

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

May 21, 2014

Via E-mail
John McDonough
President and Chief Executive Officer
T2 Biosystems, Inc.
101 Hartwell Avenue
Lexington, Massachusetts 02421

Re: T2 Biosystems, Inc.

**Draft Registration Statement on Form S-1** 

Submitted April 24, 2014 CIK No. 0001492674

Dear Mr. McDonough:

We have reviewed your draft 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 providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. 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 the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

#### Prospectus Summary, page 1

- 1. Please expand the disclosure in this section to disclose the amount of your net losses and your accumulated deficit as of December 31, 2013.
- 2. Please expand the disclosure in your summary to clarify the material hurdles, including expected costs, that remain until you can sell a product commercially. In this regard, you state that you "expect to apply for clearance" from the FDA in the second quarter of 2014, but this does not describe what the clearance process entails, in terms of time and financial resources, from where you currently stand.

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- 3. In addition, please clarify here and elsewhere as appropriate, whether you have made any PMA or 510(k) submission to the FDA, since your use of the term "clearance" is not specific. Also, explain in more detail how you concluded that you would likely get "clearance" in the first half of 2015.
- 4. Please address here, in your business section, and in the risk factors, as appropriate, whether you have data showing that speed of test results is the only or most common reason why initiation of therapy may be delayed.
- 5. Please explain what you mean when you say that your product candidates "can deliver actionable results as fast as three-and-one-half hours." In particular, to which candidates are you referring? Also, explain why say that they "can deliver" the results that rapidly. Is this time an average, or something else?
- 6. Please expand the disclosure in the last sentence on page 1 and in the last paragraph on page 71 to state when the study was published in the *American Journal of Respiratory and Critical Care Medicine*.

#### <u>Implications of Being an Emerging Growth Company, page 4</u>

7. 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.

#### Use of Proceeds, page 45

8. Please disclose the portion of the proceeds that you intend to use for each of the purposes mentioned in the third paragraph on page 45.

## Capitalization, page 46

- 9. Please revise to remove the caption relating to cash and cash equivalents from your presentation of capitalization.
- 10. We note here and throughout the filing that you have presented pro forma adjustments relating to the automatic conversion of all outstanding shares of your preferred stock into shares of common stock. We further note from page F-28 that such automatic conversion occurs either upon the closing of an offering meeting certain criteria or upon the written

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consent of the holders of a majority of the then-outstanding shares of Preferred Stock. Please explain to us why you believe these pro forma adjustments are factually supportable. Tell us whether you presently expect the offering to meet the criteria that the public offering price be equal to or exceeding \$12.4211 per share and gross proceeds of the offering be not less than \$40,000,000. If you instead have concluded that the automatic conversion will be triggered by the written consent of the holders of a majority of the outstanding shares of preferred stock, tell us your basis for this conclusion. If management subsequently concludes the conditions may not be satisfied, please revise the filing accordingly.

## Clinical Utility, page 72

- 11. We note that your summary appears to include some numeric results from your "pivotal clinical trial." Please explain how your disclosure here relates to that summary information and how you will use the results of the trial to support your FDA application.
- 12. Please revise the disclosure related to the table at the bottom of page 73 so that the information can be understood by an investor not in your industry. In making these revisions, please explain or define terms like "krusei."

### Item 16. Exhibits and Financial Statement Schedules, page II-4

- 13. We note that you plan to file a request for confidential treatment for portions of exhibits to your draft registration statement. We will provide any comments on your request separately.
- 14. We note that you refer in Item 16(b) to Rule 24b-2 under the Securities Exchange Act of 1934. Please revise to refer instead to Rule 406 of the Securities Act of 1933.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

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You may contact Gary Newberry, Staff Accountant, at (202) 551-3761 or Kevin Vaughn, Accounting Branch Chief, at (202) 551-3643 if you have questions regarding comments on the financial statements and related matters. Please contact Tom Jones at (202) 551-3602 or me at (202) 551-3528 with any other questions.

Sincerely,

/s/ Amanda Ravitz

Amanda Ravitz Assistant Director

cc (via e-mail): Johan V. Brigham