

DELCATH SYSTEMS INC
Form S-3
March 13, 2013
Table of Contents

As filed with the Securities and Exchange Commission on March 13, 2013

Registration No. 333-

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

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of

06-1245881
(I.R.S. Employer

Edgar Filing: DELCATH SYSTEMS INC - Form S-3

Incorporation or Organization)

Identification No.)

810 Seventh Avenue

35th Floor

New York, NY 10019

(212) 489-2100

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Eamonn P. Hobbs

Chief Executive Officer

Delcath Systems, Inc.

810 Seventh Avenue

35th Floor

New York, NY 10019

(212) 489-2100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Andrea L. Nicolas, Esq.

Skadden, Arps, Slate, Meagher & Flom LLP

Four Times Square

New York, NY 10036

Telephone: (212) 735-3000

Facsimile: (212) 735-2000

Approximate date of commencement of proposed sale to the public:

Edgar Filing: DELCATH SYSTEMS INC - Form S-3

From time to time after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer <input type="checkbox"/>	Accelerated filer	x
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

Title of Each Class of Securities to be Registered	Amount to be Registered ⁽¹⁾⁽²⁾	Proposed Maximum Offering Price Per Share ⁽¹⁾⁽²⁾	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee ⁽³⁾
Common stock, par value \$0.01 per share				
TOTAL			\$50,000,000	\$6,820.00

(1) This registration statement covers up to \$50,000,000 of an indeterminate number of shares of common stock.

(2) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate (A) number of shares of common stock and such shares of common stock issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(3) Calculated pursuant to Rule 457(o) under the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated March 13, 2013

PROSPECTUS

\$50,000,000

Common Stock

Delcath Systems, Inc. (the Company) has entered into a sales agreement with Cowen and Company, LLC, or Cowen, relating to shares of our common stock, \$0.01 par value per share, offered by this prospectus. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to \$50,000,000.

Our common stock is traded on the NASDAQ Capital Market under the symbol DCTH. On March 12, 2013, the last reported sale price of our common stock on the NASDAQ Capital Market was \$1.91.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties referenced under the heading Risk Factors on page 6 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Cowen and Company

The date of this prospectus is .

Table of Contents

TABLE OF CONTENTS

	Page
<u>PROSPECTUS SUMMARY</u>	6
<u>RISK FACTORS</u>	6
<u>DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS</u>	7
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	7
<u>USE OF PROCEEDS</u>	8
<u>DESCRIPTION OF CAPITAL STOCK</u>	8
<u>PLAN OF DISTRIBUTION</u>	10
<u>LEGAL MATTERS</u>	11
<u>EXPERTS</u>	11

Table of Contents

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission. We may sell shares of common stock described in this prospectus in one or more offerings up to a total aggregate dollar amount of \$50,000,000. This prospectus provides you with a general description of the securities we may offer. We may provide a prospectus supplement that will contain additional or amended information about the terms of the offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading **Where You Can Find Additional Information**.

You should rely only on the information contained in this prospectus and any accompanying prospectus supplement or incorporated by reference in these documents. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. If anyone provides you with different, inconsistent or unauthorized information or representations, you must not rely on them. This prospectus and the accompanying prospectus supplement are an offer to sell only the securities offered by these documents, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or any prospectus supplement is current only as of the date on the front of those documents.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the section entitled Risk Factors, any applicable prospectus supplement and the documents that we incorporate by reference into this prospectus and any prospectus supplement, before making an investment decision.

DELCATH SYSTEMS, INC.

We are a specialty pharmaceutical and medical device company focused on oncology. Our proprietary technology 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. Our initial focus is on the treatment of primary and metastatic liver cancers. We believe that the proprietary technology is a platform that may have broader applicability, including the use of other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. In 2010, we announced that our randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. We have also completed a multi-arm Phase 2 trial to treat other liver cancers.

Outside of the United States, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT Delivery System for Melphalan). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT System for Melphalan in Europe. We have initiated commercialization efforts in Europe. In October 2012, we satisfied all of the requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin hydrochloride injection (CHEMOSAT System for Doxorubicin), which we believe will provide a regulatory pathway for approval in Asia.

In the United States, our proprietary system for the administration of melphalan hydrochloride to the liver is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration (FDA). We submitted our New Drug Application (NDA) to the FDA on August 15, 2012, with the proposed trade name Melblez Kit™ (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) (Melblez Kit), and are seeking approval for commercial sale of the Melblez Kit in the treatment of patients with unresectable metastatic ocular melanoma in the liver. Our NDA was accepted for filing by the FDA on October 15, 2012 and has been designated for standard review with a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013. An Oncologic Drugs Advisory Committee (ODAC) panel will be convened May 2, 2013 as part of the FDA's review.

