



DIVISION OF  
CORPORATION FINANCE

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

June 20, 2013

Via E-mail

Noreen Griffin  
Chief Executive Officer  
TNI BioTech, Inc.  
6701 Democracy Blvd., Suite 300  
Bethesda, Maryland 20817

**Re: TNI BioTech, Inc.  
Amendment No. 1 to Registration Statement on Form 10-12G  
Filed June 7, 2013  
File No. 000-54933**

Dear Ms. Griffin:

We have reviewed your amended registration statement and response letter dated June 7, 2013 to our comment letter dated May 20, 2013 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 within ten business days by amending your filing, 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 or do not believe an amendment is appropriate, please tell us why in your response.

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

General

1. We acknowledge that in response to prior comment 2 you have included unaudited financial statements as of March 31, 2013 in your filing. In addition, please update the other sections of your filing with updated financial information as applicable. For example, management's discussion and analysis of financial condition and results of operations should include a comparison of your most recent interim period with the same interim period of the previous year.
2. We note that you have submitted an application for confidential treatment relating to certain of your exhibits. Please be advised that we will perform an independent review of this application and will issue any comments under separate cover.

3. We note your response to prior comment 4 and reissue the comment in part. Please revise Note 2 to your notes to financial statements to disclose your election to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) in your discussion of your significant accounting policies.

Item 1. Business

Our Business and Patents, page 4

4. We note your response to prior comment 8. Please further amend your disclosure to identify what CD3, CD4, CD8, CD25, and CD56 refer to. Please also disclose the benefits of the increase in CD cells, as well as NK and lymphoproliferative activity, and disclose what you mean by “increased killing activity.”
5. We note your response to prior comments 9 and 10. Please amend your disclosure to list which INDs are currently active and which are currently inactive, as well as whether you currently hold those INDs. We suggest that you organize this list in tabular form.
6. We note your response to prior comment 13 and your indication that you are seeking confidential treatment for certain terms of the agreements cited in our prior comment. Please note that we are not willing to grant confidential treatment for material terms of significant agreements. That said, we are generally willing to grant confidential treatment for individual milestone payment terms and specific royalty provisions provided that the aggregate potential milestone payments and a percentage range of royalty payments are disclosed in the registration statement. Accordingly, please revise your disclosure to include the following information about your material agreements under section headings which identify the specific agreement to which your disclosure applies:

For your Sale of Technology Agreement with Dr. Nicholas P. Plotnikoff:

- the amount of consideration provided in exchange for the technology transferred;

For your License Agreement with Ms. Jacqueline Young:

- the estimated expiration date for the patents licensed under this agreement;

For your Patent License Agreement with Dr. Jill Smith and LDN Research Group, LLC:

- a percentage range of royalties within a ten-percent range (e.g., “between 25-percent and 35- percent, “high single digits,” etc.) and,
- the estimated expiration date for the patents licensed under this agreement;

For your exclusive licensing agreement with The Penn State Research Foundation:

- the license initiation fee;
- a percentage range of royalties within a ten-percent range;
- the aggregate amount of potential milestone payments to be made; and
- the estimated expiration date for the patents licensed under this agreement;

For your Patent License Agreement with Professor Fengping Shan:

