,032)	(2,623,160)	(13,535,755)	(8,066,023)
Derivative instrument (expense) income	(270,959)	296,335	(8,567,917)	1,103,682
Interest income	1,850	20,317	73,833	299,956
Other expense	(3,441)	(202,500)	(26,753)	(202,500)
Interest expense	-	-	-	-
Net loss	$ (5,697,582)	$ (2,509,008)	$ (22,056,592)	$ (6,864,885)
Common share data:				
Basic and diluted loss per share	$ (0.18)	$ (0.10)	$ (0.82)	$ (0.27)
Weighted average number of basic and diluted shares outstanding	31,040,910	25,346,756	27,072,556	25,300,703

Delcath Systems, Inc.
Statement of Cash Flows as of December 31, 2009 and 2008

	2009	2008
Cash flows from operating activities:		
Net loss	$ (22,056,592)	$ (6,864,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	1,578,673	379,546
Stock and warrant compensation expense	736,416	287,566
Depreciation expense	7,981	5,861
Amortization of organization costs	-	-
Loss on disposal of equipment	3,442	-
Derivative liability fair value adjustment	8,567,917	(1,103,682)
Changes in assets and liabilities:		
Increase in prepaid expenses and other assets	(438,070)	(5,894)
Increase (decrease) in accounts payable and accrued expenses	1,137,991	578,211
Net cash used in operating activities	(10,462,242)	(6,723,277)
Cash flows from investing activities:		
Purchase of equipment or furniture and fixtures	(515,440)	(8,313)
Proceeds from sale of equipment	200	-
Purchase of short-term investments	-	(200,710)
Purchase of marketable equity securities	-	(46,200)
Proceeds from maturities of short-term investments	4,048,614	9,878,700
Net cash provided by investing activities	3,533,374	9,623,477
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of stock options and warrants	35,475,954	-
Repurchases of common stock	-	-
Dividends paid on preferred stock	-	-
Proceeds from short-term borrowings	-	-
Net cash provided by financing activities	35,475,954	-
Increase in cash and cash equivalents	28,547,086	2,900,200
Cash and cash equivalents at beginning of period	6,939,233	7,886,937
Cash and cash equivalents at end of period	$ 35,486,319	$ 10,787,137
Supplemental cash flow information:		
Cash paid for interest	$ -	$ -
Supplemental non-cash activities:		
Cashless exercise of stock options	$ -	$ 1,950
Conversion of debt to common stock	$ -	$ -
Common stock issued for preferred stock dividends	$ -	$ -
Conversion of preferred stock to common stock	$ -	$ -
Common stock issued as compensation for stock sale	$ -	$ -
Fair value of warrants issued	$ 2,190,979	$ -

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EXHIBIT 99.2

Delcath 4Q09 Financial Results Conference Call
March 12, 2010, 8:30 AM ET
Chairperson: Doug Sherk

Operator: Good morning, ladies and gentlemen. Thank you for standing by. Welcome to the Delcath Systems progress report conference call. During today's presentation, all parties will be in a listen-only mode. Following the presentation, the conference will be open for questions. If you have a question, please press the *, followed by the 1, on your Touch-Tone phone. If you'd like to withdraw your question, please press the *, followed by the 2. If you're using speaker equipment, please lift the handset before making your selection. This conference is being recorded today, Friday, the 12th of March, 2010. I would now like toturn the conference over to Doug Sherk. 60;Please go ahead.

Doug Sherk: Good morning, everyone and thank you for joining us for the Delcath Systems progress report conference call. A press release providing an update on recent corporate developments was issued this morning and is hosted on the Delcath website. If you can't access the release, please feel free to call our office in New York at (646)201-5445 and we'll get one to you immediately.

A taped replay of the conference call will be available beginning one hour after the call's conclusion and will be available for seven days. The operator will provide replay details at the conclusion of today's call. This call is also being webcast live by the Company's website at www.delcath.com and the call will also be archived on the website.

Before we begin, let me quickly reference the Private Securities Litigation Reform Act of 1995, which provides a safe harbor for forward-looking statements made by the Company. Today's call may contain 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 Company's ability to successfully complete Phase III clinical trials and secure regulatory approval of current or future drug delivery systems and uncertainties regarding the 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 filings with the Securities and Exchange Commission including the Form 10-K for the fiscal year ended December 31, 2009, which was filed on February 26, 2010. You should not place undue reliance on these forward-looking statements which speak only as of the date they are made. The Company has no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made. Now, I'd like to turn the call over to Eamonn Hobbs, President and Chief Executive Officer of Delcath Systems.