We have financed our operations primarily through public and private placements of equity securities. We have incurred net losses since we were founded and we expect to continue to incur significant net losses throughout 2013. We expect that the average amount of capital required for operations to increase in the foreseeable future, as we commercialize the Delcath CHEMOSAT system in Europe, continue research and development activities, continue the approval process with the FDA and prepare for potential US commercialization.

Our principal executive office is located at 810 Seventh Avenue, 35th Floor, New York, NY 10019. Our telephone number is (212) 489-2100. Our website address is <http://www.delcath.com>. Information contained in, or accessible through, our website does not constitute a part of this prospectus.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risk factors set forth in the documents and reports filed by us with the Securities and Exchange Commission, which we refer to as the SEC, that are incorporated by reference into this prospectus, as well as any risks described in any applicable prospectus supplement, before deciding whether to buy our securities. Additional risks not known to us or that we believe are immaterial may also significantly impair our business operations and could result in a complete loss of your investment.

Table of Contents

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, any prospectus supplement and the documents incorporated by reference into this prospectus contain certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as anticipates, expects, intends, plans, predicts, believes, seeks, estimates, could, would, will, may, can, continue, potential, should, and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this prospectus and the other documents incorporated by reference that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 in Item 1A under Risk Factors as well as in Item 7A Quantitative and Qualitative Disclosures About Market Risk and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;

the progress and results of our research and development programs;

the commencement of future clinical trials and the results and timing of those clinical trials;

submission and timing of applications for regulatory approval and approval thereof;

our ability to successfully source certain components of the system and enter into supplier contracts;

our ability to successfully manufacture the Delcath CHEMOSAT/Melblez kitsystem;

our ability to successfully commercialize the Delcath CHEMOSAT/Melblez kit system and successfully obtain reimbursement; and

our ability to successfully negotiate and enter into agreements with strategic and corporate partners.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this prospectus or, in the case of documents incorporated by reference, as of the date of such documents. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of a registration statement we filed with the SEC. You should rely only on the information contained in this prospectus, any applicable prospectus supplement or documents incorporated by reference into this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of securities.

We file reports, proxy statements and other information with the SEC. You may read and copy any reports, proxy statements or other information filed by us at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You may obtain information on the

Edgar Filing: DELCATH SYSTEMS INC - Form S-3

operation of the Public Reference Room by calling the SEC at (800) SEC-0330. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including Delcath Systems, Inc. The address of the SEC website is <http://www.sec.gov>.

Table of Contents

Important Information Incorporated By Reference

The SEC allows us to incorporate by reference information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The documents incorporated by reference into this prospectus contain important information that you should read about us.

The following documents are incorporated by reference into this document:

SEC Filing (File No. 001-16133)	Date of Filing
Annual Report on Form 10-K for year ended December 31, 2012	March 13, 2013
Current Report on Form 8-K	March 13, 2013

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial registration statement and prior to effectiveness of the registration statement, or (ii) from the date of this prospectus but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus, other than exhibits which are specifically incorporated by reference into such documents. Requests should be directed to Controller at Delcath Systems, Inc., 810 Seventh Avenue, 35th Floor, New York, New York 10019 or by calling us at 212-489-2100.

USE OF PROCEEDS

We intend to use the net proceeds from the sale of our shares of common stock covered by this prospectus for general corporate purposes, including, but not limited to, obtaining regulatory approvals, commercialization of our products, funding of our clinical trials, research and development projects, capital expenditures and working capital.

DESCRIPTION OF CAPITAL STOCK

The following description of our common stock, together with the additional information we include in any prospectus supplement and in any related free writing prospectuses, summarizes the material terms and provisions of the common stock that we may offer under this prospectus. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated By-Laws, which are exhibits to the registration statement of which this prospectus forms a part, and by applicable law. We refer in this section to our Amended and Restated Certificate of Incorporation, as amended, as our certificate of incorporation, and we refer to our Amended and Restated By-Laws as our by-laws. The terms of our common stock may also be affected by Delaware law.

Authorized Capital Stock

Our authorized capital stock consists of 170,000,000 shares of our common stock, \$0.01 par value per share, and 10,000,000 shares of undesignated preferred stock, \$0.01 par value per share. As of March 11, 2013, we had 91,173,443 shares of common stock outstanding and no shares of preferred stock outstanding.

Table of Contents

Common Stock

Voting

Holders of our common stock are entitled to one vote per share on matters to be voted on by stockholders and also are entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. Holders of our common stock have exclusive voting rights for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our certificate of incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment or filling vacancies on the board of directors.

Dividends

Holders of common stock are entitled to share ratably in any dividends declared by our board of directors, subject to any preferential dividend rights of any outstanding preferred stock. Dividends consisting of shares of common stock may be paid to holders of shares of common stock. We do not intend to pay cash dividends in the foreseeable future.