- the upfront license fee;
  - a percentage range of royalties within a ten-percent range; and
  - the estimated expiration date for the patents licensed under this agreement.
7. We note your response to prior comment 14 and that you have included certain of the patent numbers in your revised disclosure. However, you have not provided expiration dates nor is it always made clear to which of your product candidates these patents relate. Please revise your disclosure to provide a table which identifies the patents that are most material to your product development efforts. This disclosure of your most material patents should be organized by the underlying product candidate to which the patents relate. Where there are numerous material patents essential to the development of an underlying product candidate please provide a range of the expected expiration dates for the underlying patents. Your tabular disclosure should also identify the jurisdiction of any issued patent or patent application.
  8. We note your response to prior comment 16. Please further amend your disclosure to identify the standard of care drugs used in your Phase II trials for LDN for Crohn's disease. Please also amend your disclosure to explain what CDAI and PCDAI scores are and how they impacted the results of the trials.
  9. We note your responses to prior comments 17 and 18. Please amend your disclosure to include your analysis supporting the use of 505(b)(2) as a basis for your pivotal Phase II trial for LDN to treat Crohn's disease. Please also revise your disclosure to include your statement concerning the guidance received from the FDA and the expected timing of the submissions for final protocols of your Phase III trials and expected initiation of the trials.
  10. We note your response to prior comment 19. Please expand your disclosure on page 6 to elaborate on your statement regarding the skepticism by the Zagon/Smith team regarding the immunodulatory mechanism of action for MENK. Specifically, please discuss the specific concerns that the Zagon/Smith team expressed and how such skepticism could impact the development of MENK as an immunomodulatory therapy. Please also include an independent risk factor that addresses how the assumptions you have made about your product development may prove to be incorrect and incorporate the skepticism expressed by the Zagon/Smith team and any related discussion into the body of that risk factor.
  11. We note your response to prior comment 21. Please revise your disclosure to provide a summary of the clinical studies you discuss in your response. Please also include a discussion of the adverse events experienced by patients in the trials.

The Products, page 12

12. We note your response to prior comment 22 and in particular your discussion of the regulatory status for your product candidates. Please revise this section of your disclosure to provide define the terms “EOP1 meeting,” and “type C meeting” and what such meetings indicate about the regulatory development of the underlying product.
13. We note your response to comment 24. Please clarify whether the studies conducted by Drs. Plotnikoff and Bihari resulted in MENK being defined as a “therapeutic vaccine.” If so, please reinstate this disclosure and revise your disclosure to explain how a therapeutic vaccine differs from an immunomodulatory drug and how the conclusions of Drs. Plotnikoff and Bihari impact the development of MENK as an immunomodulatory drug.
14. We note your response to prior comment 26. Please revise your disclosure in this section to include the discussion provided in your response and explain more fully the relationship you have with GB Oncology & Imaging Group, LLC, the Brewer Group, American Hospitals and Resorts, etc., including a description of the material terms of your agreement with GB Oncology and any other agreement you have entered into with the other entities, including your financial commitments to them. Please also revise your disclosure to identify the “large employers who operate on-site clinics” and discuss the terms of your underlying relationship with these entities.

Distribution and Production, page 15

15. We note your response to prior comment 28 and reissue the comment in part. Please amend your disclosure to include the material terms of your agreement with Laboratorios Ramos including exclusivity provisions, duration, and termination provisions. Please also file this agreement as an exhibit to your registration statement or provide an analysis as to why the agreement is not required to be filed.
16. We note your response to prior comment 29. Please include this information in your disclosure where appropriate.

Government Regulations, page 16

17. We note your response to prior comment 31. Our comment was intended to solicit a broad discussion of the drug regulatory process in the United States and the other countries where you intend to operate. Please revise this discussion to include such a discussion, explaining, for example, the process of applying for an IND, conducting at least three phases of clinical trials, submitting an NDA, etc., along with a comparable discussion of the non-U.S. regulatory process you will be subject to.

Item 1A. Risk Factors, page 18

18. We note that your Form 10-Q for the period ended March 31, 2013 discloses that your principal executive officer and principal financial officer have concluded that your disclosure controls and procedures are ineffective. Please revise your risk factor disclosure to include a separate risk factor which identifies the basis for the conclusion that your disclosure controls and procedures are ineffective. Your disclosure should discuss all material risks resulting from the issues identified.

“Failure to obtain regulatory approvals in foreign jurisdictions....” page 40

19. We note your response to prior comment 42. Please amend your disclosure to state the country which Minister of Health, Drug Regulatory Authorities you are working with and list the other African nations where an FDA exists. Please briefly summarize the regulatory process(es) you must pursue in each of these countries, and note any significant differences among them. Similarly, briefly summarize the regulatory process mandated by the State Food and Drug Administration in China.

