JUDGE SCHOFIELD

13 CIV 3116

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

[redacted], Individually and On Behalf of All Others Similarly Situated, Plaintiff,- v. DELCATH SYSTEMS, INC., EAMONN P. HOBBS, and KRISHNA KANDARPA, Defendants.	**Civil Action No.** CLASS ACTION COMPLAINT **JURY TRIAL DEMANDED**

Plaintiff [redacted] ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his Class Action Complaint against defendants, alleges upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, based on, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things: a review of the defendants' public documents; conference calls and announcements made by defendants; Securities and Exchange Commission ("SEC") filings; wire and press releases published by and regarding Delcath Systems Inc. ("Delcath" or the "Company"); securities analysts' reports and advisories about the Company; and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities fraud class action on behalf of all persons or entities who purchased or otherwise acquired the securities of Delcath during the period from April 21, 2010 through and including May 2, 2013 (the "Class Period"), seeking to pursue remedies under the

Securities Exchange Act of 1934 (the "Exchange Act"). This class action is brought under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a); and SEC Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

2. Throughout the Class Period, Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the Company's New Drug Application ("NDA") for Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable ocular melanoma metastatic to the liver contained risks including substantial and severe toxicity and deaths associated with the drug's adverse reactions; and (2) the Company's manufacturing facilities were in violation of Current Good Manufacturing Practices ("cGMP").

3. On February 22, 2011, the Company disclosed that it had received a "refusal to file" letter from the U.S. Food & Drug Administration ("FDA") for its NDA for its proprietary chemosaturation system. The letter "requested information involving manufacturing plant inspection timing, product and sterilization validations and additional safety information … as well as additional statistical analysis clarification."

4. As a result of the Company's disclosure, Delcath shares plummeted $4.29 or 38%, to close at $7.01 per share.

5. On April 30, 2013, the FDA published briefing documents ahead of a meeting by the Oncologic Drugs Advisory Committee ("ODAC") on May 2, 2013. The briefing documents concluded, among other things, that "substantial evidence of effectiveness in adequate and well controlled clinical trials utilizing the proposed drug-device combination product and a favorable

benefit risk profile is required for approval." Moreover, the briefing documents revealed that a staggering 7% of the 122 patients treated with the Melbaz kit died as a result of the treatment.

6. On this news, Delcath shares declined $0.558 per share or over 40%, to close at $0.832 per share on April 30, 2013.

7. On May 2, 2013, the Company announced that the ODAC voted 16 to 0 that benefits of treatment with Delcath's Melblez Kit do not outweigh the risks associated with the procedure.

8. On this news, Delcath shares declined $0.3326 per share or nearly 42%, to close at $0.46 per share on May 3, 2013.

9. As a result of defendants' wrongful acts and omissions, and the precipitous declines in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

12. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

13. In connection with the challenged conduct, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

14. Plaintiff , as set forth in the accompanying certification, incorporated by reference herein, purchased Delcath securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

15. Defendant Delcath is a Delaware corporation with its principal executive offices located at 600 Fifth Avenue, 23rd Floor, New York, New York 10020. Delcath claims to have developed a system to isolate the liver from the circulatory system and to administer chemotherapy and other therapeutic agents directly to the liver. This system filters patients' blood removing most of the harmful chemotherapy agents lessening the side-effects of the treatment. The aggregate number of shares of Delcath securities outstanding as of March 7, 2011 is approximately 43 million shares. Delcath common stock is listed on the NASDAQ Stock Market ("Nasdaq") under the ticker "DCTH."

16. Defendant Eamonn P. Hobbs ("Hobbs") was at all relevant time the Company's President, Chief Executive Officer ("CEO") and a director on the Company's Board of Directors.

17. Defendant Krishna Kandarpa, M.D., Ph.D. ("Kandarpa") was at all relevant the Company's Executive Vice President, Research and Development; and, Chief Medical Officer, and Chief Scientific Officer since September 2012.

18. The defendants referenced above in ¶¶ 16 and 17 are collectively referred to herein as the "Individual Defendants."

SUBSTANTIVE ALLEGATIONS

Background

19. Delcath is a specialty pharmaceutical and medical device company focused on oncology. The Company's proprietary drug/device combination product, the Delcath Hepatic Delivery System, is designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company focuses on the development of its product, the CHEMOSTAT/Melblez Kit system which administers concentrated regional chemotherapy to the liver. This "whole organ" therapy is performed by first isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and filtering the blood prior to returning it to the patient. The CHEMOSTAT/Melblez Kit system is designed to address many of the limitations of traditional treatments by permitting the delivery of much higher doses of chemotherapeutic drugs directly to the liver while minimizing the systemic exposure of such drugs.

