



DIVISION OF  
CORPORATION FINANCE

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

October 2, 2013

Via E-mail

Sharon Mates, Ph.D.  
President and Chief Executive Officer  
Intra-Cellular Therapies, Inc.  
3960 Broadway  
New York, NY 10032

**Re: Intra-Cellular Therapies, Inc.  
Form 8-K  
Filed September 5, 2013  
File No. 000-54896**

Dear Dr. Mates:

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

Please respond to this letter within 10 business days by providing the requested information or by advising us when you will provide the requested response. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing the information you provide in response to these comments, we may have additional comments.

General

1. We note your pending confidential treatment request and advise you that we will not be in a position to conclude our review of your filing until all comments on your confidential treatment request have been resolved. We will deliver any comments to your confidential treatment request under separate cover.

Item 2.01

Our Clinical Programs, page 12

2. Please revise the narrative discussion of your clinical programs on pages 12-15 to ensure that the discussion corresponds to the table of your therapeutic pipeline on page 12. If you include a product or specific treatment indication in the table, this should be covered by the discussion that follows. Likewise, if the narrative discussion refers to a product or specific treatment indication, this should be accurately reflected in the table. For example, the table suggests that all seven of the indications in development for your ITI-

007 program are in some stage of clinical trials, yet the narrative that follows on pages 12-14 does not appear to be entirely consistent with this. As another example, you state on page 13 that “ITI-007 has completed multiple Phase 1 and 2 clinical trials.” However, the table on page 12 suggests that ITI-007 has not yet completed Phase 2 for any indication.

3. Similarly, the table on page 12 suggests that ITI-007 is currently in Phase 1 trials for treatment of several sleep disorders, major depressive disorder, autism, PTSD and IED. However, we note risk factor disclosure on page 34 where you indicate that you have “never tested ITI-007 in clinical trials” for indications other than acute schizophrenia. Please reconcile your disclosure as necessary to reconcile this apparent discrepancy.
4. Please expand the discussion on pages 12-15 to include the following information for each of your product candidates, on an indication-by-indication basis, to the extent clinical trials have been completed, are currently being conducted, or are expected to commence in the near future:
  - the dates and respective locations of the trials;
  - the design and goals of the trials;
  - the number of patients involved; and
  - if applicable, a brief summary of the data and results obtained from the trials

In your discussion, please identify any significant clinical endpoints and the extent to which such endpoints were met. In addition, please disclose the nature and frequency of any adverse events which have occurred.

5. We note your disclosure on page 13 that Phase 3 clinical trials to address the therapeutic utility of ITI-007 in bipolar disorder “are planned to be conducted in parallel with” Phase 3 trials for schizophrenia. As it does not appear that you have completed Phase 1 trials for bipolar disorder or Phase 2 trials for schizophrenia, please revise your disclosure to clarify your intended timeline for the parallel Phase 3 studies of ITI-007.
6. Please disclose in this section whether there is an active investigational new drug application (IND) for each of the following:
  - ITI-007 for treatment of schizophrenia;
  - ITI-007 for treatment of sleep maintenance insomnia;
  - ITI-007 for treatment of bipolar disorder;
  - ITI-007 for behavioral disturbances associated with dementia and Alzheimer’s; and
  - ITI-214 for treatment of cognitive dysfunction in schizophrenia

In each case, if an IND has been filed for the compound and corresponding treatment indicated, please disclose the identity of the filer and the date of the filing. If a separate IND has not been filed, please explain why.

License Agreement, page 16

7. We note your discussion of the license agreement with Bristol-Myers Squibb. Please expand to disclose the amount of payments made under the agreement to date, the total aggregate potential milestones you may be required to make in the future, and the applicable royalty rate you may be required to pay on sales of licensed products.

Collaboration Agreement, page 17

8. We note your discussion of the license and collaboration agreement with Takeda. Please disclose the applicable royalty rate Takeda must pay to you based on net sales of a licensed product.

Risk Factors

“Safety issues with our product candidates...,” page 34

9. Please disclose in this section whether you are currently aware of any side effects associated with your own product candidates or similar products of third parties that could adversely affect the development, regulatory approval or commercialization of your product candidates.

“Consumers may sue us for product liability...,” page 52

10. We note your disclosure that you currently have product liability insurance. Please provide the dollar amount of your product liability insurance coverage in this risk factor.

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 all information the Securities Exchange Act of 1934 and all applicable Exchange 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.

In responding to our comments, please provide a written statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and

Sharon Mates, Ph.D.  
Intra-Cellular Therapies, Inc.  
October 2, 2013  
Page 4

- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

You may contact Ibolya Ignat at (202) 551-3656 or Jim Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Austin Stephenson at (202) 551-3192, 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  
William Hicks, Esq.  
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.