Intra-Cellular Therapies, Inc. 3960 Broadway New York, NY 10032

October 15, 2013

## VIA EDGAR & FEDEX

Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

Attention: Jeffrey P. Riedler, Assistant Director

Ibolya Ignat Jim Rosenberg Austin Stephenson Daniel Greenspan

Re: Intra-Cellular Therapies, Inc. Form 8-K Filed September 5, 2013

File No. 000-54896

## Ladies and Gentlemen:

Intra-Cellular Therapies, Inc. (the "Company") is hereby filing with the Securities and Exchange Commission (the "Commission") Amendment No. 1 (the "Amendment") to the Company's Current Report on Form 8-K, initially filed with the Commission on September 5, 2013 (the "Form 8-K"). Set forth below are the Company's responses to the comments of the staff (the "Staff") of the Division of Corporation Finance of the Commission provided by letter dated October 2, 2013 (the "Comment Letter") from Jeffrey P. Riedler, Assistant Director, to Sharon Mates, Ph.D., the Company's Chairman, President and Chief Executive Officer.

For convenient reference, we have set forth below in italics the Staff's comments set forth in the Comment Letter and have keyed the Company's responses to the numbering of the comments and the headings used in the Comment Letter. Where appropriate, we have responded to the Staff's comments by making changes to the disclosure in the Form 8-K set forth in the Amendment. Page numbers referred to in the responses below reference the applicable pages of the Amendment. The Amendment also includes other updated or additional disclosure provided by the Company.

We are delivering one marked complete courtesy copy of the Amendment and one courtesy copy of this letter to Mr. Riedler, as well as to each of Ibolya Ignat, Jim Rosenberg, Austin Stephenson and Daniel Greenspan of the Staff.

#### General

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.

**Response:** The Company respectfully acknowledges the Staff's comment and confirms its understanding that all comments with respect to the confidential treatment request must be resolved to conclude the Staff's review of the Form 8-K.

### 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 page12. 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 12 to 15, including the therapeutic pipeline chart on page 12.

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.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 13 and 34.

- 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.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 13 to 15.

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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 13.

- 5. 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on pages 13 and 14. In addition, the Company advises the Staff supplementally that it has not filed separate INDs for each potential indication of ITI-007, including for the treatment of sleep maintenance insomnia, bipolar disorder or behavioral disturbances associated with dementia and Alzheimer's disease, because the rules and regulations of the U.S. Food and Drug Administration do not require separate INDs for Phase 1 studies even though the data can be used to support multiple indications.

## 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 16.

### 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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 17.

### **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.

Response: In response to the Staff's comment, the Company has revised the disclosure on page 34.

### "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.

**Response:** In response to the Staff's comment, the Company has revised the disclosure on page 52.

In responding to the Staff's comments, the Company acknowledges 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
- 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.

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We hope that the above responses and the related revisions reflected in the Amendment will be acceptable to the Staff. Please do not hesitate to call me at (212) 923-3344 or the Company's legal counsel, William C. Hicks or Scott A. Samuels of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. at (617) 542-6000 with any comments or questions regarding the Amendment and this letter. We thank you for your time and attention.

Sincerely,

/s/ Sharon Mates, Ph.D.

Sharon Mates, Ph.D. Chairman, President and Chief Executive Officer

:: <u>Securities and Exchange Commission</u>
Jeffrey P. Riedler, Assistant Director
Ibolya Ignat
Jim Rosenberg
Austin Stephenson
Daniel Greenspan

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. William C. Hicks, Esq. Scott A. Samuels, Esq.