Defendants' False and Misleading Statements

20. On April 21, 2010, the Company issued a press release entitled, "Delcath Phase III Trial Results Exceed Primary Endpoint Expectations." The press release stated the following in relevant part:

> Delcath Systems, Inc., a development stage, oncology-focused, specialty pharmaceutical and medical device company, announced that its Phase III National Cancer Institute (NCI)-led multi-center clinical trial has successfully met the study's primary endpoint of extended hepatic progression-free survival (hPFS) in patients with melanoma metastases to the liver based on an independently corroborated intent-to-treat analysis. Comparing treatment with the Delcath PHP System™ with melphalan to Best Alternative Care (BAC), based on independent core lab review of

> patient scans, the statistical analysis revealed that the PHP patients had a statistically significant longer median hPFS of 214 days compared to 70 days in the BAC arm (p=0.001). This reflects a 144-day prolongation of hPFS over that of BAC control arm, with less than half the risk of progression and/or death in the PHP group compared to the BAC group (Hazard Ratio = 0.46).
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> "We believe that these data support that the Delcath PHP System may provide a significantly better treatment option for patients suffering from melanoma metastases in the liver," said Eamonn P. Hobbs, President and CEO of Delcath. "With the treatment arm having a median hPFS of more than three-fold that of the control arm, we easily exceeded our expectations of clinical trial success. This is a major step forward in our plan to introduce what we believe is an effective treatment for patients who currently have very few viable options."

21. On June 5, 2010, the Company issued a press release entitled, "Delcath Highlights Phase III Trial Results Presented at ASCO." The press release stated the following in relevant part.

> In the PHP arm of the study, patients showed median hepatic progression free survival (hPFS) of 245 days compared to 49 days in the BAC arm, a 5x extension of hPFS. Median overall survival in the PHP arm was 298 days, compared to median overall survival of 124 days for those patients in the BAC arm that did not crossover.
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> The hepatic response rate in the PHP arm was 34.1% compared to 2% for the BAC arm and 22.2% for patients who crossed-over to receive PHP upon progression of their tumors. 52.3% of patients in the PHP arm achieved stable disease, compared with 26.5% in the BAC group, and 40.7% in the crossover group.
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> "We are obviously very pleased with these results," said Eamonn P. Hobbs, President and CEO of Delcath. "This study supports our belief that chemosaturation via PHP has potential life-extending benefits as a treatment for patients suffering with terminal, metastatic disease in the liver. Our rolling submission to the FDA is underway, and we are extremely excited by the future of this promising new treatment."

22. On December 6, 2010, the Company issued a press release entitled, "Delcath Submits CE Mark Technical File For Hepatic Chemosat (TM) Delivery System." The press release stated in relevant part the following:

> Delcath Systems, Inc. today announced that the Company has submitted its CE Mark Technical File to its European Notified Body to obtain CE Mark approval for its proprietary chemosaturation system, which the Company intends to market in the European Union (EU) as the Delcath Hepatic ChemoSAT(TM) Delivery System. CE Marking is an indication that a medical device complies with the essential requirements of applicable medical device directives, and that the device has been subjected to conformity assessment procedures. Receipt of the CE Mark will allow Delcath to market and sell the product in countries in the EU.
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> "The EU represents an attractive opportunity for this product," said Eamonn P. Hobbs, CEO & President of Delcath Systems. "Our filing in the EU is seeking an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver. With the EU's aging population and liver cancer rates on the rise we believe the Hepatic ChemoSAT Delivery System will fulfill an unmet clinical need for many liver cancer patients in this region. With the submission of our Technical File, and successful completion of the audits of our quality system and manufacturing facility, we expect potential CE Mark approval in mid-2011."

