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

DIVISION OF
CORPORATION FINANCE

May 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.
Registration Statement on Form 10-12G
Filed April 22, 2013
File No. 000-54933

Dear Ms. Griffin:

We have reviewed your filing 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. Pursuant to section 12(g)(1) of the Securities Exchange Act of 1934, your registration statement will become effective by operation of law on June 21, 2013 at which time you will be required to begin filing all of the reports mandated by Section 12(g) of the Exchange Act. If the review process has not been completed before that date you should consider withdrawing the registration statement prior to June 21, 2013 to prevent it from becoming effective and re-filing it at such time as you are able to respond to any remaining comments.

2. Please include updated interim financial information in your next amendment.

3. You identify yourself as a Smaller Reporting Company and provided only two years of financial information in your registration statement. Please explain to us how you qualify

as a Smaller Reporting Company after the April 24, 2012 share exchange agreement. Refer to Item 10(f)(1) of Regulation S-K.

4. Since you appear to qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, please disclose on your cover page that you are an emerging growth company, and revise your registration statement to:

    - Describe how and when a company may lose emerging growth company status;
    - Briefly describe the exemption from Section 404(b) of the Sarbanes-Oxley Act of 2002 and Section 14A(a) and (b) of the Securities Exchange Act of 1934; and
    - State your election under Section 107(b) of the JOBS Act:
        - If you have elected to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b), include a statement that the election is irrevocable; or
        - If you have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1), provide a risk factor explaining that this election allows you to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Please state in your risk factor that, as a result of this election, your financial statements may not be comparable to companies that comply with public company effective dates. Include a similar statement in your critical accounting policy disclosures.

    In addition, consider describing the extent to which any of these exemptions are available to you as a Smaller Reporting Company.

Item 1. Business
Explanatory Note, page 3

5. We note your statement that you have not independently verified the market data and other statistical information contained in the prospectus. It is not appropriate to disclaim information included in your filing. Please delete this statement or specifically state that you are responsible for the referenced information.

Company History, page 4

6. Please define the term "immunomodulatory therapies" at your first use of this term.

7. Please explain what active and adoptive forms of immunotherapies are and how they are distinct from one another.

Our Business and Patents, page 4

8. Please revise your disclosure to whether the double-blind study conducted in December 2004 represents a Phase I or Phase II study. Please also identify the number of patients treated, what "sustained levels of cytotoxic T-cells" indicates about the efficacy of MENK in treating HIV-infected patients, and whether any adverse effects from treatment were observed in the patients.

9. Please also indicate when the IND for ampouled MENK was filed and whether it remains active with the Food and Drug Administration.

10. Please indicate whether you have filed an Investigational New Drug Application (IND) for any of your product candidates with the Food and Drug Administration. If you have filed an IND but it is no longer active, please amend your disclosure to state this fact. Please also indicate whether the clinical trials that you intend to perform will be conducted outside the United States.

11. Please indicate whether Dr. Plotnikoff has or plans to transfer the IND in relation to the use of MENK to treat HIV/AIDS.

12. Please state the names of the peer-reviewed international journals that have published Professor Shan and Dr. Plotnikoff's research results involving MENK and regulatory t-cells, as well as the dates of publication.

13. In your discussion of your patents and licenses, please amend your disclosure to include the material terms of each of the following agreements including exclusivity provisions, upfront fees, royalty provisions, potential milestone payments, duration and termination provisions:

    - The agreement through which you acquired the patents and intellectual property of Dr. Plotnikoff and Professor Shen;

    - The exclusive licensing agreement for all of the intellectual property developed at Pennsylvania State University by Drs. Zagon, McLaughlin, and Smith;

    - The agreement through which you acquired the licensing rights to the patent portfolio and intellectual property developed by Dr. Bihari; and

    - The licensing agreement relating to the exclusive patent rights for the intellectual property of Dr. Smith and LDN Research Group, LLC.

    Furthermore, please file the agreements as exhibits to your registration statement, as each appears to be material to you pursuant to Item 601(b)(10) of Regulation S-K. If you do

not believe that one or more of these agreements are material, please provide us with an analysis to that effect.

14. For each of the patents that you identify, please identify the specific product candidate to which the patent applies and the expected expiration date of the patent protection. It may be helpful to provide this information in the form of a table.