Eamonn Hobbs: Thank you, Doug, and good morning everyone. Thank you for joining us. With me this morning are Dave McDonald, our CFO; Dr. Kris Kandarpa, our Chief Medical Officer; and Barbra Keck, our VP and Controller. Our agenda includes reviewing the Phase III trial data analysis process, the preparation of our new drug application to the FDA, our revised CE Mark application timetable, and our strategic partnership status. Dave will review some financial highlights and then we'll be delighted to take your questions.

Since I started as CEO last July, our team has virtually remade Delcath Systems into a company with world-class practices in product design and development, clinical and regulatory affairs, manufacturing, sales and marketing and finance. One of our key highlights since we last communicated with shareholders in mid-November, was to reach a sufficient number of events in the Company's Phase III trial. Once we confirm that a sufficient number of events had occurred, we began an intensive data analysis process. This morning I'd like Dr. Kris Kandarpa to provide you with an update on where we are in the process. Kris?

Kris Kandarpa: Thank you, Eamonn, and good morning everyone. We've begun the preliminary data analysis following confirmation from our research team that a sufficient number of events totaling 73 had occurred. The first step in the process is an initial review of the data by the trial's principal clinical investigators. That initial review is well underway.

The next step is a thorough review of the data by Delcath retained clinical research organization or CRO. The CRO reconciles the data with the principal clinical investigators. Once this step is completed, a review of some medical images for verification of results is conducted by an independent core lab. Finally, the statistical results are formally compiled by an independent biostatistical group.

As Eamonn has mentioned, we remain confident that the trial will meet the primary endpoint and we expect to provide topline data and results in April. Our confidence in the trial meeting a primary endpoint was further enhanced by the FDA's recent decision to allow Delcath to initiate the expanded use protocol for patients with ocular and cutaneous melanomas, metastatic to the liver. Expanded access programs make certain treatments being treat-- evaluated in late-stage trials, such as the Delcath PHP system, available to patients for whom no satisfactory alternatives are available. I hope that helps to clarify some of the processes. Eamonn?

Eamonn Hobbs: Thanks, Kris. Once the data analysis is complete, we plan to release topline data upon availability. Then with the data analysis in hand, we will begin to prepare our NDA to the FDA. On March 9th, we had a pre-NDA meeting with the FDA. Pursuant to the Company's fast-track status, the FDA confirmed the rolling submission filing strategy. Once data analysis is complete, we expect to begin the rolling submission of our NDA with he FDA as soon as practically possible. We believe that we've maintained on-track to achieve approval in the USA by midyear 2011.

Now, let's turn to our application for CE Mark approval. We recently confirmed that, although regulated as a drug delivery system covered under an NDA in the USA, the Delcath PHP System will be treated as a Class III device in Europe. This requires additional validation testing and documentation. We anticipate filing for this approval by the

end of the year or approximately six months later than originally envisioned. Once complete, these data will also be used to complete the CMC module of our rolling NDA submission in the US.

Operationally, we are on-track to have an inspectable quality system at our Queensbury manufacturing facility by April, which is a key step in the positioning of the Company for commercialization. Aside from the CE Mark timeline, we've been executing our plan and achieving our goals. One of those goals is to create strategic partnerships with international entities that grant exclusive geographic market rights for the PHP System.

We achieved our first milestone in this effort in February with the signing of an agreement with Chi-Fu Trading Company, Ltd., for the exclusive right to market and sell the Delcath PHP System in Taiwan. Specifically, the agreement grants Chi-Fu Trading the exclusive right to market the system for hepatic malignancies and infectious disease, such as viral hepatitis, upon approval from the Taiwan Food and Drug Administration, as well as any other approved use. We also granted them a conditional option for Singapore.

Under the terms of the agreement, Chi-Fu will fund and manage clinical studies at up to four sites to gather data for submission to Taiwan government regulatory agencies for approval. Any regulatory filings will be in the name of Delcath Systems, Inc. For the clinical studies, Chi-Fu will purchase, at a discount, Delcath PHP Systems to treat up to 200 patients with hepatic cancer. Any additional systems required will be sold at a confidential distributor price. It is intended that at least two of the clinical sites will become reference sites when this-- these studies are completed.

