

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

March 16, 2014

Via E-mail
Dr. Eric Leire
Chief Executive Officer
DanDrit Biotech USA, Inc.
P.O. Box 189
Randolph, VT 05060

Re: DanDrit Biotech USA, Inc.

Registration Statement on Form S-1

Filed February 14, 2014 File No. 333-193965

Dear Dr. Leire:

We have reviewed your registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

General

- 1. We note that your Form 8-K, filed on February 14, 2014 in connection with your consummation of an Agreement and Plan of Share Exchange on February 12, 2014, provides certain required disclosures by reference to the information included in this Form S-1. Please be advised that Form 8-K allows incorporation by reference so long as the referenced document or statement is filed as an exhibit to the Form 8-K. See Instruction F. to Form 8-K for further guidance. Accordingly, you must file an amendment to your Form 8-K that expressly includes the S-1 as an exhibit.
- 2. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 3. Please confirm that the images included in your registration statement are all of the graphic, visual or photographic information you will be including. If you intend to use

any additional images, please provide us proofs of such materials. Please note that we may have comments regarding this material.

4. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

Prospectus Summary, page 1

5. In your discussion of the offering here and in the Plan of Distribution section, please clarify when the offering by the selling shareholders will commence. If it will not commence until after completion of the company's offering, please make this clear and describe any agreements, written or oral, with the selling shareholders to ensure that they will adhere to these constraints. If the shareholders' resale offering will commence and could be conducted during a period when the company's offering is still ongoing, please advise investors of this in the prospectus and add a risk factor addressing the risks of this concurrent offering to the company's ability to raise necessary funds in its own offering. Please make any comforting changes, as necessary, to the separate resale prospectus as well.

Summary of Consolidated Financial Data, page 7

6. Please tell us how the "earnings per share" that you present here and elsewhere outside of the financial statements based on the DanDrit Biotech A/S and subsidiaries' capital structure is relevant to an investor. Also advise why you use the term "earnings" when only losses have been incurred.

Risk Factors, page 9

- 7. Please revise your disclosure to include a risk factor related to the risks posed by the self-underwritten nature of your offering. The risk factor should explain that no underwriter has engaged in any due diligence activities and that an underwriter's due diligence obligations go to confirming the accuracy of the disclosure in the prospectus as well as providing input as to the offering price.
- 8. On page 59, you state that the focus of your product approval efforts is primarily on the U.S. market. As your clinical trials have to date been conducted in Denmark and Singapore, please add a risk factor that discusses any risks to your U.S. commercialization strategy from conducting trials outside of the United States. For

example, you should address the possibility that the FDA may not accept the results of such trials and how such lack of acceptance could impact the regulatory approval process.

Risks Associated with DanDrit's Business and Industry, page 9 "DanDrit has occurred losses in prior periods and expect...," page 9

9. Please disclose the amount of your accumulated deficit.

"DanDrit is dependent on its ability to recruit and retain...," page 12

10. Please disclose any past difficulties you have experienced recruiting and retaining qualified scientific and management personnel.

"There may be delays or difficulties in the recruitment...," page 14

11. Please disclose any past difficulties you have experienced recruiting patients for your clinical trials.

"We have insufficient funds to develop our business..." page 15

12. Please disclose in this risk factor how long you expect your business operations to continue given your current amount of cash and funds, which should also be provided here. If you expect that your business operations cannot continue for twelve months given your current amount of cash and funds, please disclose the amount of additional financing necessary to continue operations for twelve months.

Risks Related to Ownership of Our Common Stock, page 19

13. We note that, as an emerging growth company under the Jumpstart Our Business Startups Act, you have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1). Please state in this risk factor that, as a result of this election, your financial statements may not be comparable to companies that comply with public company effective dates. Include a similar statement in your critical accounting policy disclosures. In addition, consider describing the extent to which any of the disclosure requirement exemptions available to you as an emerging growth company are also available to you as a Smaller Reporting Company.