15. The first paragraph of your disclosure on page 7 is almost entirely duplicative of the penultimate one on the preceding page. Please remove it.

16. Please revise your disclosure to identify the published randomized controlled phase II trials for LDN and identify where they were conducted. Please also explain how these trials showed "considerably better efficacy than the comparator standard of care."

17. Please explain why you believe that you will be able to rely on the phase II trials for LDN as the basis for conducting a pivotal phase III trial for LDN in the next 15 months under the 505(b)(2).

18. Please disclose whether you have obtained FDA approval for your proposed phase III trials of LDN for the treatment of Crohn's disease in children and adults.

19. We note that your disclosure that Professor Shen and Dr. Plotnikoff have published articles proving MENK's role in immune restoration, and that clinical trial evidence indicates that LDN dosing at certain levels stimulates the immune system, among other statements relating to the efficacy of your immunomodulatory therapies. Please revise your disclosure to discuss whether any controversy remains in the medical and/or scientific community as to the efficacy of MENK or LDN as immune-modulating drugs and whether any such disagreement casts doubt on your ability to develop and commercialize your product candidates. To the extent appropriate, any such controversies should also be addressed in an independent risk factor.

20. We note your reference to various studies demonstrating successful use of LDN in HIV/AIDS. Please revise your disclosure to provide an expanded description of the studies conducted including the number of patients, the specific tests that were taken during the studies and what they were attempting to measure, the results of the studies and any adverse effects events that were observed during the studies.

21. We note your discussion of clinical trial of LDN in relation to Crohn's disease. Please indicate whether patients experienced any adverse effects as a result of treatment with LDN and describe these effects.

<u>The Products, page 12</u>

22. In this discussion, you omit any mention of your lead product candidate, IRT-103. Please amend your disclosure to include a complete description of IRT-103 at the same level of

detail as the descriptions of your other product candidates. Please also revise your disclosure to discuss the current regulatory status of each of your product candidates, the specific indications that each candidate is intended to treat, and your anticipated developmental timeline for each. In this regard, please indicate why IRT-103 represents your lead product candidate.

Treatment Focus, page 13

23. Please state which of your product candidates is being developed to treat each of the indications discussed listed.

24. Please revise your disclosure to explain what a "therapeutic vaccine" is and why the studies conducted by Drs. Plotnikoff and Bihari in December 2004 resulted in MENK being defined as such.

25. In your discussion of Crohn's disease, several of the footnotes in your text do not have corresponding footnote disclosure at the bottom of page 14. Please amend your disclosure to include these citations, to the extent you believe them to be material, or remove the footnotes from the relevant paragraph.

Business Strategy, page 14

26. Please explain more fully your goal to establish various treatment facilities, including how you intend to finance this venture and your anticipated timetable for opening these facilities.

27. We note your reference to various agreements relating to your product development and current plans to commercialize IRT-103. Please amend your disclosure to discuss the material terms of the following agreements:

    - the joint venture agreement with the Hubei Qianjiang Pharmaceutical Company;
    - the contracts with the Republic of Malaria and Equatorial Guinea for the delivery of IRT-103 for the treatment of HIV/AIDS and/or cancer in 2013; and
    - the exclusive distributor agreement with G-Ex Technologies/St. Maris Pharma and GB Pharma Holdings LLC for the Federal Republic of Nigeria.

    In your description of these agreements you should specifically identify any exclusivity provisions, the financial and funding obligations of any parties to the agreement, the expected duration of the agreement and any termination provisions. In addition, please file each agreement as en exhibit to your registration statement as required under Item 601(b)(10) of Regulation S-K.

Distribution and Production, page 15

28. We note your entry into agreements with ViPharma and Laboratorios Ramos in relation to the manufacturing of IRT-103. Please revise your disclosure to identify any exclusivity provisions, the duration of the agreements, and any termination provisions. Please also file these agreements as exhibits to your registration statement or provide an analysis as to why the agreements are not required to be filed.

