

September 25, 2019

VIA EDGAR TRANSMISSION

Mr. Russell Mancuso
Branch Chief
United States Securities and Exchange Commission
Division of Corporation Finance
100 F Street, N.E.
Washington, D.C. 20549

Re: Delcath Systems, Inc.
Registration Statement on Form S-1
Filed August 21, 2019
File No. 333-233396

Dear Mr. Mancuso:

Delcath Systems, Inc. (the “Company”) hereby submits this letter in response to the letter dated September 11, 2019 (the “Comment Letter”) from the staff (the “Staff”) of the Securities and Exchange Commission (the “Commission”) relating to the Company’s above-referenced Registration Statement initially filed with the Commission on August 21, 2019 (the “Registration Statement”).

For the convenience of the Staff’s reference, we have set forth below in bold each of the Staff’s comments contained in the Comment Letter immediately followed by the response. The numbered paragraphs and headings correspond to those set forth in the Comment Letter. Concurrently with the submission of this response letter, the Company is filing Amendment No. 1 to the Registration Statement (the “Amended Registration Statement”), which includes revisions made to the Registration Statement in response to the Comment Letter, and to reflect certain additional information. The electronic version of the Amended Registration Statement has been filed concurrently with the Commission through its EDGAR system. The enclosed copy of the Amended Registration Statement has been marked to reflect changes made to the Registration Statement. Capitalized terms used in this response letter but not defined herein have the meaning given to such terms in the Amended Registration Statement.

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1. Given the nature and size of the transaction being registered, advise the Staff of the Company’s basis for determining that the transaction is appropriately characterized as a transaction that is eligible to be made on a shelf basis under Rule 415(a)(1)(i). For guidance, please see the Division of Corporation Finance’s Securities Act Forms Compliance and Disclosure Interpretation Question 214.02 available on the Commission’s website.

Response:

We note the Staff's comment and, specifically, the reference to Compliance and Disclosure Interpretation Question 214.02 ("C&DI 214.02") and we respectfully submit that the proposed resale of shares of the Company's Common Stock by the Selling Stockholders as contemplated in the Registration Statement is not an indirect primary offering and is appropriately characterized as a transaction that is eligible to be made on a shelf basis under Rule 415(a)(1)(i) of Regulation C under the Securities Act of 1933, as amended (the "Securities Act").

Rule 415(a)(1)(i) provides that securities may be registered for an offering on a continuous or delayed basis in the future provided, among other things, that the registration statement pertains only to securities which are to be offered or sold solely by or on behalf of a person or persons other than the registrant, a subsidiary of the registrant or a person of which the registrant is a subsidiary. With regard to the Registration Statement, neither the Company nor any subsidiary of the Company is offering securities under the Registration Statement and the Company is not a subsidiary itself nor is the offering being made on behalf of the Company.

In further consideration of this comment and, based on the Staff's suggestion, we have reviewed C&DI 214.02 and considered the six enumerated factors contained therein and offer the following discussion:

Background.

On each of July 15, 2019 and August 19, 2019, the Company closed on the sale, through bona fide private placements, of Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock, respectively, and issued related Series E Warrants and Series E-1 Warrants to purchase shares of the Company's Common Stock in connection therewith, to certain accredited investors, including the Selling Stockholders named in the Registration Statement, for aggregate gross proceeds of \$29.5 million (together, the "PIPE Financings"). Each PIPE Financing was effected as a private placement exempt from the registration requirements of the Securities Act, pursuant to Section 4(a)(2) and Rule 506 of Regulation D thereunder. The transactions were reported in Current Reports on Form 8-K on each of July 11, 2019, July 22, 2019, August 16, 2019 and August 20, 2019.

The shares to be registered for resale under the Registration Statement amount to 980,557,497 shares of Common Stock issuable to the Selling Stockholders upon the conversion of the shares of Series E Convertible Preferred Stock and Series E-1 Convertible Preferred Stock and the exercise of Series E Warrants and Series E-1 Warrants (collectively, the "Registration Shares"). As disclosed in the Company's other filings with the Commission, the Company contemplates and has recently received stockholder approval with respect to a reverse stock split. The Company's Board of Directors has fixed the split ratio at 1-for-100. It is expected that the request for effectiveness of the Registration Statement would not occur until the reverse stock split is implemented.