Use of Proceeds, page 24

14. Please expand your disclosure here to disclose your anticipated use of proceeds from the offering assuming, respectively, that only 75%, 50% and 25% of the securities offered by the company are sold.

15. Please disclose the anticipated stage of development that you estimate the proceeds from this offering will allow you to reach.

Capitalization, page 26

16. It is not clear what "on an actual basis" means as the "actual" column does not agree to historical financial statements in the filing. Please revise.

Management's Discussion and Analysis Results of Operations, pages 31 and 33

17. You explain that the reduction in 2013 and the increase in 2012 of operating expenses is due expenses incurred in 2012 for consulting related to conversion of your financial statements to IFRS and preparation of this prospectus. Please tell us the amount of these expenses and why your explanations are reasonable considering that your financial statements are prepared in accordance with U.S. GAAP and this prospectus was filed on February 14, 2014, more than a year after the end of 2012.

Liquidity and Capital Resources, page 34

18. Please consider whether the numerous events listed in the current format clearly and concisely communicate the registrant's capital and liquidity requirements, and revise as necessary.

Our Business, page 37

- 19. We note your statement on page 37 that "for more than a decade, [you] have developed and patented compounds successfully used in successful clinical trials in Europe and Asia." Please expand your disclosure to elaborate on this statement, providing specifics as necessary to support this assertion.
- 20. Throughout your prospectus, when characterizing the results of your clinical trials, you state that MCV has "demonstrated efficacy" or that efficacy "has been proven." We also note your characterization of MCV as "safe" and having a "perfect safety profile" several times in reference to clinical trial results. Because approval of the FDA and other comparable regulatory agencies is dependent on such agencies making a determination (according to criteria specified in law and agency regulations) that a drug or biologic is both safe and effective, it is premature for you to describe or suggest that MCV, or any other non-approved product as safe and/or effective. Accordingly, please delete this wording throughout your prospectus, as applicable. In addition, please revise your disclosure as necessary to make clear that any observations you make about your products' potential for safety and/or efficacy are your own, are not based on the FDA's or any other comparable governmental agency's assessment and do not indicate that your products will achieve favorable results in any later stage trials or that the FDA or

comparable agency will ultimately determine that your product is safe and effective for purposes of granting marketing approval.

- 21. We also note your statement that "all dendritic cell-based vaccinations are safe with no life-threatening side effects" on page 43. If true and supportable by credible, available evidence, you may state that no dendritic cell-based vaccine has to date demonstrated life-threatening side effects, but it is inappropriate to make a conclusory statement about these vaccines that could imply that your product will be determined to be "safe" by the FDA comparable regulatory agency. Similarly, please revise your statement on page 43 that vitiligo "does not" occur with MCV to state that this skin conditioned "has not" occurred, to your knowledge, with MCV in clinical trials conducted to date.
- 22. Please define the terms "antigen" and "lysed cells" the first time you use them in this section.
- 23. In your discussion on page 43 under the caption "Our Biotechnology" please briefly clarify why the use of autologous tumor lysate is "inconvenient."
- 24. We also note your statement in the second-bullet in this section that your "cancer-specific antigens are off-the-shelf and therefore DanDrit does not need a patient's tumor cells to manufacture the vaccine." However, on page 29 you state your belief that the GeniusVac technology "may allow DanDrit to develop a 100% off-the-shelf cancer vaccine." Please revise this and any other similar discrepancies throughout your prospectus.

Our Proposed Clinical Trial, page 37

- 25. Please define the term "Proof of Concept (PoC) Study."
- 26. When you discuss the possibility that will conduct your Proof of Concept study with "an adaptive design," please clarify the position of the FDA and the European Union on the use of adaptive design studies.
- 27. Please disclose whether you have filed an investigational new drug application ("IND") with the FDA with respect to any clinical activities or in anticipation of your proposed clinical trial. If so, please disclose the date of filing, the subject matter and status of the IND.