Under the terms of the agreement, we expect to receive $1 million in milestone payments comprised of $300,000 upon execution of the agreement and the balance upon receipt of the CE Mark and upon receipt of FDA approval. In addition, Chi-Fu will contractually be committed to purchase a minimum number of systems annually during the term of the agreement, commencing when commercial sales begin in Taiwan. The term of the agreement extends for five years from the month when the Taiwanese FDA approval is received. The total value of the agreement to Delcath, assuming receipt of the necessary approvals, is estimated to be at least $10 million.

Our agreement with Chi-Fu Trading illustrates the type of strategic partnership transaction we are actively negotiating for other larger markets. Given that we are so close to the completion of data analysis, we believe that any additional transaction will occur after data is available. Our goal is to create partnerships that will provide both an immediate boost to our existing cash position, as well as a longer-term consistent revenue stream. While we believe we will successfully conclude negotiations, we are exploring other opportunities to generate resources that could enhance our operational flexibility as we prepare to file our NDA and move towards commercialization.

Since we last communicated with you, we've made great strides at Delcath. We've completed enrollment in our Phase III trial, we initiated the data analysis of that trial. We've put in place the infrastructure to execute a world-class regulatory strategy. We've been granted approval to commence an expanded access clinical trial. We've completed our first strategic partnership and clinicians continue to express their confidence in the results the Delcath approach is generating for their patients, and we remain confident about our company's ability to generate enhanced quality of life for our patients while building returns for our shareholders. Before we open up the call to questions, I'd like Dave to go over a few financial highlights.

Dave McDonald: Thanks Eamonn, and good morning everyone. I'd like to focus my brief comments this morning on our cash resources and cash burn. We finished the year that ended December with about $35.5 million. Where we are at the end of February is about $32.5 million, and currently anticipate the monthly burn rate to be about $1.8 million per month, plus or minus. That's consistent with what we did in the fourth quarter, as you can see from the attached financials, also consistent with what we're doing here in the first part of 2010.

In terms of going forward, last fall we estimated we'd need to raise about $55 million or $60 million when we filed our follow-on offering. We thought that would be the required amount to get us through the commercialization plan and to cash flow positive. So we ended up raising just under $33 million after expenses on the deal, so by my math we're probably $20 million or $25 million short of where we wanted to be. So to answer the question proactively on the minds of many of you, and certainly that you've expressed to me in various meetings, yes, we'll have to raise additional cash going forward, so that shouldn't be a surprise. In what shape or form, we're not quite certain yet. The good news is we've got lots of opportunities, so clearly we're-- we continue to negotiate strategi c partnerships that could be fairly substantial.

In addition, we've got warrants outstanding that, if fully exercised, would bring the Company another $13.3 million, and potentially we could return to the capital markets, if it made sense both in terms of timing and price. So, as I said, good news is we've got lots of opportunities. Our promise to you, and I think we're all aligned on this, is that we want to do it in the least dilutive fashion possible in order to generate superior returns for the shareholders. So with that, Luke, I would like to open it up to questions.

Operator: Thank you. We will now begin the question-and-answer session. As a reminder, if you have a question, please press the *, followed by the 1, on your Touch-Tone phone. If you're using speaker equipment, it is necessary to pick up the handset before making your selection. If you would like to withdraw your question, please press the *, followed by the 2. Our first question comes from the line of Jason Mills with Canaccord Adams. Please go ahead.

Jason Adams: Thank you very much and thanks Eamonn.

Eamonn Hobbs: Good morning, Jason.

Jason Adams: Good morning to you as well. I wanted to start with the CE Mark process. When did you kind of get an inclination that the process would be delayed a bit and what changed sort of over the last couple of months, because I know that you've been working closely with them, the Company has for a while, and that said, I also know that the regulatory

agencies worldwide seem to be a lot tougher today than they were, you know, even a couple of years ago, so maybe you could give us a bit more color on the process changes.

Eamonn Hobbs: Certainly. Well, initially, we anticipated that our-- from initial feedback from the European regulatory authorities, both notified bodies and indirectly the clinical authorities, that they were going to most likely regulate the PHP System as a Class II device. Now, the regulations for Class II devices are somewhat similar to that of an easy 510(k), with the exception that you do have to have an inspectable quality system in your manufacturing facility where FDA rule would be that you're-- you have to certify you have one, but you don't have to submit to an inspection right up front and in --

Jason Adams: Right.

