CURRENT REPORT OF:
TNI BIOTECH, INC.

(OTC: TNIB)

Date of Report: May 6, 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, Inc. Receives Confirmation of Transfer of IND application and Orphan Drug Designation

TNI BioTech has received acknowledgement from the Department of Health and Human Services confirming the Food and Drug Administration's (FDA) receipt of the change in sponsorship of the investigational new drug application (IND) for Naltrexone HCL and the orphan drug designation for [met5]-enkephalin and the orphan drug designation for the use of low dose naltrexone in the treatment of pediatric patients with Crohn's Disease.

The Company signed an agreement for the acquisition of patent rights for the intellectual property of Dr. Jill Smith and LDN Research Group, LLC, whose members are Dr. Ian S. Zagon, Dr. Patricia J. McLaughlin and Moshe Rogosnitzky and orphan drug designation by the FDA to a novel late-stage drug, trademarked "LDN," for the treatment of Pediatric Crohn's Disease. The patent covers methods and formulations for treatment of the inflammatory and ulcerative diseases of the bowel, using naltrexone in low doses as an opioid antagonist. Endogenous opioids and opioid antagonists have been shown to play a role in stimulating and rebalancing the immune system and the healing and repair of tissues. For more information, please see the Material Information Disclosure filed with OTC Markets on January 8, 2013.

The Company signed an exclusive licensing agreement with The Penn State Research Foundation to license all of the intellectual property developed by Dr. Ian S. Zagon, Dr. Patricia J. McLaughlin and Dr. Jill P. Smith for the treatment of cancer titled "Opioid Growth Factor and Cancer" and "Combination Therapy with Opioid Growth Factor and Taxanes for the Treatment of Cancer." As part of the Agreement, TNI BioTech acquired the orphan drug designation (IND), and clinical data set from Dr. Jill Smith. For more information, please see the Material Information Disclosure filed with OTC Markets on January 31, 2013.

The acknowledgements of the transfers of the IND and orphan drug designation referenced above are 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 & HUMAN SERVICES

Public Health Service

Office of Orphan Products Development
Food and Drug Administration
WO32-5271
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: (301) 796-8660
Fax: (301) 847-8620

April 3, 2013

Ronald B. Herberman, MD
Chief Medical Officer
Sr. Vice President, R & D
TNI BioTech, Inc.
6701 Democracy Blvd – Suite 300
Bethesda, Maryland 20817

Re: Orphan Drug Designation Transfer No.: 09-2969

Dear Dr. Herberman:

Reference is made to the designated orphan drug applications submitted pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act for naltrexone for the treatment of pediatric Crohn's disease.

We also refer to your letter dated March 8, 2013 notifying us that the sponsorship of this application has been transferred to you from Jill P. Smith, MD, and the National Institutes of Health, NIDDKD.

Please be advised that if naltrexone is approved for an indication broader than the orphan designation, your product might not be entitled to exclusive marketing rights pursuant to Section 527 of the FFDCA (21 U.S.C. 360cc). Therefore, prior to final marketing approval, sponsors of designated orphan drugs are requested to compare the designated orphan indication with the proposed marketing indication and to submit additional data to amend their orphan designation prior to marketing approval if warranted.

Finally, please notify this Office within 30 days of submission of a marketing application for the use of naltrexone as designated. Also, an annual progress report must be submitted annually after the designation date until a marketing application is approved (21 CFR 316.30).

The information required for the complete transfer of the orphan drug application has been submitted. We look forward to your future communication.

Sincerely yours,

Mary L. Grice

Digitally signed by Mary L. Grice
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary L. Grice, 0.9.2342.19200300.100.1.1=1300019770
Date: 2013.04.03 15:02:21 -04'00'

Designation Coordinator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Orphan Products Development
Food and Drug Administration
WO32-5271
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: (301) 796-8660
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April 3, 2013

Ronald B. Herberman, MD
Chief Medical Officer
Sr. Vice President, R & D
TNI BioTech, Inc.
6701 Democracy Blvd – Suite 300
Bethesda, Maryland 20817

Re: Orphan Drug Designation Transfer No.: 12-3883

Dear Dr. Herberman:

Reference is made to the designated orphan drug applications submitted pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act for [met5]-enkephalin.

