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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): January 30, 2013 (January 26, 2013)**

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**DELCATH SYSTEMS, INC.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State of Incorporation)

**001-16133**  
(Commission  
File Number)

**06-1245881**  
(IRS Employer  
Identification No.)

**810 Seventh Avenue, 35<sup>th</sup> Floor**  
**New York, New York 10019**  
(Address of Principal Executive Offices) (Zip Code)

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 1.01. Entry Into a Material Definitive Agreement.**

On January 26, 2013, Delcath Systems, Inc. (the “Company”) entered into a First Amendment to Research and Distribution Agreement (the “Amendment”) to the Research and Distribution Agreement with CHI-FU Trading Co., Ltd. dated February 9, 2010 (the “Agreement”). The Amendment incorporates various changes to the Agreement, including but not limited to the following: (1) amending the brand name of the Company’s device to the currently used “Delcath Hepatic CHEMOSTAT® Delivery System” name; (2) clarifying that the Company will create the research protocols and have the right to make in person visits to the research locations; (3) amending the timing of the expected receipt of certain regulatory approvals, as well as the timing of milestone payments; (4) incorporating a new requirement that end-users complete training courses; (5) extending the time period for CHI-FU Trading Co., Ltd. to exercise its option to gain distribution rights in Singapore; and (6) allowing CHI-FU Trading Co., Ltd. to appoint sub-distributors and dealers.

The foregoing description of the Amendment is not complete and is qualified in its entirety by reference to the full text of the Amendment, a copy of which is filed herewith as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference, as well as to the full text of the Agreement, which was filed with the Company’s Form 10-Q on May 5, 2010, and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
10.1	First Amendment to Research and Distribution Agreement between Delcath Systems, Inc. and CHI-FU Trading Co., Ltd., dated January 26, 2013.

**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: January 30, 2013

DELCATH SYSTEMS, INC.

By: /s/ Peter J. Graham  
Name: Peter J. Graham  
Title: Executive Vice President,  
General Counsel

**EXHIBIT INDEX**

**Exhibit  
No.**

**Description**

10.1 First Amendment to Research and Distribution Agreement between Delcath Systems, Inc. and CHI-FU Trading Co., Ltd., dated January 26, 2013.

**FIRST AMENDMENT TO RESEARCH AND DISTRIBUTION AGREEMENT**

This FIRST AMENDMENT TO RESEARCH AND DISTRIBUTION AGREEMENT is dated as of January 26, 2013 is by and between **Delcath Systems, Inc.**, a corporation organized and existing under the laws of the State of Delaware, U.S.A. and having offices at 810 Seventh Avenue, 35<sup>th</sup> Floor, New York, New York 10019, U.S.A. (“Delcath”) and **CHI-FU Trading Co., Ltd.**, a corporation organized and existing under the laws of Taiwan, and having offices at 69, Lane 77, Xin Ai Road, 7<sup>th</sup> Floor, Neihu District, Taipei, Taiwan 114 (“Distributor”).

## RECITALS

WHEREAS, Delcath and Distributor entered into a Research and Distribution Agreement dated February 9, 2010 (the “Agreement”); and

WHEREAS, the parties now desire to amend the Agreement.

## TERMS

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Delcath and Distributor agree as follows:

1. All references to “the Delcath Percutaneous Hepatic Perfusion System™” are hereby changed to “the Delcath Hepatic CHEMOSAT® Delivery System.”
2. All references to the “PHP System” are hereby changed to the “CHEMOSAT System.”

Amendment to Section 1

3. Section 1 (I) “PHP System” is hereby deleted in its entirety and replaced by the following: “CHEMOSAT System” shall mean the Delcath Hepatic CHEMOSAT Delivery System to deliver and filter melphalan hydrochloride.”
4. In Section 1(e) the phrase “United States” is hereby added before the word “FDA.”