Eamonn Hobbs: -- the European system you do. So the-- we pursued that and the initial feedback we got upon further diligence was, well, you know, in-- from the notified bodies was, well, we're-- maybe we're going to have to file drug labeling in Europe. So we had to do an exhaustive study of European drug labeling to put an argument together that we didn't need to change the drug labeling in Europe. That unlike the US, the European drug labeling for Melphalan is for many multiple indications and multiple dosage levels, including the dosage that we're going after.

So we believe we've put together a very cogent argument. We've run it by notified bodies and they've-- a number of them have given us feedback, okay, absolutely we believe your device is-- your PHP System should be regulated as a device, but they moved it up to Class III which is the highest level of-- or the highest bar in the CE Mark universe. So that requires-- is going to require us to conduct a significant amount of additional testing and validations. Nothing that is alarming on our part, it's just going to take longer than we anticipated.

And we'll-- you know, we'll get double duty out of all that testing in that we'll use it as part of our CMC module for our NDA as well, to bolster that. So, you know, the-- it's a good news, bad news scenario, in that the good news is, for any competition in Europe, they'll also have to go through the most stringent device approval pathway, so the barrier of entry is higher. The bad news is it's going to cost us six months in the timeline. As you're aware, we really weren't looking for any material revenues out of Europe this fiscal year anyway.

Jason Adams: Right. Right.

Eamonn Hobbs: So it really doesn't change our burn or our revenue picture.

Jason Adams: No change to that. Okay. That's helpful. That's very good. Back over here stateside, perhaps the most important part of the story in the approval-- the FDA approval, the NDA approval, and wanted to get your sense for, in addition to the topline data, the primary endpoint data, when may we expect to see some data on what we've heard from clinicians, that could be maybe not equally as important, but fairly important, and those data that I'm speaking about are specifically interested in the crossover data and the benefit to patients that you may have seen, for those patients that were in the BAC arm originally, crossed over to PHP? In talking to clinicians, they're very interested in those data as well, and the FDA might be as well. And then, also the safety data, will that be presented alongside the primary endpoint data when you get around to it in April? And in our conversations with clinicians, what has been pleasantly surprising that-- is that even though you expanded quite significantly in the number of centers over the last 18 months, which may give some some concern or originally gave some some concern that, you know, as you dilute the number of centers that you could see some safety concerns as focused on the learning curve. We haven't heard that. In fact, just the opposite, as people get more used to using it and you're seeing fewer safety issues. Maybe you could comment on both of those things.

Eamonn Hobbs: Well, sure. As far as topline data, we still expect to be able to release that via an 8-K in April. More detailed or full data release will most likely come at a presentation potentially at ASCO in early June. The principal investigators are shooting for that. There may be some other meetings prior to that where data, at least topline data, could be discussed and maybe a little more detail applied. But I think they're shooting for ASCO and they're also shooting for publication in The New England Journal of full data.

On the safety side, you know, are-- there are a number of things to consider and that is, first, that the safety profile of the trial, the Phase III trial was reviewed by the DSMB numerous times, four times, and we are comfortable that the safety profile is virtually identical to that of the already approved FDA labeling for Melphalan, albeit for a different indication, multiple myeloma.

It is-- the safety AEs and SAEs that we've seen in the trial match up extremely well to the approved labeling, which makes sense in that we're delivering an approximate systemic dose back to the patient after we've knocked the concentration down post filtering.

With regard to center expansion, I absolutely agree that we haven't seen problems bringing centers up to speed. In fact, we-- one of our sites, Atlantic Health Systems, Morristown Hospital in New Jersey, is a community hospital and they were a good enroller in the trial and did very well and we've watched them very carefully to see if they had any logistics issues not being a major cancer center, and they didn't. So I think that bodes well for the-- once we get FDA approval and expanding.

Now, going back to the crossover data, kudos to you, you don't miss much, that's for sure. There's a lot of interesting data there that I think is going to get a lot of consideration. We think it's all very positive in that the clinicians have told us that-- one, they've told us that the-- approximately half the patients in the Phase III trial crossed over after progressing in the BAC arm and that they've done extremely well, once they started to receive PHP. Now, you know, clearly that's, at best, a secondary endpoint to the trial in that the trial was not set up to have that be a primary endpoint.