23. On December 22, 2010, the Company issued a press release entitled, "Delcath Completes New Drug Application Submission to the FDA for the Chemosaturation Delivery System." The press release stated in relevant part the following:

> Delcath Systems, Inc. today announced that the Company has submitted the remaining modules of its 505(b)(2) New Drug Application (NDA) for its proprietary chemosaturation system to the U.S. Food & Drug Administration (FDA). The Company had previously submitted Module 4, consisting of literature based non-clinical data, to the FDA in late April 2010. The Company is seeking an indication for the percutaneous intra-arterial administration of melphalan hydrochloride for use in the treatment of patients with metastatic melanoma in the liver.
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> "Our team has achieved a significant milestone with the filing of our NDA," said Eamonn P. Hobbs, CEO & President of Delcath Systems. "We believe that our application is comprehensive and complete, and we are optimistic that it will be accepted for review by the FDA. Considering

> the limitations of current treatment options, we believe the chemosaturation system can offer hope to patients with metastatic melanoma in the liver. We have requested priority review of our NDA by the FDA, which if granted could result in a 6-month review of the application. Priority review is granted by the FDA to those products that address significant unmet medical needs or have the potential to provide significant improvement compared to marketed products. With the strength of our Phase III data, we believe that our application meets the FDA's criteria for priority review."

24. On February 17, 2011, the Company issued a press release entitled, "Delcath Achieves ISO 13485 Certification." The press release stated in part the following:

> Delcath Systems, Inc. today announced that the Company has achieved ISO 13485:2003 Certification--an internationally recognized quality standard designed to ensure that medical device manufacturers have the necessary comprehensive management systems in place to safely design, develop, manufacture and distribute medical devices in the European Union (EU). ISO 13485 Certification is a regulatory requirement of the EU's Medical Device Directive, and represents an important step toward attaining European CE Mark approval for the Company's proprietary Hepatic ChemoSAT(TM) Delivery System.
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> Commenting on the announcement, Eamonn P. Hobbs, CEO & President of Delcath Systems, said, "ISO 13485 Certification confirms that our manufacturing and quality systems meet the high standards required of medical device companies selling into Europe, and we are pleased to have achieved this important milestone toward the receipt of CE Mark approval. Our technical file for CE Mark is pending, and we continue to expect CE Mark approval for our product in mid-2011."

25. On February 22, 2011, the Company disclosed that it had received a "refusal to file" letter from the FDA for its proprietary chemosaturation system. Specifically, the "FDA's letter requested information involving manufacturing plant inspection timing, product and sterilization validations and additional safety information … as well as additional specific statistical analysis clarification."

26. As a result this disclosure, Delcath shares plummeted $4.29 or 38%, to close at $7.01 per share.

27. On September 23, 2011, the Company issued a press release entitled, "Delcath Announces Updated Efficacy Results From Phase 3 Trial of Chemosaturation for Melanoma Metastases in the Liver Presented at European Multidisciplinary Cancer Congress." The press release stated the following in relevant part:

> With respect to the study's primary endpoint of hepatic progression free survival ("hPFS"), the updated investigator-assessed results showed that patients in the chemosaturation arm demonstrated median hPFS of 8.0 months compared to 1.6 months in the BAC arm, a significant 6.4 month extension of hPFS (hazard ratio 0.35, $p<0.0001$). Median overall PFS in the chemosaturation arm was 6.7 months compared to 1.6 months in the BAC arm, an increase of 5.1 months (hazard ratio 0.36, $p<0.0001$).
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> As reported previously, the hepatic response rate in the chemosaturation arm was 34% compared to 2% for the BAC arm. In addition, 52% of patients in the chemosaturation arm achieved stable disease, compared with 27% in the BAC group, giving a tumor growth control rate of 86% for the chemosaturation group versus 29% for the BAC group ($p<0.001$). Patients who crossed from the BAC arm to chemosaturation treatment after progression of liver disease showed consistent efficacy with patients treated on the chemosaturation arm. As expected, there was no difference in overall survival in the randomized study due to the crossover trial design. An analysis of survival trends by patient cohorts indicated that patients treated with chemosaturation, including crossover patients, had a median survival of 11.4 months compared to 4.1 months for BAC patients who did not receive chemosaturation. As of June 30th, 11 patients treated with chemosaturation were still alive compared to two patients in the BAC arm who did not receive chemosaturation.
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> "The additional 12 months of data and extended survival for a significant percentage of the treated patients confirm our belief that chemosaturation may provide a significantly better option than the few treatments presently available for patients with melanoma metastases in the liver," said Eamonn P. Hobbs, President and CEO of Delcath. "The hepatic PFS, overall PFS and response rate are consistent with past investigator assessments and highly statistically significant. We are encouraged by the data presented in Stockholm today."