Amendment to Section 2

5. The following language is added to the first paragraph of Section 2 as a new second sentence: “The first clinical study of the CHEMOSAT System will focus on HCC (as defined in Section 2 (d) below) (“Initial Study”).”
6. The following language is added to the end of section 2(c): “Delcath has the right, but not the obligation, to perform in person visits to each site selected by Distributor for inclusion in the Research, and shall have the right to disqualify such sites or to require modifications to such sites.”

7. Section 2(d) is hereby deleted in its entirety and is replaced by the following:

“The Research will be conducted in accordance with clinical protocol(s) which will be created by Delcath. The initial clinical protocol will focus on hepatocellular carcinoma (“HCC,” also known as malignant hepatoma) and will be sent by Delcath to Distributor within thirty (30) days of the Effective Date of the First Amendment to Research and Distribution Agreement (the “Initial Protocol”). Delcath will seek FDA approval of the clinical protocol(s), if such approval is necessary in Delcath’s sole discretion. The Research will be conducted in accordance with the following: (a) all Applicable Laws, rules and regulations, including but not limited to statutes and regulations pertaining to the protection of human subjects in medical research in the Territory; and (b) all standards applicable in the United States for the conduct of medical research involving human subjects. Delcath shall have the right, but not the obligation, to retain scientific advisors to review the results of the Research to determine, amongst other things, whether the results are clinically adequate.”

8. In Section 2 (g) the word “Research” is hereby deleted and replaced with “Initial Study.”

Amendment to Section 3

9. The following language is hereby deleted from section 3(b): “Promptly after Delcath’s receipt of FDA Approval.” The following language is hereby added to the end of section 3(b): “Delcath also agrees to provide to Distributor within thirty (30) days of Distributor’s written request, copies of any documentation in Delcath’s possession which is reasonably required by Distributor for its application to the Taiwan FDA for approval, notwithstanding whether Delcath has yet received FDA approval.” In addition, the sentence “Distributor is expected to obtain Taiwan FDA Approval within twenty four (24) months of Delcath’s receipt of FDA Approval” is hereby deleted and is replaced with the following: “Distributor is expected to obtain Taiwan FDA Approval within thirty six (36) months of Delcath’s receipt of CE Mark approval of its Generation 2, high-efficiency melphalan filter system.”
10. The phrase “FDA Approval” is hereby deleted from section 3(d) following the phrase “within twenty four (24) months of Delcath’s receipt of.” The following language is hereby inserted in its place: “CE Mark approval of its Generation 2, high-efficiency melphalan filter system.”

11. Section 3(h) is hereby deleted in its entirety and is hereby replaced with the following:

“All clinical and other test protocols for the CHEMOSAT System shall be subject to prior written approval by Delcath before testing is undertaken; on an annual basis, Distributor shall provide Delcath with requested data and information from such tests with a cut-off date no more than sixty (60) days prior to the anniversary date of the first use by Distributor of the CHEMOSAT System in the Territory. The report shall be submitted to Delcath no more than thirty (30) days after the anniversary date of the first use by Distributor of the CHEMOSAT System in the Territory.”
12. The following language is hereby added to the end of section 3(i): “Delcath shall have the right to review these data documents at any of the clinical sites involved in the Research.”

Amendment to Section 4

13. A new Section 4(d)(vii) is hereby added as follows: “attend and provide support for the CHEMOSAT System at appropriate medical trade shows and congresses each year in the Territory at Distributor’s sole expense and as agreed upon by Delcath and the Distributor, including, without limitation, relevant national and international medical trade shows and congresses with a suitable booth displaying the CHEMOSAT System; and”
14. A new Section 4(e) is hereby added as follows: “In case Delcath has reason to believe that CHEMOSAT Systems are actively resold it may require Delcath’s independent accountant to verify the administration of the Distributor in this respect and to report to Delcath. The Distributor shall fully cooperate to provide the information requested by the independent accountant;”
15. A new section 4(f) is hereby added as follows:

“Prior to any CHEMOSAT System being shipped by Distributor to an end-user customer, each end-user customer in the Territory must successfully complete a training course including didactic training and either proctoring by a certified proctor team or by a certified preceptorship team. The certified training course must be approved by Delcath and comply with all Applicable Laws and Government Approvals. Distributor understands and agrees that each end-user must

successfully complete the training course and be certified by the proctor or preceptorship team in order to purchase, receive and use the CHEMOSAT System, except that Distributor may ship initial training CHEMOSAT Systems to the end user customer for the sole purpose of initial training (and identify the CHEMOSAT System and advise the end user customer accordingly).”

