



DIVISION OF
CORPORATION FINANCE

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

September 19, 2016

Noreen Griffin
Chief Executive Officer
Immune Therapeutics, Inc.
37 North Orange Avenue, Suite 607
Orlando, FL 32801

**Re: Immune Therapeutics, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted August 25, 2016
CIK No. 0001559356**

Dear Ms. Griffin:

We have reviewed your amended 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.

Risk Factors, page 8

“We have a limited operating history...,” page 9

1. We note your response to our prior comment 4. In addition to your cumulative losses, please disclose the amount of your accumulated deficit.

“We may need additional financing...,” page 14

2. We note your response to our prior comment 5. Please expand your disclosure in this risk factor to state how long you expect your business operations to continue given your current amount of cash and cash equivalents.

Description of Business, page 44

3. We note that in addition to the clinical trials referenced in your initial draft registration statement, you have added several lists of completed clinical trials that appear to be related to IRT-101 and IRT-103 in this amendment. For each clinical trial referenced in this section, please disclose the relevant product candidate, the stage of development (e.g., Phase 1, Phase 2, etc.) and the precise timeframe from commencement of the clinical trial to completion. Please also put this selected information into its full and proper context by providing the specific details and parameters of the study from which this data was drawn, including clinical endpoints, duration of treatment, comparison against placebo or standard treatment, metrics utilized, statistical significance, etc. Without this contextual information, it may be difficult for the reader to draw an accurate and balanced assessment of these favorable results. If you cannot provide this information for any clinical trials that you reference, please delete such reference.
4. We note that for several of the clinical trials that you reference in this section, it is not clear who conducted the clinical trial, what your level of involvement was, if any, or whether the results can be used to support regulatory approval for any of your product candidates. Please ensure that this information is disclosed for each trial or study that you reference.

Business, page 44

5. We note your response to our prior comment 8. Please expand your discussion in this section to provide a brief explanation of compounded drugs, including a discussion of regulatory oversight in manufacturing and distribution. Please also explain how you are able to market LDN for prescription use in the U.S. without FDA approval.
6. We note your response to our prior comment 9. Please disclose the aggregate amounts paid or received to date under the agreement. Additionally, we note that your disclosure states that you entered into the agreement with Complete Pharmacy and Medical Solutions, LLC on December 8, 2014. However, the agreement filed as Exhibit 10.1 to the Current Report on Form 8-K filed May 20, 2016 states that the agreement was entered into on May 16, 2016. Please explain this discrepancy.
7. Please revise this section to discuss the effect of the Compounding Quality Act on your business, to the extent it is material. Please refer to Item 101(h)(4)(ix).

FDA and EMA Development Plan, page 47

8. We note your statement that after the completion of the spin-off of Cytocom, Inc., all work with the FDA is “under the supervision of Cytocom, Inc.” We also note your statements on page 53 that you intend to sponsor a Phase 2b study of MENK. Please

clarify which product candidates are being developed by you and which are being developed by Cytocom, Inc.

9. Please clarify the indications for which you or Cytocom, Inc. have active INDs with respect to IRT-101 and IRT-103.
10. We note your response to our prior comment 17. Please clarify whether you are currently conducting pivotal Phase III trials with respect to IRT-103. If not, please delete the reference to “current pivotal Phase III trials” in the risk factor on page 13.
11. We note your discussion of the Phase 2a clinical trial for IRT-103. Please expand your discussion of this clinical trial to disclose the number of patients enrolled and whether each of the primary endpoints was met. Please clarify whether any statistical analysis was performed relating to clinical improvement based upon the Crohn’s Disease Activity Index (CDAI) Score or mucosal healing by colonoscopy and, if so, disclose the corresponding p-values.
12. We note your statement with respect to IRT-103 that: “88% of the patients treated with LDN 4.5 mg had a significant improvement in their colitis activity by the CDAI score compared to those that received the placebo after 3 months.” Please revise your disclosure to indicate whether the improvement was “statistically significant.” If not, please delete the word “significant.” If you are referring to statistical significance, please provide a brief explanation of the term “statistically significant” and how it relates to the FDA’s evidentiary standards of efficacy. Please make corresponding changes throughout the registration statement where you use the word “signigicant” to describe clinical trial results.
13. We note your response to our prior comment 19 and your revised disclosure on page 47. Please revise your disclosure to briefly explain “Type A” and “Type B” meetings, since you use those terms to define a “Type C” meeting.

Terminated Trials, page 48

14. Please explain why the trial listed under this heading was terminated.

MENK, page 50

15. We note your response to our prior comment 11. Please revise your discussion to disclose any active INDs related to IRT-101, the date of filing for each IND, the sponsor, the subject matter and status of the IND.