Liquidation and Dissolution

Upon our liquidation or dissolution, the holders of our common stock will be entitled to receive pro rata all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock at the time outstanding.

Other Rights and Restrictions

Our common stock has no preemptive or other subscription rights, and there are no conversion rights or redemption or sinking fund provisions with respect to such stock. Our common stock is not subject to redemption by us. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer the stockholder's shares of common stock. If we issue shares of common stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Listing

Our common stock is listed on The NASDAQ Capital Market under the symbol DCTH.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

Certain Anti-Takeover Provisions of Delaware Law and our Certificate of Incorporation and Bylaws

We are not subject to Section 203 of the Delaware General Corporation Law, which prohibits Delaware corporations from engaging in a wide range of specified transactions with any interested stockholder, defined to include, among others, any person other than such corporation and any of its majority owned subsidiaries who own 15% or more of any class or series of stock entitled to vote generally in the election of directors, unless, among other exceptions, the transaction is approved by (i) our board of directors prior to the date the interested stockholder obtained such status or (ii) the holders of two thirds of the outstanding shares of each class or series of stock entitled to vote generally in the election of directors, not including those shares owned by the interested stockholder.

Staggered Board of Directors

Our certificate of incorporation and by-laws provide that our board of directors be classified into three classes of directors of approximately equal size. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings.

Authorized But Unissued Shares

Edgar Filing: DELCATH SYSTEMS INC - Form S-3

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions, employee benefit plans and stockholder rights plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Table of Contents

PLAN OF DISTRIBUTION

We have entered into a sales agreement with Cowen and Company, LLC, or Cowen, under which we may issue and sell from time to time up to \$50,000,000 of our common stock through Cowen as our sales agent. Sales of the common stock, if any, will be made at market prices by any method that is deemed to be an at the market offering as defined in Rule 415 under the Securities Act, including sales made directly on The NASDAQ Capital Market and any other trading market for the common stock, and sales to or through a market maker other than on an exchange.

Cowen will offer the common stock subject to the terms and conditions of the sales agreement on a daily basis or as otherwise agreed upon by us and Cowen. We will designate the maximum amount of common stock to be sold through Cowen on a daily basis or otherwise determine such maximum amount together with Cowen. Subject to the terms and conditions of the sales agreement, Cowen will use its commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us. We may instruct Cowen not to sell common stock if the sales cannot be effected at or above the price designated by us in any such instruction. We or Cowen may suspend the offering of the common stock being made through Cowen under the sales agreement upon proper notice to the other party. We and Cowen each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party's sole discretion at any time.

The aggregate compensation payable to Cowen as sales agent shall not exceed 3.0% of the gross sales price of the shares sold through it pursuant to the sales agreement.

The remaining sales proceeds, after deducting any expenses payable by us and any transaction fees imposed by any governmental, regulatory, or self-regulatory organization in connection with the sales, will equal our net proceeds for the sale of such common stock.

Cowen will provide written confirmation to us following the close of trading on The NASDAQ Capital Market as applicable, each day in which common stock is sold through it as sales agent under the sales agreement. Each confirmation will include the number of shares of common stock sold through it as sales agent on that day, the gross sales price per share, the net proceeds to us and the compensation payable by us to Cowen.

We will report at least quarterly the number of shares of common stock sold through Cowen under the sales agreement, the net proceeds to us and the compensation paid by us to Cowen in connection with the sales of common stock.

Settlement for sales of common stock will occur, unless the parties agree otherwise, on the third business day that is also a trading day following the date on which any sales were made in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

In connection with the sales of the common stock on our behalf, Cowen may be deemed to be an underwriter within the meaning of the Securities Act, and the compensation paid to Cowen may be deemed to be underwriting commissions or discounts. We have agreed in the sales agreement to provide indemnification and contribution to Cowen against certain liabilities, including liabilities under the Securities Act. In addition, we have agreed, under certain circumstances, to reimburse a portion of the expenses of Cowen in connection with this offering up to a maximum of \$35,000. As sales agent, Cowen will not engage in any transactions that stabilize our common stock.

We estimate that the total expenses of the offering payable by us, excluding commissions payable to Cowen under the sales agreement, will be approximately \$250,000.

Table of Contents

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, Skadden, Arps, Slate, Meagher & Flom LLP, New York, New York will provide opinions regarding the authorization and validity of the securities. Skadden, Arps, Slate, Meagher & Flom LLP may also provide opinions regarding certain other matters. Certain legal matters will be passed upon for the sales agent by LeClairRyan, A Professional Corporation, Newark, New Jersey.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2012 and the effectiveness of our internal control over financial reporting as of December 31, 2012, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's reports given on their authority as experts in accounting and auditing.