29. Please indicate the approximate amount you intend to expend to open your first cancer treatment center in Malawi.

Analysis, page 16

30. We note your disclosure in relation to your ability to potentially generate $27 million in operating revenue in 2013. However, we also note your statement in the risk factor on page 18 that you do not expect to generate revenue from the sale of your products for the foreseeable future and your statement in Note 1 to your financial statements that you expect operating losses and negative cash flows to continue at more significant levels in the future, and that you may never achieve profitability. In light of these statements and the significant uncertainty surrounding your ability to generate revenue please delete your statement regarding your estimated operating revenue for 2013.

Government Regulations, page 16

31. Please expand this disclosure to describe in greater detail how the clinical development process in the United States functions, including the filing of an IND, the different phases of clinical trials that must be performed and the requisite approval of a New Drug Application. You should also include a discussion of the 505(b)(2) regulatory pathway you intend to pursue for certain indications. Furthermore, since it appears that you intend to initiate commercial sales of IRT-103 in China and several countries in Africa prior to the United States, please also describe the regulatory processes in those countries and the agencies from whom you must obtain approval before any sales can be made, e.g. the National Agency for Food and Drug Administration and Control of Nigeria and the State Food and Drug Administration of China.

Risk Factors
General

32. Please include a separate risk factor that discloses that you have generated no revenues to date, that you experienced heavy operating losses in fiscal year 2012, and that you have a working capital deficiency that your independent registered public accounting firm believes raises substantial doubt about your ability to continue as a going concern.

"We will see losses from our clinical trials for the foreseeable future . . .," page 18

33. In this risk factor, please estimate the amount you estimate spending on clinical trials this fiscal year and in fiscal year 2014.

34. In the second paragraph of this risk factor, you state that you have "3 other" drug candidates in clinical trials, in addition to IRT-103. Please amend your disclosure to correct this, as it appears that you have only two other drug candidates.

"We may need additional financing and may be unable to raise capital on acceptable terms, or at all, when needed . . .," page 24

35. In this risk factor, you cite a figure of $330,000 as your total cash and cash equivalents as of the end of 2012. In your Results of Operations and Balance Sheet, you state a figure of $313,095. Please amend your disclosure as necessary to resolve this discrepancy.

"TNIB's revenue depends on a small number of industries and clients," page 29

36. It is unclear from your other disclosure exactly how this risk factor is material to you, since the core of your operations appears to be product development and you are not actually providing any "services" at this time. Please either provide us with an analysis as to why you believe this risk factor is material to you or, alternatively, delete it.

"Any failure by TNIB to comply with existing health care and drug regulations…," page 30

37. Please revise your risk factor to the extent that you have experienced any failure to comply with existing regulations or received issuance of an FDA notice indicating a finding of a material violation of good clinical practice, good laboratory practice or good manufacturing practice requirements.

"If serious or unexpected adverse side effects are identified during the development of our treatment . . .," page 32

38. This risk factor is duplicative of the one concerning potential side effects on page 21. Please delete it from your disclosure.

"TNIB may incur substantial expenses by developing products that will never be successful, fully developed and/or commercialized," page 33

39. Please include in this risk factor the aggregate amount you have expended on your various licensing and acquisition agreements and an estimate of the research and development expenses you expect to incur this fiscal year and in fiscal year 2014.

"Our treatments, even if approved may not be accepted in the marketplace; therefore, we may not be able to generate significant revenue, if any," page 33

40. This risk factor has significant overlap with the second one on page 21. Please condense them into a single risk factor.

"TNIB's inability to adequately protect its intellectual property rights could hurt business," page 35

41. Please expand this risk factor to identify your most important patents, particularly those relating to your most advanced product candidate, IRT-103.

"Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally," page 40

42. Please expand this risk factor to include a brief description of the regulatory pathways in China and the African nations where you are currently developing your products and where you wish to commercialize them.

43. Please include a separate risk factor which discusses the risks relating to conducting clinical trials for your product candidates outside of the United States. Please specifically highlight the risk that the FDA may not accept the results of clinical trials conducted outside of the United States.

"Healthcare reform measures could hinder or prevent the commercial success of our drug candidates," page 40

44. This risk factor is largely duplicative of the one concerning healthcare reform on page 33. Please condense them into a single risk factor.

"Because of their significant stock ownership, our chief executive officer, our other executive officers . . .," page 42

45. Please include the percentage of common stock ownership held by your directors and officers as a group, and note in both the sub-caption and body of this risk factor that your other stockholders will have limited ability to influence corporate actions or decisions.