28. On August 15, 2012, the Company issued a press release entitled, "Delcath Submits New Drug Application For Proprietary Chemosaturation System To The U.S. Food And Drug Administration." The press release stated the following in relevant part:

Delcath Systems, Inc. (NASDAQ: DCTH) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration seeking approval for the Company's proprietary chemosaturation system for use with melphalan hydrochloride in the treatment of patients with unresectable metastatic melanoma in the liver. The Company included its Generation 2 filter in its NDA submission as a technical change to the Chemistry, Manufacturing, and Control (CMC) module.

"Our team has achieved a significant milestone with the filing of our NDA," said Eamonn P. Hobbs, President and CEO of Delcath Systems. "We believe that our chemosaturation system provides the opportunity to satisfy a high unmet medical need to treat patients with unresectable metastatic melanoma in the liver. We also believe including our Generation 2 filter in the CMC module represents the fastest regulatory review path for the Generation 2 system, and that it is in the best interest of U.S. patients that we accelerate the potential availability of Generation 2."

"We have requested priority review of our NDA by the FDA. Assuming the NDA is accepted and that priority review is granted, our expected Prescription Drug User Fee Act (PDUFA) date would be in February of next year. Based upon the strength of our Phase 1, 2 and 3 data, along with the limited treatment options available for patients with unresectable melanoma metastases in the liver, we believe that our application meets the FDA's criteria for priority review."

In Delcath's Phase 3 clinical trial (April 2010 data cutoff), comparing treatment with the Company's proprietary chemosaturation system to best alternative care (BAC) revealed that patients treated with chemosaturation therapy experienced a statistically significant extension in median hepatic progression free survival (hPFS) of 5.4 months ($p=0.0001$, hazard ratio 0.39) longer than patients treated with BAC according to independent review committee (IRC) blinded intent-to-treat (ITT) analysis. Previously reported investigator ITT analysis of these data showed an extension in median hPFS of 6.4 months ($p<0.0001$, hazard ratio 0.28) longer than patients treated with BAC. Priority review is granted by the FDA to those products that address significant unmet medical needs or have the potential to provide significant improvement compared to marketed products. The FDA has previously granted Delcath two orphan drug designations for melphalan in ocular and cutaneous melanoma, which will provide the Company with exclusivity in these indications for seven years if the NDA is accepted, reviewed and approved.

29. On September 19, 2012, the Company issued a press release entitled, "Expert Symposium at CIRSE Annual Congress Discusses Advantages of Using Delcath Chemostat System to Treat Cancers in the Liver." The press release stated the following in relevant part:

> Key presenters at the symposium-Hepatic Chemosaturation Therapy: Expanding the Therapeutic Approaches of Interventional Radiology-included Franco Orsi, MD, PhD, and Pier Francesco Ferrucci, MD, both from the European Institute of Oncology, Milan, Italy, and Thomas J. Vogl, MD, from Johann Wolfgang Goethe-Universitat, Frankfurt, Germany. The physicians expressed their opinions on the advantages of CHEMOSAT and presented case studies on patients who have been treated with the technology.
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> "With CHEMOSAT, we are able to isolate and directly treat the whole organ, which allows us to address both the visible tumors, as well as the micro-metastases, with higher dosing designed to improve tumor-killing efficacy," Dr. Ferrucci said. "Based on our experience thus far, this treatment approach may expand the window of opportunity to treat the primary or metastatic disease in the liver."
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> Historically, control of cancers in the liver can be challenging because traditional procedures, such as surgery, radiofrequency ablation and cryotherapy, treat visible tumor sites, but tumors too small to be seen go untreated. Systemic chemotherapy, in which anti-cancer drugs are administered through a vein or given by mouth, spreads throughout the entire body. Because the drug dose in systemic chemotherapy is limited by systemic toxicity, the amount of drug reaching the liver is lower than can be administered with CHEMOSAT. For this reason, CHEMOSAT could potentially achieve efficacy for cancers in the liver that conventional chemotherapy cannot.
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> Discussion during the symposium focused on potential side effects and the range of cancer types that can be treated using the technology. The panel noted that the typical side effects from a CHEMOSAT procedure are predictable and manageable by medical oncologists / hematologists. The physicians also noted that studies utilizing chemosaturation have shown potential for a range of cancer types using melphalan.

