CURRENT REPORT OF:
TNI BIOTECH, INC.

(OTC: TNIB)

Date of Report: May 8, 2013

Name of Company: TNI BioTech, Inc.

State of Incorporation: Florida

Address of Principal Office: 6701 Democracy Blvd., Suite 300, Bethesda, Maryland 20817

TNI BioTech, Inc. (the "Company") hereby discloses the following events and actions:

TNI BioTech Receives Confirmation of Meeting with FDA Regarding LDN

In a letter dated May 1, 2013, the Company received confirmation of a Type C meeting with the FDA to discuss the Phase 3 clinical development program for a proposed 505(b)(2) application for Low Dose Naltrexone ("LDN") in the treatment of adults and pediatric patients with Crohn's Disease.

A redacted version of the confirmation letter from the Department of Health and Human Services is attached hereto.

The Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TNI BioTech, Inc.

By: /s/ Noreen Griffin
Noreen Griffin
Chief Executive Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND 67442

MEETING REQUEST GRANTED

TNI Bio Tech Inc.
Attention: Ronald Herberman, M.D.
Senior Vice President for Research and Development
6701 Democracy Boulevard, Suite 300
Bethesda, Maryland 20817

Dear Dr. Herberman:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for Naltrexone HCL.

We also refer to your April 18, 2013, correspondence requesting a type C meeting to discuss the Phase 3 clinical development program for a proposed 505(b)(2) application for Low Dose Naltrexone (LDN) in the treatment of adults and pediatric patients with Crohn's disease. Based on the statement of purpose, objectives, and proposed agenda, we consider the meeting a type C meeting.

The meeting is scheduled as follows:

Confidential

Date:
Time:
Location:

Invited CDER Participants:

Confidential

Confidential

Please e-mail me any updates to your attendees at *Confidential* , at least one week prior to the meeting. For each foreign visitor, complete and email me the enclosed Foreign Visitor Data Request Form, at least two weeks prior to the meeting. A foreign visitor is any non-U.S. citizen who does not have Permanent Resident Status or a valid U.S. Federal Government Agency issued Security Identification Access Badge. If we do not receive the above requested information in a timely manner, attendees may be denied access.

A few days before the meeting, you may receive an email with a barcode generated by FDA's Lobbyguard system. If you receive this email, bring it with you to expedite your group's admission to the building. Ensure that the barcode is printed at 100% resolution to avoid potential barcode reading errors.

Please have all attendees bring valid photo identification and allow 15-30 minutes to complete security clearance. Upon arrival at FDA, provide the guards with either of the following numbers to request an escort to the conference room: *Confidential*

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Submit background information for the meeting (three paper copies or one electronic copy to the application and five desk copies to me) at least four weeks prior to the meeting. If the materials presented in the information package are inadequate to prepare for the meeting or if we do not receive the package by *Confidential* 2013, we may cancel or reschedule the meeting.

Submit the five desk copies to the following address:

Confidential

Food and Drug Administration
Center for Drug Evaluation and Research
Confidential

Please be advised that you must submit a Pediatric Study Plan (PSP) within 60 days of your scheduled end-of-Phase 2 meeting. The PSP must contain an outline of the pediatric study or studies that you plan to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach); any request for a deferral, partial waiver, or waiver, if applicable, along with any supporting documentation, and any previously negotiated pediatric plans with other regulatory authorities. For additional guidance on

submission of the PSP you may contact the Pediatric and Maternal Health Staff at *Confidential*

If you have any questions, call me, Regulatory Project Manager, at *Confidential* .

Sincerely,

{See appended electronic signature page}

Confidential
Regulatory Project Manager
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure:
Foreign Visitor Data Request Form

FOREIGN VISITOR DATA REQUEST FORM

VISITORS FULL NAME (First, Middle, Last)	
GENDER	
COUNTRY OF ORIGIN/CITZENSHIP	
DATE OF BIRTH **(MM/DD/YYYY)**	
PLACE OF BIRTH **(city and country)**	
PASSPORT NUMBER COUNTRY THAT ISSUED PASSPORT ISSUANCE DATE: EXPIRATION DATE:	
VISITOR ORGANIZATION/EMPLOYER	
MEETING START DATE AND TIME	
MEETING ENDING DATE AND TIME	
PURPOSE OF MEETING	
BUILDING(S) & ROOM NUMBER(S) TO BE VISITED	
WILL CRITICAL INFRASTRUCTURE AND/OR FDA LABORATORIES BE VISITED?	
HOSTING OFFICIAL **(**name, title, office/bldg, room number, and phone number)	
ESCORT INFORMATION (If different from Hosting Official)	

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Confidential

05/01/2013