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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): August 6, 2014

TNI BioTech, Inc.
(Exact name of registrant as specified in its charter).

Florida 000-54933 59-3226705
(State or other jurisdiction (Commission (IRS Employer
or incorporation) File Number) Identification Number)

37 North Orange Avenue, Suite 607, Orlando, Florida 32801
(Address of principal executive offices) (Zip Code)

(888) 613 - 8802
(Registrant’s telephone number, including area code)

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

(1)
1.01 Entry into a Material Definitive Agreement.

On August 6, 2014, TNI BioTech, Inc. (the “Company”) entered into a Supplementary Agreement on New Drug Methionine – Enkephalin Cooperation (the “Amendment”) with Hubei Qianjiang Pharmaceutical Co., Ltd., a Chinese listed company (“Qianjiang Pharmaceutical”), amending that certain Venture Cooperation Agreement on New Drug Methionine Enkephalin dated October 18, 2012, as amended by an Addendum to Venture Cooperation and a Supplementary Cooperation Agreement on New Drug Methionine Enkephalin.

The Company and Qianjiang Pharmaceutical executed the Amendment to accelerate clinical trials in both the United States and China, and agreed to immediately initiate three month Good Laboratory Practice (“GLP”) Toxicology Studies (rat and dog) within 30 days of signing the Amendment. The Amendment requires that the GLP Toxicology Studies Trials are conducted in China in accordance with international standards and standards acceptable to the U.S. Food and Drug Administration and that the studies include the following:

Exploratory Toxicology (nGLP)
- Dose range finding studies
- Different species and methods of administration
- Multiple dosing regimens
- Estimate the response vs. dose given

Definitive Toxicology (GLP)
- Performed in collaboration with Calvert Laboratories (USA) and MPI/Medicillon (China)
- General toxicology studies
- Different species and methods of administration
- Immunogenicity study with NHPs

Special Toxicology Studies (planned)

Pursuant to the Amendment, Qianjiang Pharmaceutical will make certain funds available from a co-administrative account, opened by Qianjiang Pharmaceutical for the develop of Methionine [Met5] - enkephalin (“MENK”) in China, in accordance with an approved budget and timeline set forth in the Amendment. A portion of these funds are expected to be used by Cytocom Inc., a wholly-owned subsidiary of the Company (“Cytocom”), to run PK and Dosing trials for MENK in the United States.

The Amendment requires Cytocom and Qianjiang Pharmaceutical to meet with the China State Food and Drug Administration (“SFDA”) to determine that PK and Dosing Trials completed in the United States will be acceptable to the SFDA. All developments and trials run by Cytocom in the U.S. or the European Union will be used for requesting registration approval in China.

On August 6, 2014, Professor Fengping Shan Ph.D., a member of the Company’s Board of Directors, executed an Assignment (the “Assignment”) pursuant to which he transferred his entire right, title and interest in and to the following listed Patents and/or Patent Applications in China to the Company: (1) CN 200710158742.7 Met-enkephalin, its application in in treating leukemia and other blood cancers; (2) CN 200710051586.4 Met-enkephalin, its application in preparation of human and animal vaccine; (3) CN 200610046249.1 A nasal spray formulation containing Met-enkephalin; (4) CN 201210290150.1 Low dose naltrexone, combined with MENK, its application in preparation of anticancer drug; (5) CN 201210302259.2 Low dose naltrexone, combined with MENK, its application in preparation of leukophoresis for anticancer; (6) CN 200810229085.5 Compound met-enkephalin as a drug for colon cancer and pancreatic cancer using a method of by isolating and enriching a patient’s own immune cells and following an enriching external incubation are transfused back into the patient thereby providing the patient with a passive immunity containing large amounts of auto-amplified immune cells that combat cancer cells; (7) CN 200910011030.1 Naltrexone; and (8) CN 201210302259 Application of combination of low-dose naltrexone and methionine-enkephalin to preparation of anti-cancer drug.
The Amendment is filed as Exhibit 1.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Assignment is filed as Exhibit 1.2 to this Current Report on Form 8-K and is incorporated herein by reference. The foregoing description of the material terms of the Amendment and the Assignment and the transactions contemplated thereby does not purport to be complete and is qualified in its entirety by reference to such exhibit.

9.01 Financial Statements and Exhibits.

Exhibit 1.1 Supplementary Agreement on New Drug Methionine – Enkephalin Cooperation, dated August 6, 2014, between TNI BioTech, Inc. and Hubei Qianjiang Pharmaceutical Co., Ltd.

Exhibit 1.2 Assignment by Professor Fengping Shan Ph.D. to the Company, executed August 6, 2014.
SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant 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
Supplementary Agreement on New Drug Methionine-Enkephalin Cooperation

In October, 2012, Hubei Qianjiang Pharmaceutical Co., Ltd (a Chinese listed company) and TNI Biotech, Inc. (an American company) signed Cooperation Agreement on New Drug Methionine Enkephalin in Qianjiang, Hubei Province, China.

In August 5, 2014, Hubei Qianjiang Pharmaceutical Co., Ltd (hereinafter referred to as "Qianjiang Pharmaceutical") and TNI Biotech, Inc. (hereinafter referred to as "TNI Biotech") signed Supplementary Cooperation Agreement on New Drug Methionine Enkephalin in America. TNI Biotech has established a great deal of studies since signed the agreements, including basic studies such as pharmaceutical studies, pharma toxicology studies, clinical trials and new-developed indications. Such trials work smoothly, and several results have got the approval of the Food and Drug Administration.