Jason Adams: Right.

Eamonn Hobbs: But nonetheless, it's still, we believe, incredibly compelling that patients who have literally failed everything being thrown at them, still respond positively to PHP in the same biology. So we think that you've put your finger right on a very, very interesting aspect of what's going to come out of the trial.

Jason Adams: That's helpful. One follow-up. I'll get back in queue and let others jump in. Could you help us out? You mentioned a couple things, you mentioned that you're shooting for-- the investigators are shooting for publication in The New England Journal of Medicine, which would be very catalytic given how ubiquitous the dissemination of that journal is into your customer base, or potential customer base, and wanted to see what other journals you could possibly be shooting for if, in fact, The New England Journal of Medicine doesn't come to fruition?

And then, secondly, as it relates to your potential customer base, in talking to some folks that are familiar with the PHP System, they believe that this procedure could be done in any hospital in the United States where-- that are at a community hospital level or above. Just doing an easy Google search on it you've got over 4,000 hospitals there. Now, I know you're not expecting to penetrate that many, but perhaps you could corroborate or refute that assertion, in terms of your target customer base, and then talk about as you move forward beyond FDA approval what sort of your center expansion plans may look like into that population? And thank you very much.

Kris Kandarpa: Thank you, Jason. This is Kris. I'll answer the first part of that question. We're also considering Lancet Surgical Oncology Journal and also the Journal of Clinical Oncology, in that order, should The New England Journal not accept the manuscript.

Jason Adams: Thank you.

Eamonn Hobbs: As far as the hospital universe, you know, as I mentioned, we are quite pleased to-- with our experience with a community hospital nearby in Morristown, New Jersey. So, clearly, it-- the potential for the procedure to migrate out into a much, much broader base than major cancer centers is very, very real and something that we will pursue in the course of time. But the way we plan to roll the product out in the United States is to, by far, focus primarily on major cancer centers, the top 50 NCI cancer centers, and then as we saturate those, start to branch out from there and from a operational perspective, we plan to start with 10 to 12 very experienced sales reps who are well supported with training and clinical support, to go after the top 50. And then as those sales territories grow, we'll split them, divide them and ultimately we think we'll be able to cover the hospital universe where this procedure will be conducted routinely in the United States with about 50 to 60 very top-notch sales representatives and, of course, their support team.

Jason Adams: Thank you very much, Eamonn.

Eamonn Hobbs: Thank you, Jason

Operator: Thank you. Our next question comes from the line of Brooks West with Craig-Hallum Capital. Please go ahead.

Brooks West: Good morning. Can you hear me?

Eamonn Hobbs: Good morning, Brooks, how are you?

Brooks West: I'm doing well. Thanks for taking the questions. Let me start with the expanded use protocol. Can you, Dave, maybe quantify the potential financial benefit there, if any? And then, are you tracking those patients and is there a use for that data potentially in any of the filings?

Dave McDonald: Well, morning Brooks. So I'll let Kris talk about the expanded access study but in terms of financial benefit, I think it's-- well, Kris, go ahead.

Kris Kandarpa: Yeah, you know, we have approval for the expanded use protocol. We haven't actually initiated it because we, you know, at this point we have enough on our hands if we want to complete the data analysis and see where our resources would be most appropriately used.

Brooks West: Okay. That makes sense. And then, Kris, maybe to follow up on the earlier question on the crossover data, one of the concerns that we've heard from clinicians is a potential risk of diluting the data that, you know, you might not be getting as good of a benefit in the crossover patients. Maybe you could address that?

Kris Kandarpa: Did you mean overall survival?

Brooks West: Yes.

Kris Kandarpa: Yeah, that is a secondary endpoint and we knew all along when-- even as we introduced the crossover feature, if you will, that the overall survival would be diluted. The reason we had to put in the crossover feature was obviously for ethical reasons, since these patients would have nothing else to do, and this was done with-- in discussion with the FDA and understood that the overall survival would-- it, for all comers, would not look that different. However, secondary analyses can be done to tease our differences between the two groups.