30. On October 15, 2012, the Company issued a press release entitled, "Delcath Announces FDA Accepts New Drug Application for its Proprietary For its Proprietary Chemosaturation System with Melphalan Hydrocholride." The press release stated the following in relevant part:

> Delcath Systems, Inc. (NASDAQ: DCTH) announced today that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for its proprietary chemosaturation system with melphalan hydrochloride for injection. The FDA has designated the NDA for standard review. Delcath expects to be notified of its PDUFA date in the FDA's 74-Day letter, which the Company expects to receive by the end of October. Under the Prescription Drug User Fee Act (PDUFA), the FDA has the goal of completing its review of applications designated for standard review within 10 months of the NDA submission, which was submitted on August 15, 2012. The Company is seeking approval for its proprietary chemosaturation system with melphalan hydrochloride as a treatment for patients with unresectable metastatic melanoma in the liver.
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> "FDA acceptance of our NDA is a significant milestone for the Company, and we look forward to working closely with the Agency throughout the review process with the goal of securing approval of our application," said Eamonn P. Hobbs, President and CEO of Delcath Systems. "We believe that the standard review period will provide both Delcath and the FDA a manageable timeframe to thoroughly review the combination product submission. Our most important objective is to be able to provide patients with unresectable metastatic melanoma in the liver a new option for treating their disease."

31. On October 22, 2012, the Company issued a press release entitled, "Delcath Announces CE Marking for Hepatic Chemosat Delivery System for Use with Doxorubicin Injection." The press release stated the following in relevant part:

> Delcath Systems, Inc. (NASDAQ: DCTH) today announced that the Company has satisfied all of the requirements to affix the CE Mark to its Hepatic CHEMOSAT® Delivery System for use with doxorubicin hydrochloride injection. Doxorubicin is an established chemotherapeutic agent commonly used globally to treat hepatocellular carcinoma (HCC) via trans-arterial chemoembolization (TACE). Doxorubicin is well-known among physicians, has a broad label to treat many types of solid tumors and an indication in key Asian markets that is consistent with high-dose, intra-arterial delivery via the CHEMOSAT system.
> CE Marking confirms that a medical device complies with the Essential Requirements of the Medical Device Directive, and that the device has been subjected to conformity assessment procedures. Application of the CE Mark provides Delcath with a regulatory pathway for countries in Asia that accept CE Marking as part of their national regulatory requirements. In China, these requirements include conducting a local clinical trial and approval by the China State Food and Drug Administration (SFDA). Delcath intends to seek approvals for the CHEMOSAT system with doxorubicin injection in key Asian markets such as China and South Korea. The Company does not intend to market

CHEMOSAT with doxorubicin injection in the European Economic Area at this time.

"Doxorubicin is a drug widely used to treat HCC in Asia, which is where we see the market opportunity for our CHEMOSAT system with doxorubicin injection," said Eamonn P. Hobbs, President and CEO of Delcath Systems. "According to GLOBOCAN, more than 550,000 new cases of HCC in Asia are diagnosed every year, and with median survival of less than 11 months for those patients with intermediate stage disease (Lovet, JM, et al; NEJM 2008), HCC is a prevalent disease in this region. Based upon prior discussions, several potential strategic partners in Asia have indicated that they believe that our CHEMOSAT system with doxorubicin may be well received by the medical community in the region. The availability of a CE Marked doxorubicin system provides us with a regulatory pathway for the product in Asia, and we believe it will help us advance partnership discussions in this market."

32. On December 5, 2012, the Company issued a press release entitled, "Delcath Provides Update on NDA Submission for its Chemosaturation System." The press release stated the following in relevant part:

Delcath Systems, Inc. (NASDAQ: DCTH) announced today that after recent discussions with the U.S. Food & Drug Administration (FDA), management has elected to modify the label indication it is seeking in its New Drug Application (NDA) for its proprietary chemosaturation system with melphalan hydrochloride for injection.

Although the Company's Phase 3 trial demonstrated a very positive signal in patients with liver dominant cutaneous melanoma, based upon a recommendation from the FDA, Delcath has decided to focus the Company's NDA indication on the treatment of patients with unresectable metastatic ocular melanoma in the liver. This decision is primarily due to the fact that 90% of the patients enrolled in the Company's Phase 3 trial had ocular melanoma metastases to the liver and the statistically significant efficacy data generated in the trial for this disease. Additionally, FDA-approved treatment options have evolved significantly for metastatic cutaneous melanoma over the past several years, while treatment options for unresectable metastatic ocular melanoma continue to be lacking. Given these facts, the Company believes that its data in ocular melanoma metastases in the liver, coupled with the large unmet need for treatments for this disease, presents the most compelling case for the Company's NDA. The Company hopes that a timely approval of its Chemosaturation system will represent an important step to bring benefits to those cancer patients afflicted with the disease.