"The market price of our Common Stock may fluctuate significantly, which could cause a decline in the value of your shares," page 45

46. This risk factor has considerable overlap with the one concerning stock price volatility on page 42. Please condense them into a single risk factor.

Item 2. Financial Information
Overview, page 47

47. You state again here that you have "3 other" drug candidates in clinical trials, in addition to IRT-103. As the only product candidates you describe are IRT-101, IRT-102, and IRT-103, we ask that you amend your disclosure here and wherever else applicable in your registration statement to remove any discrepancies.

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, page 47

48. Your discussion focuses on the goodwill impairment and selling, general, and administrative expenses. Please revise to also discuss the other significant expenses such as the $22 million loss on settlement of debt.

Summary, page 48

49. Please also state here that the opinion of your independent registered public accounting firm included in this registration statement indicates substantial doubt about your ability to continue as a going concern.

Item 5. Directors and Executive Officers, page 50

50. With the exception of your Chief Financial Officer, please be more specific in describing the business experience of each of your directors and officers, including their places of employment and positions over the last five years and, for your directors, the actual experience, qualifications, attributes or skills that led you to conclude that the person should serve on your Board. We refer you to Item 401(e) of Regulation S-K.

Item 6. Executive Compensation, page 54

51. The total compensation of your chief executive officer and chief operating officer is less than the sum of the salaries and other compensation awarded to them in fiscal year 2012. Please amend your disclosure to resolve this discrepancy.

52. We note that in the footnotes to your table on page, you describe the $18,000 payments to your CEO and COO as "unaccountable expense." Please revise you disclosure to explain what "unaccountable" expense refers to in this context.

53. In the footnotes below your summary compensation table, please indicate when the awards of common stock or warrants were made and the fair market value of the common stock awards as of the date of grant pursuant to FASB ASC Topic 718.

Item 10. Recent Sales of Unregistered Securities, page 56

54. Please state the exemption from registration you relied upon for each of the sales described herein and explain more fully the restrictions imposed on the relevant transactions by Rule 144, e.g. the reason these shares were restricted and the holding periods applicable.

Financial Statements
Balance Sheet, page F-2
Statements of Operations, page F-3

55. Please revise to clarify the nature of the expenses included in Stock issued for services, Amortization of stock issued for prepaid services, and Stock warrant expense. For example, include these costs in general and administrative expenses, research and development expenses, etc. based on the nature of the costs. Expand Management's Discussion and Analysis to clearly discuss the nature of these costs and why they increased from the prior year.

Statement of Stockholders' Equity, page F-4

56. Please tell us why prepaid services and the amortization of prepaid expenses are included in stockholders' equity. Based on your disclosure on page 57, it appears the prepaid services relate to consulting services to be performed and should be accounted for as an asset on your balance sheet.

57. In order for us to fully understand the equity fair market valuations reflected in your financial statements please provide an itemized chronological schedule covering all equity instruments issued in 2012 and in Note 13, subsequent to the balance sheet date. Please provide the following information separately for each equity issuance:

    - The date of the transaction;
    - Management's estimated fair market value per share and how the estimate was developed;
    - The trading value on the date of each issuance. If you did not use the trading value as the fair value, please tell us why;
    - The identity of the recipient, indicating if the recipient was a related party;
    - The nature and terms of concurrent transactions; and
    - The amount of any compensation or interest expense element.

58. With regards to your issuance of equity instruments to non-employees, you state in Stock-Based Compensation and Issuance of Stock for Non-Cash Consideration on page F-10 that you value the shares based on the value of the services provided. Please tell us how you considered the guidance in ASC 505-50-30-2 which states that share-based payment transactions with nonemployees shall be measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. Given that your stock is trading, please tell us why the fair value of the stock is not more reliably measurable. If you believe that the fair value of the services is more reliably measurable, please tell us why for each stock issuance. For example, please help us understand why $23 million in prepaid consulting services is reliably measurable for the services provided.

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, page F-7

60. You disclose in Risk Factors on page 37 that some of your existing drug candidates, including LDN and MENK, and some of your research and development work are funded, at least in part, by the U.S. government research grants. Please disclose your accounting policy for grant revenues.