Brooks West: Okay. Great. And then, lastly, on the Asia partnerships. You know, it makes sense with the trial data coming to fruition here to maybe put some of those on hold. Do you feel like you would need to go back to the drawing board with any of these guys, or is it just another bargaining chip on your side of the table and you can kind of quickly accelerate those negotiations again?

Eamonn Hobbs: Well, it's a very good point in that, you know, we have been pursuing numerous strategic partnerships in China, Korea and Japan, and we were-- we felt we were very close to closing a Chinese partnership-- and this is for mainline China, not to be confused with Taiwan-- way back in-- you know, way back now in Delcath time, in October. And I think you

put your finger on a very, very good point in that that deal, although it was extremely attractive and we were in-- very, very enthusiastic about closing it in October, we would not be interested in closing that exact structured deal today. Because the risk-benefit profile back then was much different than it's going to be post data release. And you know, the fact of the matter is, we'll be expecting our partner to be deriving much lower risk profile and muc h higher value proposition today and we'd expect that we'd be renegotiating a deal with that partner, if that partner steps up. So we are start-- not necessarily starting from scratch, but we definitely would not sign that deal today. We are very actively involved in strategic partner negotiations but we're certainly not going to close one until data release has settled in because we, you know, our partners and we want to make sure that all our cards are on the table.

Brooks West: Okay. Great. Thanks, guys.

Operator: Thank you. Once again, ladies and gentlemen, if you would like to ask a question, please press the *, followed by the 1 on your Touch-Tone phone. If you are using speaker equipment, it is necessary to pick up the handset before making your selection. Our next question comes from the line of Sara Michelmore with Cowen. Please go ahead.

Sara Michelmore: Yes, good morning.

Eamonn Hobbs: Good morning, Sara.

Sara Michelmore: You know, Eamonn, I don't know if it came up your pre-NDA meeting, but I would just be curious to hear your thoughts on the special protocol assessment and, you know, I know how it's supposed to work but, you know, there's always some wiggle room there too for the FDA, so just curious if you have any feedback on that and how you're feeling about the SPA, and what that means in terms of, you know, if you hit the primary endpoint and the approvability of the product?

Eamonn Hobbs: Sure. Well, we-- the way these pre-NDA meetings work is we send a-- sent a very detailed package to the FDA in writing requesting a pre-NDA meeting back in January-- oh, I'm sorry, back in December, and we received written replies to the package that we sent, which was very broad-based, and there were no questions or concerned expressed in writing from the FDA in January about our protocol design and-- nor were we expecting any.

But it's always good news when-- if the FDA has a problem, that's the venue that they can easily bring it up and make it clear to the Company that, you know, we need to address the problem. And the protocol design and the SPA was not at all a mention. In our face-to-face meeting with the FDA, once again, which just happened this week, once again the FDA did not bring that up. Matter of fact, we were very pleased with the interaction with the agency in that we had posed a request for clarification on a number of the answers and/or questions the FDA posed to us, mostly associated with the mechanics of labeling this combination product. And we got everything we wanted out of that meeting. We were very pleased at the attention that was paid to us. And Dr. Pazdur had originally signed t he SPA and he attended the meeting, which I think bodes very well that, you know, we have some continuum there of FDA folks.

And, you know, clearly, if he had had a question about the protocol or how we'd followed it, he-- I would imagine he would have taken advantage of that opportunity to express it. So we walked out of the pre-NDA meeting feeling very good that we were on the right track and it's all going to come down to data.

Sara Michelmore: Okay. That's helpful color.

Eamonn Hobbs: The only other thing that came out of that meeting that's important, is we had requested a rolling submission and we-- and they approved it, so-- which is, again, a very good sign.

Sara Michelmore: And then just a clarification on, I think, an earlier answer on the expanded access program, I assume, and maybe you could give us a little color too, that the centers that are currently in the trial would like to continue to offer that procedure. I'm surprised that you would, you know, consider not going forward with that. Just hoping you could clarify that, I mean, how resource intensive would a program like that be feeling for you?

Eamonn Hobbs: Well, the-- certainly all the center would love to continue the-- it would be unusual for the FDA to allow all of our centers to continue on an access trial, especially one structure like ours. But they did give us five centers, which geographically cover the US pretty well. And logistically, you know, one of the things from a company perspective, we want to make sure is that we can juggle the management of the access trial while we do everything else to move towards FDA approval and not get distracted. So we have to-- five is a manageable number for us.