Healthcare reform measures could hinder or prevent the commercial success....” page 40

20. Please revise your risk factor disclosure with respect to the ongoing adjudication of the constitutionality of the Patient Protection and Affordable Health Care Act to reflect the Supreme Court’s determination to uphold PPACA in June 2012.

Item 2. Financial Information

Management’s Discussion and Analysis of Financial Condition and Results of Operations

Results of Operations – Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Operating Expenses, page 47

21. Please refer to your responses to comments 48 and 55 and the additional disclosure provided. Please revise the disclosure to discuss the loss from extinguishment of debt. In addition, the disclosure relating to selling, general, and administrative expenses and research and development expenses does not agree with the amounts on the Statements of Operations. Also, reconcile the disclosure with the disclosure on page 33 which states that you’ve spent \$1,200,000 in cash plus stock for acquisition and research and development. Please revise the Statements of Operations to properly reflect the nature of each expense item such that research and development and selling, general, and administrative costs properly reflect all costs.

Stock Issued for Services and Stock Warrant Expense, page 48

22. We acknowledge the information provided in response to prior comment 57. We note that the trading value was not used for many of these transactions. Please disclose and tell us how you accounted for the difference between the trading value and the amount

paid for your common stock. Provide additional disclosure in the filing as applicable to clearly indicate your accounting policy for these transactions, the amount of compensation or other expense recorded in your financial statements for the difference between the trading price and the amount issued and provide us the detail of how the amounts were derived.

Item 5. Directors and Executive Officers, page 50

23. We note your response to prior comment 50. Please revise this disclosure to more clearly state the business experience of your President over the last five years and the experience, qualifications, attributes or skills that led you to conclude that your Chief Operating Officer should also be a member of your Board of Directors.

Item 6. Executive Compensation, page 54

24. We note your responses to prior comments 51 and 53. Your revised executive compensation disclosure is significantly different from that you provided in your previous filing. Please confirm that you did not in fact issue common stock purchase warrants to either your Chief Executive Officer or your Chief Financial Officer in fiscal year 2012, but rather paid each of them a base salary and a bonus in the form of a common stock award. Please also confirm that the base salaries you report, all of which are different from those included in your last filing, are accurate and explain the reason(s) for the discrepancy in the disclosure between the two filings.

Item 10. Recent Sales of Unregistered Securities, page 56

25. We note your response to prior comment 54. Please revise your disclosure to include this response and expand it to discuss the holding periods that are applicable to the holders of the restricted shares.

Financial Statements

Statement of Stockholders' Equity, page F-4

26. We do not see the changes made in response to comment 59. Please revise the description of the "Issuance of common stock for issuance of warrants" line item to clarify that no common stock was issued.

Notes to the Financial Statements

2. Summary of Significant Accounting Policies

27. Please refer to your response to comment 60. It is unclear what you meant by your statement that pursuant to the Jumpstart Our Business Startups Act an emerging company is not required to adopt new accounting policies for a period of 5 years and we did not understand your statement that "there are no accounting policies." Please disclose the

accounting policy you have used to record the U.S. government research grants that you apparently received.

Basis of Presentation, page F-7

28. Please refer to your response to comment 61. It does not appear that the statement recommending that the footnote disclosures made in your financial statements be read in conjunction with your financial report has been removed. Please readdress prior comment 61.

Intangible Assets, page F-9

29. Please refer to your response to comment 62. Please revise your disclosures to consistently describe that patent license agreements were acquired. For example, in this note you state that licenses and patents were acquired and in another place you state that only patents were acquired. On pages F-4 and F-6 you state that patents were acquired. On page F-16 you refer to license agreements of \$16,006,000. Please revise throughout the filing for consistency.