> "We are very appreciative of the FDA's interest in our NDA and the progress made to date towards our June 15th 2013 PDUFA goal date," said Eamonn P. Hobbs, President & CEO of Delcath Systems. "Assuming our NDA is approved, we believe our decision to focus the initial labeling of our proprietary chemosaturation system on ocular melanoma, where there is a significant unmet medical need, will have little impact on the Chemosaturation system's revenue potential in the U.S., where physicians typically prescribe cancer treatment options based on clinical data and medical professional experience.
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> "We plan to initiate clinical studies in 2013 to study the use of our chemosaturation system in other tumor types that potentially represent significant commercial opportunities beyond the ocular metastatic melanoma market. Currently, we intend to pursue studies to support label expansion for the use of our system to treat hepatocellular carcinoma and neuroendrocrine cancer patients, and depending on feedback from the FDA could potentially enroll our first patients before the end of 2013."

33. The statements referenced above in ¶¶ 20-32 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts, which were known to defendants or recklessly disregarded by them that: (1) the Company's NDA for Melblez contained risks including substantial and severe toxicity and deaths associated with the drug's adverse reactions; and (2) the Company's manufacturing facilities were in violation of cGMP.

The Truth Emerges

34. On April 30, 2013, the FDA published on its website briefing documents for the Company's Melblez Kit for the upcoming ODAC meeting on May 2, 2013. The briefing documents concluded the following in relevant part:

> The assessment of safety included data obtained in 122 Melblez-Kit treated patients consisting of 70 patients randomized to Melblez Kit treatment (n=42) or who received Melblez Kit treatment following hepatic disease progression (n=28) in Study 1 and 52 patients with primary hepatic cancers or with hepatic metastases from a variety of primary cancers enrolled in an open-label, single center, parallel group, activity estimating trial (Study 2). Substantial and severe toxicity was identified in all three trials with a toxic death rate of 7%. FDA-identified toxic deaths consisted of hepatic failure (n=3), gastrointestinal hemorrhage (n=1), streptococcal sepsis in the setting of bone marrow failure

(n=1), bone marrow failure (n=1), gastric perforation (n=1), and hemorrhagic brain lesions in the setting of bone marrow failure and neutropenic fever (n=1). The serious adverse reactions arising from Melblez Kit treatment were severe hypotension during treatment procedure (despite patients receiving vigorous pretreatment hydration and aggressive vasopressor support during the procedure), prolonged and severe marrow suppression in ≥ 80% of patients, Grade 3-5 infections in 23%, Grade 3-5 hemorrhage in 6%, Grade 3-4 elevations in transaminases or bilirubin in ≥ 20%, gastrointestinal perforation or ulceration due to reflux of melphalan into the gastrointestinal branches of the hepatic artery, and severe electrolyte abnormalities requiring close monitoring post-procedure.

During the clinical development program of the Melblez Kit, an increase in the risk of serious and fatal toxicities was identified following device modifications involving the hemoperfusion filter cartridge component. In exploratory safety analyses, the FDA medical officer identified clinically important differences in the adverse reaction profile in subgroups treated with the devices containing one of the two hemoperfusion filter cartridges in clinical trials. Based on additional exploratory analyses, there appear to be lot-by-lot differences in the risk of fatal adverse reactions. It is FDA's conclusion that differences in the clinical adverse reaction profile were not predicted by bench testing and that Delcath has not identified the critical quality attributes correlate with the changes in the incidence and severity of clinically important adverse reactions. Until the critical quality attributes are defined and validated, FDA will require clinical testing to support approval of modifications of the device for changes in the hemoperfusion filter cartridge component, to characterize the risks of such changes

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Deaths Due To Treatment Related Adverse Reactions
Overall, 7% of the 122 patients in whom Melblez Kit treatment was attempted died as a result of treatment related adverse reactions.