16. A new Section 4(g) is hereby added as follows: “Delcath will provide the process for training and certifying end user customers to Distributor as may be amended from time to time by Delcath in its sole and absolute discretion. Distributor shall comply with this process at all times.”
17. A new Section 4(h) is hereby added as follows:

“Distributor may appoint dealers, sub-distributors, agents or sub-contractors (“collectively, the Agents”) to support the distribution of the CHEMOSAT Systems in the Territory, provided, that Distributor shall ensure that each such Agent complies with the terms and conditions of this Agreement and further provided, that Distributor shall be responsible for any and all actions or inactions of each Agent it so appoints and shall indemnify, defend and hold, Delcath and its officers, directors and employees, harmless from and against any and all claims, actions, suits or loss arising out of or related to the actions or inactions of any Agent. Prior to Distributor appointing any Agent, it shall provide written notice to Delcath at least ten (10) days in advance of such appointment and provide the complete name and address and sufficient detail of the proposed scope of services to be provided by each Agent. If Delcath requests a change of Agent, either before or after an appointment, then Distributor will use its reasonable efforts to change such Agent, if reasonably practical.”

#### Amendment to Section 5

18. The following language is added to the end of section 5(a): “for services rendered related to the development of a high efficiency CHEMOSAT System capable of receiving the CE Mark.”
19. The following language is hereby deleted from section 5(b): “Delcath’s receipt of CE Approval of the PHP System.” The following language is added in its place: “enrollment by Distributor of the first patient in a Taiwan FDA approved Initial Study.” The following language is also added to the end of section 5(b): “for services rendered in preparation of said clinical study, including but not limited to protocol development, physician training and site evaluation.”



20. The following language is hereby deleted from section 5(c): “Within thirty (30) days of Delcath’s receipt of FDA Approval.” The following language is hereby added in its place: “Within thirty (30) days of the earlier of: (a) Delcath’s receipt of FDA Approval of the CHEMOSAT System; or (b) either party’s receipt of Taiwan FDA Approval of the CHEMOSAT System.” The following language is also added to the end of section 5(c): “so long as there has been at least one (1) subject enrolled by Distributor in a Taiwan FDA approved Initial Study for use of the CHEMOSAT System, provided, that if one subject has not been enrolled at the time of receipt of FDA or Taiwan FDA Approval, the milestone payment as set forth in this Section 5 (c) shall be made within thirty (30) days of the first subject enrolled in the Initial Study.”

Amendment to Section 7

21. Section 7(c) is hereby deleted in its entirety and is replaced by the following: “The Singapore Option may be exercised by providing written notice to Delcath, no later than ninety (90) days after receipt of regulatory approval in Singapore.”

Amendment to Section 8

22. The following language is hereby deleted from Section 8: “the Effective Date of this Agreement.” The following language is inserted in its place: “the receipt of Taiwan FDA Approval of the use of the CHEMOSAT System.”

Amendment to Section 9

23. The following language is hereby deleted from Section 9: “the Effective Date of this Agreement.” The following language is inserted in its place: “the receipt of Taiwan FDA Approval of the use of CHEMOSAT System.”

Amendment to Section 10

24. A new Section 10(f) is hereby added as follows: “Delcath will endeavour to meet the requested delivery date but Distributor acknowledges that Delcath cannot guarantee delivery dates for any CHEMOSAT Systems, and Distributor agrees that failure to meet any delivery date shall not constitute a breach of this Agreement or any accepted order.”