In connection with each PIPE Financing, each Selling Stockholder entered into a Securities Purchase Agreement in which, among other things, the Selling Stockholder made customary investment and private placement representations to the Company, including that such Selling Stockholder (i) was an “accredited investor” as defined in Rule 501(a) under the Securities Act, (ii) was acquiring the securities acquired pursuant to an exemption from registration under the Securities Act solely for investment with no present intention to distribute any of the securities to any person, (iii) would not sell or otherwise dispose of any of the securities, except in compliance with the registration requirements of the Securities Act and any other applicable securities laws or pursuant to an applicable exemption therefrom, (iv) had such knowledge and experience in financial and business matters and in investments of this type that such Selling Stockholder was capable of making an informed investment decision and has so evaluated the merits and risks of such investment and (v) was able to bear the economic risk of an investment in the securities and able to afford a complete loss of such investment.

In addition, the Company granted certain customary registration rights to each Selling Stockholder in connection with the PIPE Financings by virtue of a Registration Rights Agreement executed by each Selling Stockholder pursuant to which the Registration Statement was filed.

Factor 1: How Long the Selling Stockholders Have Held the Shares.

The Selling Stockholders have held the securities convertible or exercisable into the Registration Shares as of July 15, 2019, as to the Series E Convertible Preferred Stock and Series E Warrants, and as of August 19, 2019, as to the Series E-1 Convertible Preferred Stock and Series E-1 Warrants, the closing dates of each of the PIPE Financings under which the Selling Stockholders acquired such securities. In addition, pursuant to the Securities Purchase Agreements and related Registration Rights Agreements, the Selling Stockholders understood that the transaction contemplated a minimum holding period of several months until certain conditions were satisfied, including implementation of the reverse stock split (then subject to approval of the Company’s stockholders, which was obtained on September 17, 2019) and the related review by FINRA as well as the completion of the review of the Registration Statement by the Commission.

This holding period demonstrates that the Selling Stockholders acquired the securities convertible or exercisable into the Registration Shares for investment, do not have intent to distribute the Registration Shares on behalf of the Company, and are not acting as underwriters.

Compliance and Disclosure Interpretations Question 116.19 (the “C&DI 116.19”) setting forth the Staff’s views with regard to private placements in public equity provides, in pertinent part, that: “In a PIPE transaction, a company will be permitted to register the resale of securities prior to their issuance if the company has completed a Section 4(2)-exempt sale of the securities (or in the case of convertible securities, of the convertible security itself) to the investor, and the

investor is at market risk at the time of filing of the resale registration statement. The closing of the private placement of the unissued securities must occur within a short time after the effectiveness of the resale registration statement.” Additionally, C&DI 116.19 provides that the investor must be irrevocably bound to purchase a set number of shares at a set price at the time of the effectiveness of the registration statement or thereafter.

Under the circumstances presented, the Selling Stockholders have already purchased and own the securities in question and are at market risk. C&DI 116.19 also indicates that a valid secondary offering could occur immediately following the closing of the private placement and does not provide for a mandatory holding period required for a PIPE transaction to be followed by a valid secondary offering. We submit that the already established holding period of the Selling Stockholders demonstrates a valid secondary offering.

At the time of the purchase of the Company’s securities in the PIPE Financings, the Selling Stockholders appreciated that the market for the Company’s Common Stock was not sufficiently liquid to accommodate sales of a significant portion of the Registration Shares. Trading volume in the Company’s Common Stock is very limited given that the shares are not listed on a national securities exchange, but on the OTCQB, further reflecting the market risk and limited ability to sell the Common Stock. Moreover, based on the size of the Selling Stockholders’ respective investments, which are substantial, it is unlikely that any of them would consider selling their Registration Shares unless there was sufficient liquidity at a trading price substantially above their respective investment amounts, which has not been the case.

Factor 2: Circumstances under which the Selling Stockholders Acquired Their Shares.

As described above under “Background,” the Selling Stockholders acquired the convertible preferred stock and warrants that are convertible or exercisable into the Registration Shares in the PIPE Financings, bona fide private placement transactions conducted pursuant to an exemption from registration under Section 4(a)(2) and Rule 506 of Regulation D of the Securities Act.