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Melblez Kit is an active treatment with anti-tumor activity; however active treatments are not equivalent to treatments that impart a clinical benefit. The improvements in hPFS and hORR demonstrated in Study 1 did not correlate into clinically important improvements in progression free survival or in overall survival. There is no statistical method that can be applied to demonstrate that crossover of patients to receive Melblez kit treatment is obscuring a survival benefit.

There are unavoidable, life-threatening risks of hypotension-associated stroke and myocardial infarction, bone marrow suppression, hemorrhage, hepatic failure, and gastrointestinal perforation associated with Melblez Kit treatment. Despite careful selection of patients and rigorous training of those who performed the procedure in the clinical trials, there was a high treatment related mortality rate that in the best-case scenario would be replicated in the post marketing setting. Although the

> proposed REMS may assure that new treatment teams will be taught the procedure and be properly certified, there is no basis for concluding that the outcomes will be superior to those observed in clinical trials, that is, that the adverse reaction profile will be better. The REMS program is designed to mitigate the severe risks of Melblez Kit treatment but cannot be expected to eliminate toxicities inherent to this treatment. In addition to the serious risks identified in the review of this application, it is important to include the number of days that the patient is expected to be hospitalized in determining the risk-benefit profile.
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> The proposed drug-device combination product is being reviewed as a NDA under CDER jurisdiction. Under NDA regulations, substantial evidence of effectiveness in adequate and well controlled clinical trials utilizing the proposed drug-device combination product and a favorable benefit risk profile is required for approval.

35. On this news, Delcath shares declined $0.558 per share or over 40%, to close at $0.832 per share on April 30, 2013.

36. On May 2, 2013, the Company announced that the ODAC voted 16 to 0 with no abstentions that benefits of treatment with Delcath's Melblez Kit do not outweigh the risks associated with the procedure.

37. On this news, Delcath shares declined $0.3483 per share or over 44%, to close at $0.4443 per share on May 3, 2013.

CLASS ACTION ALLEGATIONS

38. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf a Class of all persons who purchased or acquired Delcath securities during the Class Period (the "Class"). Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which defendants have or had a controlling interest.

39. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Delcath securities were actively traded on the

Nasdaq. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Delcath or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

40. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

41. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

42. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by defendants' acts as alleged herein;
- whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Delcath;
- whether the Individual Defendants caused Delcath to issue false and misleading financial statements during the Class Period;
- whether defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Delcath securities during the Class Period were artificially inflated because of the defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

43. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

44. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Delcath securities are traded in efficient markets;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the Nasdaq, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased and/or sold Delcath securities between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

45. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

CLAIMS FOR RELIEF

COUNT I

(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)

46. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

47. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

48. During the Class Period, defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Delcath securities; and (iii) cause Plaintiff and other members of the Class to purchase Delcath securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

49. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to

influence the market for Delcath securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Delcath's finances and business prospects.

50. By virtue of their positions at Delcath, defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

51. Information showing that defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of Delcath, the Individual Defendants had knowledge of the details of Delcath internal affairs.

52. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Delcath. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Delcath's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements,

the market price of Delcath securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Delcath's business and financial condition which were concealed by defendants, Plaintiff and the other members of the Class purchased Delcath securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities, and/or upon statements disseminated by defendants and were damaged thereby.

53. During the Class Period, Delcath securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased shares of Delcath securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased said shares, or would not have purchased them at the inflated prices that were paid. At the time of the purchases by Plaintiff and the Class, the true value of Delcath securities were substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Delcath securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

54. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

55. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

56. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

57. (a) During the Class Period, the Individual Defendants participated in the operation and management of Delcath, and conducted and participated, directly and indirectly, in the conduct of Delcath's business affairs. Because of their senior positions, they knew the adverse non-public information about Delcath's misstatement of income and expenses and false financial statements.

(b) As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Delcath's financial condition and results of operations, and to promptly correct any public statements issued by Delcath which had become materially false or misleading.

(c) Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Delcath disseminated in the marketplace during the Class Period concerning Delcath's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Delcath to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Delcath within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Delcath securities.

58. Each of the Individual Defendants, therefore, acted as a controlling person of Delcath. By reason of their senior management positions and/or being directors of Delcath, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause Delcath to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Delcath and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

59. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Delcath.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Awarding compensatory damages in favor of Plaintiff and the other class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs;

D. Awarding rescissionary damages; and

E. Awarding such equitable, injunctive or other relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff hereby demands trial by jury of all issues that may be so tried.

Dated: May 8, 2013