Amendment to Section 18

25. A new Section 18(i) is hereby added as follows:

“Distributor hereby represents, warrants and covenants to Delcath that (a) it has and will comply with the United States’ Foreign Corrupt Practices Act, as amended, and (b) neither it, nor any of its agents has, and covenants and agrees that neither it, nor any of its agents will, in connection with the transactions contemplated by this Agreement or in connection with any other business transactions involving Delcath, make, offer to make or promise to make any payment or transfer anything of value, directly or indirectly: (i) to any Foreign Official (as defined below) or to an intermediary for payment to any Foreign Official; (ii) to any political party; (iii) to any officer, director or employee, of any actual or potential customer of Distributor; (iv) to any officer, director or employee of Delcath or any of its affiliates; or (v) to any other person or entity, if such payment or transfer would violate the laws of the country in which the transfer is made or the laws of the United States, including without limitation the Foreign Corrupt Practices Act, as amended. It is the intent of the parties that no payments or transfers of value shall be made which have the purpose or effect of public commercial bribery, acceptance or acquiescence in extortion, kickbacks or other unlawful or improper means of obtaining business. This Section 18(i) shall not, however, prohibit normal and customary business entertainment or the giving of business mementos of nominal value in connection with Distributor’s performance under the Agreement. Distributor also hereby represents, warrants and covenants to Delcath that neither it, nor any of its agents, nor any of their owners, officers, directors, or employees, is a Foreign Official. For purposes of this Agreement, the term “Foreign Official” shall include: (i) any officer or employee of the government of any foreign (i.e., non-U.S.) nation or any federal, regional or local department, agency, state-owned enterprise or corporation or other instrumentality thereof; (ii) any employee or official of a public international organizational (iii) any person acting in an official capacity for or on behalf of any of such entities identified in clauses (i) or (ii); and (iv) any official of a political party, or candidate or nominee of any political party in any foreign (i.e., non-U.S.) nation.”

26. A new Section 18(j) is hereby added as follows:

“Distributor agrees to comply with all Applicable Laws including without limitation economic sanctions and export control laws and regulations of the United States of America.

Without limiting the foregoing, Distributor shall not, directly or indirectly, (i) export, re-export, or otherwise dispose of any items received in connection with this Agreement to any person, entity, or destination, or for any use, prohibited under Applicable Laws, without obtaining prior authorization from Delcath, or (ii) engage in transactions with or make any payment to any unauthorized person or entity designated in Applicable Laws. Distributor's breach of this provision shall constitute cause for immediate termination of this Agreement. Distributor agrees to indemnify and hold harmless Delcath for Distributor's noncompliance with such laws or regulations. This provision shall survive termination or cancellation of this Agreement."

27. A new Section 18(k) is hereby added as follows: "Distributor shall complete and send to Delcath an Export Control and Anti-Corruption Compliance Certificate in the form attached hereto as Exhibit A on an annual basis within thirty (30) days of its receipt of Delcath's written request. Delcath shall be entitled to terminate this Agreement immediately in the event of any violation or breach of this Section 18(k) by Distributor."

Amendment to Section 19

28. A new Section 19(e) is hereby added as follows:

"All intellectual property rights, whether existing as of the date of this Agreement or in the future, relating to Delcath, its business, the CHEMOSAT System and this Agreement, including, without limitation, all names, trademarks, copyrights, patents, mask works, trade secrets, know-how, technology, data, designs, specifications, materials, processes, computer software and related documentation and source code and other intellectual property rights ("Delcath Intellectual Property"), are and shall remain the exclusive property of Delcath and nothing in this Agreement shall be deemed to transfer or grant to Distributor a license or other right to use Delcath Intellectual Property, except as expressly provided in this Agreement. Distributor agrees that it shall not, either during the Term or at any time thereafter, reverse engineer or copy the CHEMOSAT System or Delcath Intellectual Property or otherwise use or infringe upon Delcath's Intellectual Property. Upon the termination or expiration of this Agreement, Distributor shall immediately discontinue all use of all Delcath Intellectual Property. Distributor shall immediately notify Delcath if it becomes aware of any infringement, potential infringement