As further noted above, each Securities Purchase Agreement contains, among other things, customary investment and private placement representations of the Selling Stockholders to the Company, including, in pertinent part that each such Selling Stockholder “***was acquiring the securities acquired pursuant to an exemption from registration under the Securities Act solely for investment with no present intention to distribute any of the securities to any person.***”

Rule 100 of Regulation M defines a “distribution” as “an offering of securities, whether or not subject to registration under the Securities Act, that is distinguished from ordinary trading transactions by the magnitude of the offering **and** the presence of special selling efforts and selling methods.” The Company is not aware of any evidence that would suggest that any such special selling efforts or selling methods (such as investor presentations or road shows) by or on behalf of the Selling Stockholders have or will take place if the Registration Statement is declared effective.

Factor 3: The Selling Stockholders’ Relationship to the Company.

Based upon information supplied to the Company by the Selling Stockholders, the Selling Stockholders are private investment funds and individual investors purchasing securities for their own accounts and not with a view to resale or distribution. The Company does not have an underwriting relationship with any of the Selling Stockholders or any contractual, legal or other relationship that would control the timing, nature and amount of resales of the Registration Shares following the effectiveness of the Registration Statement or even whether the Registration Shares are resold at all under the Registration Statement. To the Company’s knowledge, at no time has any Selling Stockholder been affiliated with or acted as securities broker-dealers or representatives thereof. Further, as noted above, each of the Selling Stockholders represented to the Company that they were acquiring the securities for their own accounts and not with a view to resale or distribution.

The registration rights granted to the Selling Stockholders under the Registration Rights Agreements entered into in connection with the PIPE Financings are traditional registration rights and are not indicative of any desire of the Selling Stockholders to sell or distribute the Common Stock on behalf of the Company, or at all. The Selling Stockholders negotiated for the customary registration rights set forth in the Registration Rights Agreements for a variety of business reasons, and the registration rights were not granted by the Company for the purpose of conducting an indirect primary offering. In addition, the Selling Stockholders are responsible for paying any broker-dealer fees or underwriting discounts or commissions directly to any broker-dealers they engage to assist in selling any securities, as applicable.

To the extent that the Selling Stockholders sell their Registration Shares, the Selling Stockholders will retain all proceeds from the sale pursuant to the Registration Statement and the Company will not receive any of the proceeds from any resale of the Registration Shares.

Factor 4: The Amount of Registration Shares Involved.

The Company is seeking to register 980,557,497 (prior to the effectiveness of the 1-for-100 reverse stock split noted above) shares of Common Stock for resale.

While the number of shares being registered may remain a factor considered by the Staff in determining whether an offering should be deemed to be a primary or secondary offering, we submit that undue weight on this factor is inconsistent with C&DI 214.02 which, in adherence to the Staff’s prior positions, continues to enumerate six factors for consideration.

We submit that emphasis solely on the number of shares being registered in relation to the shares outstanding or the public float can severely limit a smaller public company's financing alternatives, which are generally few. The Staff has acknowledged this by accepting, as valid, many secondary offerings where a significant number of shares are being registered but the facts do not otherwise demonstrate that the selling stockholders are acting as conduits for the issuer to effect a primary offering.

Notwithstanding the number of shares being registered, the other factors discussed in this response letter such as the Selling Stockholders' investment intent and the circumstances under which the Selling Stockholders acquired their securities, support the position that the offering is correctly characterized as a secondary offering. To wit, none of the circumstances of the offering indicate that the Selling Stockholders are reselling the Registration Shares on behalf of the Company. The duration of the Selling Stockholders' investment in the Registration Shares demonstrates investment intent. The Selling Stockholders did not acquire the Registration Shares under circumstances that would indicate that such persons or entities were receiving compensation from the Company in connection with the resale of the Registration Shares or that the Company had any financial interest in the resale of the Registration Shares. Additionally, as noted above, there is no evidence of special selling efforts or selling methods that would suggest a view to "distribution." Finally, as explained below, to the Company's knowledge, the Selling Stockholders are not in the business of underwriting securities. In light of these circumstances, we submit that the number of Registration Shares being registered for resale should not restrict the Company's ability to use Rule 415(a)(1)(i) for this offering.

We note further that, even if the number of shares being registered were given disparate weight over the other factors to be considered, we submit that the offering should not raise concerns about a primary offering being made due to the extremely limited trading activity in the Company's Common Stock which will limit the ability to sell pursuant to the Registration Statement.

Factor 5: Whether the Selling Stockholders are in the Business of Underwriting Securities.