Basis of Presentation, page F-7

61. Please explain the reason for making the statement that you recommend that the footnote disclosures be read in conjunction with your financial report. Clarify the financial report you reference in this paragraph.

Intangible Assets, page F-9

62. Please separately disclose patents and licenses, if significant. Refer to ASC 350-30-50-1.

Recent Accounting Standards, page F-10

63. Please name the accounting pronouncements that you adopted during the periods presented and describe the effect of their adoption. For pronouncements that you expect to adopt in future periods, please discuss the impact that the adoption of the standard is expected to have on your financial statements; if impact not known or not estimable, a statement to that effect should be made.

5. Promissory Notes, page F-12

64. You state that you issued 2,901,450 shares of common stock for the retirement of $370,043 of promissory notes payable and accrued interest and recorded a loss on

conversion of the above debt of $22,105,265. Please clarify if the note was convertible and if so what the conversion rate was. In addition, please clarify if the note was to a related party and tell us why loss on conversion is the appropriate classification instead of compensation expense for services.

65. In Item 10- Recent Sales of Unregistered Securities on page 56 you disclose that several notes were converted to common stock. Please revise this note to disclose the conversions, the accounting treatment for the conversions, and the amount of the notes outstanding at the end of each reporting period. Please tell us how your accounting complies with GAAP and cite for us the accounting literature that you relied upon in accounting for the transactions disclosed.

6. Capital Structure-Common Stock and Common Stock Purchase Warrants, page F-12

66. You state that during 2012, the Company received $1,136,500 from the sale of units consisting of a total of 7,285,000 shares of common stock and common stock purchase warrants for the purchase of up to 7,260,000 shares of common stock. In "Stock Warrants" on page F-13 you state that you valued the warrants at $25,810,469 based on the Black Scholes method. Please tell us why the value of the warrants is greater than the proceeds of the units of $1,136,500 and explain to us the basis for your accounting treatment, citing the literature you used. If the warrants are accounted for as derivatives pursuant to ASC 815, please clarify your accounting treatment and the basis thereof. Please provide us the journal entry for recording the issuance of stock and warrants.

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

67. Your acquisition of TNI IP, Inc. appears to be a business combination pursuant to ASC 805-10-20. Refer also to ASC 805-10-55-4 through 55-9. If the acquisition is a business combination, please provide the following information:

- The financial statements of the business acquired and the related pro forma information pursuant to Rules 8-04 and 8-05 or 3-05 and 11-01, if required, or tell us why you believe the information is not required;

- Include all of the disclosures required by ASC Topic 805. For example, provide the disclosures required by ASC 805-10-50-2 and ASC 805-30-50-1 and ensure that this disclosure discusses how you valued the consideration conveyed;

- Tell us what consideration was given to identifying assets apart from goodwill and the patent in the business acquisition. For example, tell us what consideration was given to recording in-process research and development or other assets. Refer to ASC 805-20-55; and

- It appears the patent was acquired in connection with the subsidiary acquisition. If so, please revise throughout the filing to clarify. For example, your stockholders' equity section currently separately denotes the patent acquisition from the subsidiary acquisition.

68. Please tell us your consideration of whether the share exchange agreement executed by pH Environmental for the acquisition of all of the outstanding shares of TNI BioTech, Inc. qualifies for reverse acquisition accounting treatment and provide us your analysis. Refer to ASC 805-10-25, 805-40, and any authoritative literature you rely upon to support your accounting. Tell us if there was any common control between the two entities prior to the merger and provide us your analysis of your accounting in that regard with reference to the authoritative literature that supports your accounting treatment.

69. Please tell us the basis for treating the 1,182,474 shares issued to the shareholders of TNI Biotech, Inc. prior to the acquisition of TNI Biotech, Inc. as a dividend. Please consider the guidance in ASC 805 in analyzing the accounting for this transaction.

11. Commitments and Contingencies, page F-18

70. Please disclose your accounting policy for the amounts pursuant to the agreements discussed in this note and in Note 13, Subsequent events. In addition, please assure that your disclosures describe the material terms of your arrangements, including, but not limited to any payment provisions, obligations, rights, terms and termination provisions.

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

71. Please clarify the accounting treatment for the reduced exercise price and change in term and provide us the basis for your accounting treatment.

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.

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

- 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 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