Products, page 38

- 28. When you reference Singapore's permission to use MCV for CRC on a humanitarian named patient basis, please explain:
 - what a "named patient basis" is;
 - when this permission was given;

- the criteria employed by Singapore for determining whether to allow this treatment;
- whether this humanitarian therapy continues; and
- how many patients in Singapore have received this treatment and the outcomes for these patients

Please also make conforming changes to the discussion that appears near the top of page 45.

29. We note your statements with respect to clinical trials of MCV that:

"Several patients given just months to live were alive and enjoyed high quality of life two years after MCV therapy commenced. Several patients showed stable disease with no progression of tumors. There was evidence of tumor regression in some patients."

Please delete this language or put this selected information into its full and proper context by providing the specific details and parameters of the studies from which this data was drawn, including clinical endpoints, size of patient population, comparison against placebo or standard treatment, statistical significance, etc. Without this contextual information, some of which appears in in your section entitled "Clinical Trials Data" beginning on page 43, it may be difficult for the reader to draw an accurate and balanced assessment of these favorable results.

Dendritic Cells, The Therapeutic Platform, page 39

- 30. Please disclose whether Professor Zeuthen, his c9ollegues at the Danish Cancer Society, or any other third-party retains any rights to the intellectual property underlying the company's business, technology or product candidates, including MCV. We may have further comments based on your response.
- 31. Please specify the "several technologies relevant to dendritic cell production" that DanDrit has developed and to which you make reference on page 39.
- 32. Please define the terms "cytokines" on page 41.

Clinical Trials Data and Product Approvals, page 43

33. It appears that the clinical trials for MCV that you describe beginning on page 43 all concluded several years ago. If you have not already done so, please specify the precise dates for the commencement and completion of each of these trials and make clear how long it has been since the last clinical trial of MCV was conducted.

Colorectal Cancer (CRC) in Denmark, page 43

34. Please expand your discussion of this trial to disclose the specific clinical endpoints established by the trial protocol, the duration of treatment, all of the metrics utilized and the actual results observed. For example, because evaluation of responses was made according to the RECIST criteria, you should briefly explain what the criteria are, how they are applied and provide the clinical observations about patients' RECIST responses from this trial. Similarly, you should discuss the results from the CT scans, Common Toxicity criteria and quality of life questionnaires. Then summarize the conclusions drawn and the extent to which the data suggested efficacy and safety, including whether statistical significance was demonstrated.

Please make similar revisions to the discussions of the NSCLC trial in Denmark and the CRC trial in Singapore on pages 43-44.

- 35. Please specify the criteria used for determining disease "stability" in patients.
- 36. Please specify the improvements you have made to the MCV vaccine and discuss the possibility that replacing the "early" formulation of MCV, which was used in this trial, with an "improved MCV" vaccine in future trials could negatively impact your ability to rely on the results of the prior trial in seeking FDA approval.

Non-small cell lung cancer (NSCLC) in Denmark, page 44

- 37. We note your statement that the "initial" results of this trial were encouraging. Please revise to clarify the extent to which these initial results were sustained for the entirety of the trial.
- 38. Please clarify the meaning of a "43% response rate." For example, how was it calculated and what were the criteria (magnitude, duration, etc.) for determining that an immunological reaction qualified as a sufficient "response"?
- 39. Please specify the actual results observed with respect to the secondary objectives of the trial.

Colorectal Cancer (CRC) in Singapore, page 44

40. Please quantify your characterization of the patients' quality of life as remaining "high and stable" throughout the study and make clear the criteria and specific observations on which this assessment was based. Similarly, please summarize the criteria and data which supported the conclusion that "significant immunological and clinical correlation was observed. Finally, please describe the standards used for determination of an objective response to MCV.

41. Please describe the extent of your efforts to scale up manufacturing and compassionate use in Singapore since 2009.

Future: 100% Off-the-Shelf Vaccines, page 45

42. Please disclose whether you have any oral or written agreement in place with EFS/GeniusVac. If so, please also disclose the material terms of this arrangement and include it as an exhibit to your draft registration statement.