As noted above, based upon information supplied to the Company by the Selling Stockholders, the Selling Stockholders are comprised of private investment funds and individual investors. To the Company's knowledge, none of the Selling Stockholders is in the business of underwriting securities. Additionally, the issuance of Registration Shares covered by the Registration Statement upon the conversion or exercise of the securities acquired by the Selling Stockholders from the Company was neither conditioned on the prior effectiveness of the Registration Statement nor otherwise conditioned on the Selling Stockholders' ability to resell the shares. The circumstances reflect that the Selling Stockholders made the investment decision to invest in the Company. As such, we submit that none of the elements commonly associated with acting as an underwriter are present.

Factor 6: Whether under All the Circumstances it Appears that the Selling Stockholders are Acting as a Conduit for the Company.

As noted above, the Selling Stockholders acquired the securities convertible or exercisable into the Registration Shares in a bona fide private placement transaction in which they made customary investment and private placement representations to the Company. Since the closing of each PIPE Financing, the Selling Stockholders have borne the full economic risk of ownership of the securities purchased, and likely will continue to do so for a significant period of time given the extremely limited trading activity of the Common Stock.

To the Company's knowledge, the Selling Stockholders are not involved in the business of underwriting securities and have no underwriting or similar relationships with the Company. None of the Selling Stockholders is acting on behalf of the Company with respect to the Registration Shares being registered for resale under the Registration Statement and the Company will receive no portion of the proceeds from any Selling Stockholder's sale of Registration Shares. Each Selling Stockholder has represented to the Company that it was acquiring the securities acquired for its own account and not with a view to or for distributing or reselling the securities in violation of the Securities Act. Notably, the amount of Registration Shares could not readily be sold in a market as illiquid as that for the Company's Common Stock.

For the reasons described above, we respectfully submit that the Selling Stockholders are not acting as underwriters on behalf of, or as a conduit for, the Company.

Conclusion.

We acknowledge the Staff's guidance and respectfully submit that, based on the foregoing, the proposed resale of the Registration Shares by the Selling Stockholders upon conversion and exercise of the securities acquired by them as contemplated by the Registration Statement is appropriately characterized as a secondary offering that is eligible to be made on a shelf basis under Rule 415(a)(1)(i).

The Company has a history of reverse splits..., page 28

2. We note your disclosure here and on pages 56, 60 and 97 that you are incorporating certain information into your prospectus by reference. Please provide us your analysis that led you to conclude that you are eligible to incorporate by reference as you have done.

Response:

We note the Staff's comment and advise that the Company has made revisions to the Registration Statement consistent with Item 12(a)(2) of Form S-1 to reflect that there is no intention to incorporate by reference.

Exhibits, page II-9

3. Please ensure that you have filed your complete certificate of incorporation as amended to date. In this regard, we note that Exhibit 3.4 does not appear to authorize your Board of Directors to designate series of preferred stock; however, we note that your exhibit index also includes Certificates of Designations of preferred stock which appear to reflect that your board has designated series of preferred stock. Please include in your response the date that you filed a proxy statement related to any shareholder vote amending Exhibit 3.4 to authorize preferred stock.

Response:

We note the Staff's comment and advise that the Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company dated July 20, 2016 filed as Exhibit 3.4 inadvertently omitted necessary language and was subsequently corrected by a Certificate of Correction executed and filed with the Secretary of State of the State of Delaware on June 23, 2017. This Certificate of Correction was not previously filed by the Company with the Commission. Included as Exhibit 3.1 to the Amended Registration Statement is the complete copy of the certificate of incorporation of the Company, as amended.

Undertakings, page II-10

4. Please provide the undertaking required by Item 512(a)(2) of Regulation S-K.

Response:

We note the Staff's comment and, as requested, the Amended Registration Statement has been revised to include the undertaking required pursuant to Item 512(a)(5)(2) of Regulation S-K.

We welcome the opportunity to discuss any aspect of this response letter with you further. Should there be questions regarding our response or should the Staff require additional information, please contact the undersigned at (212) 489-2100.

Very truly yours,

DELCATH SYSTEMS, INC.

By: /s/ Barbra Keck

Name: Barbra Keck

Title: Chief Financial Officer

cc: Jennifer Simpson, Chief Executive Officer, Delcath Systems, Inc.
Michele Vaillant, Esq., McCarter & English, LLP