Phase II Trial Pancreatic Cancer
AIDS Patients, page 55

16. We note your statement on page 56 that clinical trials “have demonstrated that MENK can be delivered safely to patients.” Because regulatory approval of IRT-101 is dependent on the FDA or other regulatory agency making a determination (according to criteria specified in law and agency regulations) that IRT-101 is both safe and effective, it is premature for you to describe IRT-101 as safe. Accordingly, please delete this wording throughout your prospectus, as applicable.
17. We note your response to our prior comment 12. Please clarify whether any clinical trials of IRT-101 have been conducted subsequent to the 1997 clinical trial referenced in the timeline on page 54.
18. We note your response to our prior comment 13. Please disclose whether you intend to submit the results of the Phase I and II clinical studies conducted by Dr. Nicholas Plotnikoff to the FDA to support the approval of IRT-101.

MENK as an inhibitor of cancer cell growth, page 58

19. Please explain whether Pennsylvania State University’s clinical trials of LDN will be used to support your NDA for IRT-103. If yes, please explain why you have removed the tables summarizing their clinical trials and results from this amendment.

Intellectual Property, page 61

20. We note your response to our prior comment 18. Please delete the language you have added to page 61 regarding your request for confidential treatment. Please note that we do not grant confidential treatment for material terms to an agreement and we consider all of the terms listed to be material. For each license agreement discussed in this section, please discuss the following material terms, as applicable, to the extent they are not already disclosed:
 - Nature and scope of intellectual property transferred
 - Each parties’ rights and obligations
 - Duration of agreement and royalty term
 - Termination provisions
 - Investment features or share purchases
 - Payment provisions which may include the following:
 - Up-front or execution payments received or paid
 - Aggregate amounts paid or received to date under agreement
 - Aggregate future potential milestone payments to be paid or received
 - Royalty rates
 - Profit or revenue-sharing provisions

In the alternative, please provide your analysis supporting your determination that you are not substantially dependent on these agreements.

Government Regulations, page 68

21. We note your response to our prior comment 21. Please expand your discussion to discuss your relationships with The Jack Brewer Foundation and GB Oncology and Imaging Group LTD.

Legal Proceedings, page 71

22. We note that you have removed your discussion of pending legal proceedings from this amendment. Please either restore this information, or advise us as to why it is no longer required.

Market Price, Dividends, and Related Stockholder Matters, page 72

23. We note your statement that you “do not now have, or plan to have in the near future, an equity incentive plan.” We also note that you have filed the “Immune Therapeutics, Inc. 2014 Stock Incentive Plan” as Exhibit 10.23 to this registration statement. Please provide the disclosure required by Item 201(d) of Regulation S-K.

Directors, page 84

24. We note that Dr. Plotnikoff was an executive officer of TNI Pharmaceuticals, Inc. within two years before the time of its bankruptcy filing. Please revise your disclosure in this section to provide the information required by Item 401(f)(1) of Regulation S-K for Dr. Plotnikoff with respect to this proceeding or tell us why such disclosure is not required.

Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, page 90

25. We note that you have deleted the reference in footnote (1) to the “additional 700,000 shares ... in the process of being transferred from the Plotnikoff Family Trust to a trustee in the TNI Pharma bankruptcy.” Please advise us as to why you removed this language.

Exhibits, page 139

26. Please file a copy of your securities purchase agreement with JMJ Financial as an exhibit to the registration statement.
27. Please file a copy of the most recent services agreement that you entered into with Mr. Aronstam. We note that the services agreement currently listed in the exhibit index is

incorporated by reference to the Form 10-K filed on March 30, 2016. However, the services agreement was not filed as an exhibit to the Form 10-K.

28. Please file an exhibit that identifies all of your subsidiaries, as required by Item 601(b)(21) of Regulation S-K.

Signatures, page 143

29. We note that in response to prior comment 31, the principal financial officer has signed the draft submission on behalf of the registrant. When the registration statement is filed publicly, please also include the signature of your principal financial officer in his individual capacity. See Instruction 1 to Signatures. See Instruction 1 to Signatures.

You may contact James Peklenk at (202) 551-3661 or Sharon Blume at (202) 551-3474 if you have questions regarding comments on the financial statements and related matters. Please contact Christina Thomas at (202) 551-3577 or Mary Beth Breslin at (202) 551-3625 with any other questions.

Sincerely,

/s/ Mary Beth Breslin for

Suzanne Hayes
Assistant Director
Office of Healthcare and Insurance

cc: Gina M. Austin, Esq.
Austin Legal Group, APC