We also refer to your letter dated March 21, 2013 notifying us that the sponsorship of this application has been transferred to you from Jill P. Smith, MD, and the National Institutes of Health, NIDDKD.

Please be advised that if [met5]-enkephalin is approved for an indication broader than the orphan designation, your product might not be entitled to exclusive marketing rights pursuant to Section 527 of the FFDCA (21 U.S.C. 360cc). Therefore, prior to final marketing approval, sponsors of designated orphan drugs are requested to compare the designated orphan indication with the proposed marketing indication and to submit additional data to amend their orphan designation prior to marketing approval if warranted.

Finally, please notify this Office within 30 days of submission of a marketing application for the use of [met5]-enkephalin as designated. Also, an annual progress report must be submitted annually after the designation date until a marketing application is approved (21 CFR 316.30).

The information required for the complete transfer of the orphan drug application has been submitted. We look forward to your future communication.

Sincerely yours,

Mary L. Grice

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary L. Grice, 0.9.2342.19200300.100.1.1=1300019770
Date: 2013.04.03 14:54:40 -04'00'

Designation Coordinator

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND 67442

CHANGE OF SPONSOR

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:

We acknowledge the MARCH 11, 2013, receipt of your MARCH 6, 2013, correspondence notifying the Food and Drug Administration of the change in sponsorship of the following Investigational New Drug Application (IND):

IND NUMBER ASSIGNED: 67442

PRODUCT NAME(S): Naltrexone HCL

NEW SPONSOR: TNI Bio Tech Inc.

PREVIOUS SPONSOR: Jill P. Smith, M.D.

DATE OF TRANSFER: March 8, 2013

Your submission contains all the information required to complete the change in sponsorship. Our files will be updated to list you as the sponsor of this IND.

If your IND references any DMFs, we request that you notify your suppliers and contractors who have DMFs referenced by your IND of the change so that they can submit a new letter of authorization (LOA) to their Drug Master File(s) and send you a copy of the new LOAs. Please submit these copies of the LOAs to this IND.

As sponsor of this IND, you are responsible for compliance with the FDCA (21 U.S.C. §§ 301 et. seq.) as well as the implementing regulations [Title 21 of the Code of Federal Regulations (CFR)]. A searchable version of these regulations is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm. Your responsibilities include:

- Reporting any unexpected fatal or life-threatening suspected adverse reactions to this Division no later than 7 calendar days after initial receipt of the information [21 CFR 312.32(c)(2)]. If your IND is in eCTD format, submit 7-day reports electronically

in eCTD format. If your IND is not in eCTD format, you may submit 7-day reports by telephone or fax;

- Reporting any (1) serious, unexpected suspected adverse reactions, (2) findings from other clinical, animal, or in-vitro studies that suggest significant human risk, and (3) a clinically important increase in the rate of a serious suspected adverse reaction to this Division and to all investigators no later than 15 calendar days after determining that the information qualifies for reporting [21 CFR 312.32(c)(1)]. If your IND is in eCTD format, submit 15-day reports to FDA electronically in eCTD format. If your IND is not in eCTD format, you may submit 15-day reports in paper format; and

- Submitting annual progress reports within 60 days of the anniversary of the date that the IND went into effect (the date treatment use was permitted to begin) [21 CFR 312.33].

In addition, you are responsible for any correspondence outstanding as of the effective date of the transfer.

Secure email between CDER and sponsors is useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with the FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications.

If you have any questions, call me at (301) 796-5343.

Sincerely,

{See appended electronic signature page}

Matt Brancazio, Pharm.D.
Regulatory Health Project Manager
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

MATTHEW B BRANCAZIO
03/26/2013