Sara Michelmore: Okay. And then, lastly, on-- in the press release, you highlighted a number of small conferences and venues where you would be-- where there would be some posters and abstracts and things like that. Anything new, or anything we should look for in terms of the data that's coming out in the next four to six weeks at those venues? Thanks.

Eamonn Hobbs: Well, until data release, I'm afraid there's not going to be a whole lot new. You know, at least that's the plan. We can't control the investigators and what they say, nor should we. But if they stick to the script, there won't be anything new until data release.

Sara Michelmore: Thank you.

Operator: Thank you. Our next question comes from the line of Phil Canzoneri with Wells Fargo. Please go ahead.

Phil Canzoneri: First, I'd like to congratulate all the management team at Delcath for doing just a great job in the last two years. It's been a pleasure being associated with this company.

Eamonn Hobbs: Well, thank you Phil and good morning.

Phil Canzoneri: Good morning to you, Eamonn. Question on the Stage II-- the Phase II trial, the neuroendocrine trial.

Eamonn Hobbs: Yes.

Phil Canzoneri: From what I've heard anecdotally, the data coming out of that trial is even better than the Stage III trial. And if that's the case, upon approval on the Stage III, will we get a kind of a push forward for applications on what we're treating in Stage II neuroendocrine and primary?

Eamonn Hobbs: Yes. The short answer is we believe that the answer will be yes. And certainly it's been my experience in the device arena, that the majority of device use is typically-- the vast majority of device use is typically off-label or near-label, what I would call near-label. And because of the already released interim data on the neuroendocrine arm of our Phase II trial being so good, the clinicians have told us, in no uncertain terms, that once the Delcath PHP System is approved for melanoma mets that they will clearly use the system for neuroendocrine mets and, you know, that's within their right to do so. Now, clearly, we can't market it for that.

Phil Canzoneri: Okay.

Eamonn Hobbs: Because that's a big no-no. But the clinicians are very, very free to use it in any way they deem as appropriate.

Phil Canzoneri: As-- yeah, as long as the data shows that there's a, you know, real benefit there, then I can see that, you know, coming to-- coming to, you know, fruition.

Eamonn Hobbs: Um-hmm.

Phil Canzoneri: Yeah, we're very excited about it and I just wanted to, again, say congratulations to you guys for doing a great job.

Eamonn Hobbs: Well, thank you, Phil. We really appreciate it.

Phil Canzoneri: Okay.

Operator: Thank you. Our next question comes from the line of Aaron Lehmann with LSP Partners. Please go ahead.

Aaron Lehmann: Good morning. I reit--

Eamonn Hobbs: Good morning. Hey, Aaron?

Barbra Keck Hello.

Speaker: We lost him.

Operator: Our next question comes from the line of Peter Jeffer with Jeffer Management Corporation.

Peter Jeffer: Hello. Good morning.

Eamonn Hobbs: Good morning, Peter.

Peter Jeffer: I'd like to know the size of the market in Asia versus the United States and Europe, because you seem to be actively pursuing the Asian environment, and also I didn't catch the date-- the potential date of The New England Journal article, if it were to be received and published?

Eamonn Hobbs: The Asian market is something we're working on, trying to get our arms around, but in rough numbers there are 2.6 million liver cancers to treat in the world every year, based on world health data. Only about 10% of those are in the United States, 10% are in Europe, and then it gets a little fuzzier between Africa and Asia. But we've seen everything from-- there are about 1.5 million cancers-- liver cancer cases in the combination of China, Korea and Japan, down to something in the neighborhood of 800,000. So we're working hard on that.

But needless to say, if we look at the US market and consider that the on-label indication would generate a market-- annual market in the US just for the drug delivery system, with the drug being on top of that, of $470 million, and the near-label, same drug, same organ, same drug delivery system being $4.4 billion, and that only represents 10% of the potential in the world, the numbers get awfully big, awfully fast and hence why we're paying so much attention to the Asian markets.

Peter Jeffer: And the date of the New England article?

Eamonn Hobbs: Kris?

Peter Jeffer: The date-- date of potential date?

Kris Kandarpa: Yeah, we have to wait for the data release and then we start writing the actual article. We don't think we'll be submitting anything until the summer. And then it's up, really, to the journal. They take their own review time. They could review it quickly but we'll have to depend on them for final publication. However, there is the possibility of an electronic publication which would come sooner than the printed version.