or misappropriation of any Delcath Intellectual Property and shall cooperate with Delcath in any action taken to protect or enforce any of its Delcath Intellectual Property rights. Any intellectual property which Distributor and any of its employees, officers, agents and directors may develop, either alone or jointly, in the course of performing its duties under this Agreement and which relates to the CHEMOSAT System or business of Delcath shall be the property of Delcath and is hereby transferred and assigned to Delcath without any additional compensation, payment or royalty. Distributor shall cooperate in the transfer and assignment of any such intellectual property and shall execute all documents and papers necessary to effectuate the transfer and assignment of such intellectual property to Delcath.”

Amendment to Section 27

29. Delcath’s address in section 27(b) is hereby amended to read as follows:

Delcath Systems, Inc.  
Attention: Eamonn P. Hobbs  
810 Seventh Avenue, 35<sup>th</sup> Floor  
New York, NY 10019

Amendment to Section 30

30. Section 30 is hereby amended to add sections 4(e), 4(h), 18(j) and 19(e) to the list of sections of the Agreement surviving the expiration or termination of the Agreement.

Amendment to Section 34

31. A new Section 34 is hereby added as follows:

“Force Majeure. Any non-performance by either party (other than the payment of money) shall be excused to the extent that performance is rendered impossible or commercially impracticable by fire, flood, hurricane, typhoon, earthquake, war, acts of terrorism, riots, governmental acts or orders or restrictions, strikes, lockouts, failures of suppliers or any other reason where failure to perform is beyond the reasonable control of, and is not caused by the acts, decisions, negligence or willful misconduct of, the non-performing party. A party that would be in breach of this Agreement but for the presence of this Section 34 (the “Affected Party”) shall use its best efforts to remove, remedy

or eliminate (as applicable) the condition or event that resulted in the application of this Section 34. If the Affected Party is unable to do so within sixty (60) days to the reasonable satisfaction of the other party, then the other party shall be entitled to terminate this Agreement upon ten (10) business days notice.”

Amendment to Exhibit A

32. A new Exhibit A is hereby added to the Agreement in the form attached hereto as Exhibit 1.
33. Except as modified herein, the Agreement remains in full force and effect.
34. This Amendment may be executed in one or more counterparts, each of which shall be deemed an original but all of which together will constitute one and the same agreement. Delivery of an executed counterpart by facsimile or by electronic transmission shall be as effective as delivery of a manually signed counterpart.

IN WITNESS WHEREOF, Delcath and Distributor have caused this First Amendment to Research and Distribution Agreement to be executed by their respective authorized representatives to be effective as of the date first written above.

DELCATH SYSTEMS, INC.



By: \_\_\_\_\_  
Name: Agustin Gago  
Title: Executive Vice President, International Operations

CHI-FU TRADING CO., LTD.



By: \_\_\_\_\_  
Name: Wayne Hsu  
Title: Managing Director

**EXHIBIT A**

**EXPORT CONTROL AND ANTI-CORRUPTION COMPLIANCE CERTIFICATE**

Delcath Systems, Inc. ("Delcath") and CHI-FU Trading Co., Ltd. ("Distributor") entered into that certain exclusive distribution agreement dated February 9, 2010 ("Research and Distribution Agreement").

I, \_\_\_\_\_, the duly appointed \_\_\_\_\_ for the Distributor do hereby certify on behalf of the Distributor, that the Distributor and each employee and agent (i) has complied with sections 18(i), 18(j) and 18(k) of the Research and Distribution Agreement, (ii) is not aware of any actions which are in violation of sections 18(i), 18(j) or 18(k) and (iii) will continue to comply with the provisions of sections 18(i), 18(j) or 18(k).

CHI-FU Trading Co., Ltd.

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_