Table of Contents**PART II****INFORMATION NOT REQUIRED IN THE PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The expenses relating to the registration of the securities will be borne by the registrant. Such expenses (except the SEC Registration Fee) are estimated to be as follows:

	Amount to be paid
SEC Registration Fee	\$ 6,820
Accounting Fees and Expenses	\$ 50,000
Legal Fees and Expenses	\$ 80,000
Printing expenses	\$ 20,000
Miscellaneous expenses	\$ 50,000
 Total	 \$ 206,820

- * Since an indeterminate amount of securities is covered by this registration statement, the expenses in connection with the issuance and distribution of the securities are not currently determinable. The amounts shown are estimates of expenses payable by us in connection with the filing of this registration statement and one offering of securities hereunder, but do not limit the amount of securities that may be offered.

Item 15. Indemnification of Directors and Officers.

The registrant's amended and restated certificate of incorporation, as amended, contains provisions permitted under Delaware law relating to the liability of directors. These provisions eliminate a director's personal liability for monetary damages resulting from a breach of fiduciary duty, except in circumstances involving wrongful acts, such as:

any breach of the director's duty of loyalty to the registrant or its stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of the law;

any act related to unlawful stock repurchases, redemptions or other distribution or payments of dividends; or

any transaction from which the director derived an improper personal benefit.

These provisions do not limit or eliminate the registrant's rights or any stockholder's rights to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of a director's fiduciary duty. These provisions will not alter a director's liability under federal securities laws.

The registrant has entered into indemnification agreements with each of its directors and executive officers that require it to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding or alternative dispute

Table of Contents

resolution mechanism, inquiry hearing or investigation, whether threatened, pending or completed, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of the registrant or is or was serving at the request of the Company as a director, officer or employee of another corporation, limited liability company, partnership or other enterprise, provided that such person's conduct did not constitute a breach of his or her duty of loyalty to the registrant or its stockholders, and was not an act or omission not in good faith or which involved intentional misconduct or a knowing violation of laws. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder. At present, there is no pending litigation or proceeding involving any of the registrant's directors, officers or employees for which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification by the registrant.

The registrant is required to indemnify its other employees and other agents, as permitted by the DGCL or any other applicable law.

The registrant maintains directors' and officers' liability insurance. The policy insures the registrant's directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses the registrant for those losses for which the registrant has lawfully indemnified the directors and officers.

Item 16. Exhibits.

See the Exhibit Index which is incorporated herein by reference.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time

shall be deemed to be the initial *bona fide* offering thereof.

Table of Contents

- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
 - (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

 - (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - 1. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

 - 2. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

 - 3. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

 - 4. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

- (6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Table of Contents

- (7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

- (8) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under section 305(b)(2) of the Trust Indenture Act.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, NY, on March 13, 2013.

DELCATH SYSTEMS, INC.

By: /s/ Eamonn P. Hobbs
 Name: Eamonn P. Hobbs
 Title: President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Eamonn P. Hobbs and Graham G. Miao, and each or any one of them, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement and to sign any and all additional registration statements relating to the Registration Statement and filed pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent or his substitute or substitutes, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Eamonn P. Hobbs Eamonn P. Hobbs	President and Chief Executive Officer, and Director (Principal Executive Officer)	March 13, 2013
/s/ Graham G. Miao Graham G. Miao, Ph.D.	Executive Vice President, Chief Financial Officer (Principal Financial Officer)	March 13, 2013

Table of Contents

Signature	Title	Date
/s/ Barbra C. Keck Barbra C. Keck	Vice President, Controller (Principal Accounting Officer)	March 13, 2013
/s/ Harold S. Koplewicz Harold S. Koplewicz, M.D.	Chairman of the Board	March 13, 2013
/s/ Laura Philips Laura Philips, Ph.D.	Director	March 13, 2013
/s/ Douglas Watson Douglas Watson	Director	March 13, 2013
/s/ Tasos Konidaris Tasos Konidaris	Director	March 13, 2013
/s/ Gabriel Leung Gabriel Leung	Director	March 13, 2013
/s/ Roger Stoll Roger Stoll, Ph.D.	Director	March 13, 2013
/s/ Laura Brege Laura Brege	Director	March 13, 2013

Table of Contents

EXHIBIT INDEX

Exhibit	
Number	Description of the Document
1.1*	Sales Agreement, dated March 13, 2013, between Delcath Systems, Inc. and Cowen and Company, LLC
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended to May 23, 2012 (incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K filed May 29, 2012 (Commission File No. 001-16133).
3.2	Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to Company's Registration Statement on Form SB-2 (Registration No. 333-39470))
5.1*	Opinion of Skadden, Arps, Slate, Meagher & Flom LLP
23.1*	Consent of Ernst & Young LLP.
23.3	Consent of Skadden, Arps, Slate, Meagher & Flom LLP (included in Exhibit 5.1).

* Filed herewith