Peter Jeffer: Thank you very much. Good luck and you've done and outstanding job since you took over this company.

Eamonn Hobbs: Thank you so much.

Kris Kandarpa: Thank you.

Operator: Thank you. Our next question comes is from the line of Aaron Lehmann, with LSP Partners. Please go ahead.

Aaron Lehmann: Morning. I reiterate the previous comments of commending you on your success to date.

Eamonn Hobbs: Thank you.

Aaron Lehmann: General question. You mentioned the vast market in the liver area. What other organs are likely candidates subsequent to that and what impediments, if any, do you foresee in getting the technology used in other areas of cancer treatment?

Kris Kandarpa: The first part of the question, I think we could easily go into renal tumors, although there are several competing modalities there. Pelvic treatment of, you know, tumors in the pelvis can be isolated and a system similar to ours, or our system could be used and as well as limbs, because there is, as you know, a large cutaneous melanoma population where the limbs need to be perfused. Ultimately, you know, depending on modifications and the technology, we could even try to approach certain brain tumors. That is-- the last part is speculation but we hope we can get there.

Eamonn Hobbs: Yeah, I would add to that lung, for nonresectable small-cell and, you know, primary pancreatic. The-- there was a physician-sponsored primary pancreatic pilot trial that should begin this year.

Kris Kandarpa: In the liver, obviously, we can do any metastatic lesion in the liver.

Eamonn Hobbs: Or primary.

Kris Kandarpa: Or primary. Primary or metastatic.

Aaron Lehmann: Okay. Thank you very much.

Eamonn Hobbs: Thank you, Aaron.

Operator: Thank you. And, once again, ladies and gentlemen, if you would like to ask a question, please press the *, followed by the 1, on your Touch-Tone phone. If you're using speaker equipment, it is necessary to pick up the handset before making your selection. Our next question comes from the line of Mark Sigler. Please go ahead.

Mark Sigler: Morning, and thank you all for the update this morning and thank you for taking questions.

Kris Kandarpa: You’re welcome.

Eamonn Hobbs: You’re very welcome and good morning.

Mark Sigler: There was a brief reference during the opening remarks to the facility at Queensbury. I'm wondering whether you could say a few words about what's happening at Queensbury, if anything, right now? Do you have people reporting for work there on a daily basis? If so, what are they doing, is anything being assembled there, processed, manufactured, anything you can say about that?

Eamonn Hobbs: Well, we're doing the call from Manhattan, so we hope people reported for work this morning out there, but we can't-- we-- it would take us a few hours to verify that. But in all seriousness, the-- what's happened in Queensbury is really transformational. Last fall we secured a building which is located in Catheter Valley and we're-- you know, Queensbury is right in the center where most of the big medical device companies have manufacturing facilities. Hence why we put our operational facility there. And we-- over the course of the ensuing months, have transformed that into a world-class manufacturing and R&D facility, and we've been in the process of staffing it.

So what's going on there today is we have a senior management staff there, headed up by Chuck Frigon, who has spent his career in the medical device arena, and we have brought on medical device engineering expertise in the engineering and quality area? We've brought on regulatory expertise and we are actually shipping the product that is currently being assembled there to our clinical sites in-- now, filter manufacturing is being vertically integrated into that facility and we expect that filter manufacture will be hopefully validated within the next few months. And then the remaining assembly operations will be fully validated along a parallel timeline. So there's a lot happening at the facility and currently we have how many people there?

Barbra Keck: Ten.

Eamonn Hobbs: Ten. Thank you, Barbra.

Mark Sigler: Yes, that's helpful, and these updates in general are very helpful and very well received. I hope you'll continue to do them at regular intervals. Thank you.

Eamonn Hobbs: That's our plan, Mark. And we really appreciate your support.

Operator: Thank you. And that concludes the question-and-answer session. Management, please continue.

Eamonn Hobbs: Well, thanks everyone for your attention today and I-- on behalf of the Delcath team, we really appreciate all your support and we look forward to these updates being routine and to updating you in the future. Have a great day.

Operator: Thank you. Ladies and gentlemen, this concludes the Delcath Systems progress report conference call. If you'd like to

listen to a replay of today's conference, please dial (303)590-3030, or (800)406-7325 with the access code--

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