5. Promissory Notes, page F-12

30. Please refer to your response to comment 64. Please revise this note to clarify that the note was not with a related party and disclose the conversion rate terms. Also please provide us a calculation of the loss and tell us how your calculation complies with ASC 470-20-40-13 through 470-20-40-17. If you believe you fall under ASC 470-20-40-16, please note that the expense should equal the fair value of the securities and other consideration transferred in the transaction in excess of the fair value of securities issuable pursuant to the original conversion terms. If you believe other guidance applies, please cite the guidance you are using.

6. Capital Structure-Common Stock and Common Stock Purchase Warrants  
Stock Warrants, page F-13

31. Please refer to your response to comment 66. Please tell us if the warrants fall under the scope of ASC 480-10. If not, please provide us your analysis of whether or not the warrants should be accounted for as derivatives pursuant to ASC 815. Please tell us the terms of each warrant issuance, including any conditions in which there may be adjustments to the exercise price. Provide us your calculation of the amount of warrants recorded in your Statements of Stockholders' Equity.

10. Licenses and Supply Agreements  
Patent and Subsidiary Acquisition, page F-16

32. You disclose on page 56 that you recorded 6 million shares with a fair market value of \$.001 on March 23, 2012 and 2 million shares with a fair market value of \$8 on April 24,

2012. We note that the trading value on March 28, 2012 was \$10.01 per share. As it is not clear that the \$.001 was the trading value on March 24, 2012, please clarify in the filing and tell us how the \$.001 was derived and why it represents fair value on March 23, 2012.

33. Please refer to your response to comment 67. You state that as of the acquisition, TNI BioTech IP, Inc. had no assets, no liabilities and no operations and that therefore, the disclosure of the financial statements for the business acquired and the pro forma financial statements were not material to the overall financial statements and were not included. However your disclosure in the note states that Dr. Plotnikoff and Dr. Shan have been specializing in research activities directed toward the study of cytokines, which are hormones naturally produced by the immune system. In addition, you recorded \$98 million of goodwill relating to this acquisition. Please tell us when TNI Biotech IP, Inc. was formed and the nature of its operations subsequent to being formed. Tell us who the owners were and the percentage ownership of both TNI Biotech IP, Inc. and the company at the time of acquisition. If TNI BioTech IP, Inc. was a shell company upon acquisition and thus you do not believe a business combination occurred pursuant to ASC 805-10-20 and ASC 805-10-55-4 through 55-9, please clarify in the filing the basis for your conclusion and provide us your analysis of the appropriate accounting treatment for the acquisition. If you do not believe a business combination occurred or you acquired a shell, it does not appear that recording goodwill was appropriate.

13. Subsequent Event: Common Stock Purchase Warrant Exercises, page F-19

34. Please refer to your response to comment 71. As it appears that the new exercise price is significantly below the trading value and the amount originally recorded, please provide us with a calculation of the \$60,000 and cite the applicable GAAP guidance you are using to support your accounting treatment for the change in exercise price and term.

Form 10-Q for the Quarterly Period Ended March 31, 2013

Item 4. Controls and Procedures, page 25

35. We acknowledge your disclosure that states that as of the end of the period covered by your report your principal executive officer and principal financial officer concluded that your disclosure controls and procedures were ineffective. Please provide us proposed revised disclosure to be included in future periodic reports that includes a discussion of the weaknesses identified in the design and/or operation of your disclosure controls and procedures that resulted in the conclusion that your disclosure controls and procedures were not effective. Describe the type of weaknesses identified, explain when they occurred, when they were discovered and the circumstances that led to their discovery. Tell us and disclose the procedures that you are establishing to address the weaknesses in your disclosure controls and procedures and the time frame in which these remedial procedures will be implemented. Identify the parties responsible for creating and implementing these procedures and describe their role.



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 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.

You may contact Ibolya Ignat at (202) 551-3656 or Mary Mast at (202) 551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, Bryan Pitko at (202) 551-3203 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Bryan J. Pitko for

Jeffrey P. Riedler  
Assistant Director