Proposed Clinical Trial, page 47

- 43. Please disclose the requirements for a clinical trial to be considered Phase IIb/III and explain why your proposed clinical trial will meet those requirements.
- 44. Please disclose whether you have any oral or written agreements in place, or have begun discussions with Dana Farber, the Institut Gustave Roussy or the National Cancer Institute of Milan to participate in your proposed trial. If so, please also disclose the material terms of these arrangements and include them as exhibits to your draft registration statement.
- 45. Please define the terms "DTH," "ELISPOT" and "CD" antigen profiles.
- 46. Please disclose the extent of any communications with the FDA to date about your proposed trial.

Licensing Potential and Cooperation Agreements, page 53

- 47. We note your discussion of a potential alliance with a Chinese partner. Please disclose the basis for your cost estimates of conducting a Phase III trial in China for "approximately one tenth of the cost in the U.S."
- 48. Please briefly describe the pipeline of other dendritic cell-based cancer therapies that you reference and explain how derived your estimate that this pipeline currently addresses 40% of all cancer-related deaths.
- 49. Please include your agreement with MyTomorrows regarding the patient Name Use Program for MCV as an exhibit to your draft registration statement.

Intellectual Property, page 54

50. Your patent disclosure on pages 54-58 may not be sufficiently comprehensible to readers lacking necessary technical knowledge and familiarity with this type of information. Please revise this disclosure so that the material information you wish to convey to investors can be more readily understood by a lay audience. For example, consider

breaking up each family or subset of patents and patent applications by including explanatory text that clarifies:

- How the patent or patents relate to the company's products;
- The type of protection conveyed;
- A brief discussion of the particular process, composition, manner of use covered;
- The jurisdiction granting the protection;
- The duration or expected duration of the patent;
- Whether the patent is owned or licensed and, if licensed, from whom; and
- The expiration dates

Please also provide a brief explanation of what each of the columns, such as "priority data and "national entries of PCT application" mean, if not self-evident. In sum, your revised disclosure should make clear to investors why the information you have listed is important to an understanding of the company's intellectual property and the business as a whole.

51. Please explain the meaning of each acronyms the first time you use it in this section, including "PCT", "DK", "CH", "ES", "FR" and "DE."

Competition, page 61

52. Please revise the graphic that appears at the top of page 61 to make clear what the sizes of the various bars correspond to. In addition, please make the company's name in the "Colorectal" column the same font size as the names of its competitors.

<u>Description of Securities, page 72</u> <u>Common Stock, page 72</u>

53. Please disclose the vote required by shareholders to take action, as required by Item 202(a)(1)(v) of Regulation S-K.

Shares Eligible for Future Sale, page 75 Lock-Up Agreements, page 75

54. When available, please file a form of lock-up agreement as an exhibit to the registration statement.

Pro Forma Financial Statements, F-60

55. Please remove unaudited pro forma condensed combined statements of operations other than for the latest fiscal year and interim period, if any. Refer to Rule 8-05 of Regulation S-X.

<u>Item 15. Recent Sales of Unregistered Securities, page II-2</u>

56. Please revise your disclosure so that it pertains only to transactions that involve the sale of securities. For further guidance, refer to the requirements of Item 701 of Regulation S-K.

Item 17. Undertakings, page II-4

57. Please provide the undertakings required by Item 512(i) of Regulation S-K.

Exhibit 23.2

58. This exhibit consents to the use of the February 12, 2014 report for DanDrit Biotech A/S and Subsidiaries and not to the December 31, 2013 report for the "Company." Please revise.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow

adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Scott Wuenschell at (202) 551-3705 or James Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Christina De Rosa at (202) 551-3577, Dan Greenspan at (202) 551-3623 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: Via E-mail
David N. Feldman
Richardson & Patel LLP
The Chrysler Building
405 Lexington Avenue, 49th Floor
New York, NY 10174