According to the reports of TNI Biotech, TNI Biotech has established phase I and II clinical trials as used for pancreatic cancer, and joined FDA meeting in August, 2013. In the meeting, FDA approved TNI Biotech in following aspects: developing MENK as lyophilized powder and with administration route by iv or subcutaneous approving phase I and II clinical results; holding meeting on End of Phase II and determination of Phase III in America after TNI Biotech complement pharmaceutical studies and pharma-toxicology studies on MENK; evaluating the basic studies and trials by TNI Biotech on MENK as used for treating liver cancer. FDA approved a phase IIB study but has required a PK and Dosing Trial be run in parallel with the Phase IIB Trials.

To date, Hubei Qianjiang Pharmaceutical Co., Ltd has established great of marketing research, and pre-trials on pharmaceutical and pharma-toxicology studies, which have obtained positive results. In order to accelerate clinical trials in both America and China and many other researches and developments, both parties agree:

1. According to the previous agreements, Qianjiang Pharmaceutical has opened a co-administration account for the development of MENK in China.

2. The parties agree to immediately to initiate 3-mo GLP Toxicology Studies (rat & dog) within 30 days of the signing of this agreement. GLP Toxicology Studies Trials will be run in China in accordance with international standards and acceptable to the FDA. The studies will include

   - Dose range finding studies
   - Different species and methods of administration
   - Multiple dosing regimens
   - Estimate the response vs. dose given

Exploratory Toxicology (nGLP)

- Performed in collaboration with Calvert Laboratories (USA) and MPI/Medicillon (China)
- General toxicology studies
- Different species and methods of administration
- Immunogenicity study with NHPs

Definitive Toxicology (GLP)

- Special toxicology studies (planned)

3. Qianjiang has raised the funds necessary to for clinical development and marketing of MENK.
This amendment will be going to effect after signature by two parties

/s/ Ye Jige
Mr. Ye Jige Chief Executive Officer
Hubei Qianjiang Pharmaceutical Co., Ltd
Date: August 6, 2014

/s/ Noreen Griffin
Noreen Griffin
Chief Executive Officer
TNI BioTech Inc
Date: August 6, 2014

/s/ Noreen Griffin
Cytocom Inc Chairman
Noreen Griffin
Date: August 6, 2014

EXHIBIT A

ESTIMATED DEVELOPMENT MENK BUDGET AND TIMELINE

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Revised MENK Development Plan – Key Activities

Estimated Timeline

Initiate Phase 1 PK study in healthy volunteers

Initiate 3-mo GLF Toxicology Studies (rat & dog)

Initiate Phase 2 Randomized Study

Submit Phase 2 data to support initiation of Phase 3

Submit 3-mo GLP Toxicology Reports

Initiate Phase 3

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ASSIGNMENT

WHEREAS, Professor Fengping Shan Ph.D., of No.92 North Second Road, Department of Immunology, China Medical University, Shenyang, Liaoning China 110001 (hereinafter Assignor), is the owner of the entire right, title and interest in and to the following listed Patents and/or Patent Applications (hereinafter Patents) in China by previous assignments;

1) CN 200710158742.7 Met-enkephalin, its application in in treating leukemia and other blood cancers;

2) CN 200710051586.4 Met-enkephalin, its application in preparation of human and animal vaccine;

3) CN 200610046249.1 A nasal spray formulation containing Met enkephalin;

4) CN 201210290150.1 Low dose naltrexone, combined with MENK, its application in preparation of anticancer drug;

5) CN 20120302259.2 Low dose naltrexone, combined with MENK, its application in preparation of leukapheresis for anticancer;

6) CN 200810229085.5 Compound met-enkephalin as a drug for colon cancer and pancreatic cancer using a method of by isolating and enriching a patient's own immune cells and following an enriching external incubation are transfused back into the patient thereby providing the patient with a passive immunity containing large amounts of auto-amplified immune cells that combat cancer cells.;

7) CN 200910011030.1 Naltrexone

8) CN 20120302259 Application of combination of low-dose naltrexone and methionine-enkephalin to preparation of anti-cancer drug

WHEREAS, TNI BioTech, Inc. (hereinafter Assignee), a corporation organized and existing under and by virtue of the laws of United States of America, having an office at 618 East South Street #500, Orlando, FL 32801, is desirous of acquiring the entire right, title and interest in and to the inventions described and claimed in said;

NOW, THEREFORE, for good and valuable consideration, the receipt of and sufficiency of which are hereby acknowledged, said Assignor has sold, assigned and transferred and does hereby sell, assign and transfer unto said Assignee, its successors and assigns, its entire undivided right, title and interest in and to the said Patents and the inventions therein contained, including the right to sue for past infringement, to be held and enjoyed by said Assignee, its successors
and assigns, the same as it would have been held and enjoyed by said Assignor if this assignment and sale had not been made.

Said Assignor hereby represents and warrants that there are no rights or interests outstanding inconsistent with the rights and interest granted herein and that said Assignor will not execute any instrument or grant or transfer any rights or interests inconsistent therewith, and said Assignor binds itself and its heirs, executors, administrators, employees and legal representatives, as the case may be, to execute and deliver to said Assignee, its successors and assigns, any further documents or instruments and do any and all further acts that may be deemed necessary by said Assignee, its successors and assigns, to file applications for improvements and inventions in any country where it may elect to file such applications, and that may be necessary to vest in said Assignee, its successors and assigns, the title herein conveyed, or intended so to be, and to enable such title to be recorded in the United States and foreign countries where such application or applications may be filed.

AND, said Assignor further covenants and agrees, in consideration of the premises, that it, its executors and administrators, will, at any time upon request, communicate to said Assignee, its successors and assigns, any facts relating to the said invention and improvements and the history thereof, known to it or its successors and assigns, and that it will testify as to the same in any interference or other proceeding when requested to do so by said Assignee, its successors and assigns.

The undersigned hereby grants the law firm of Birch, Stewart, Kolasch & Birch, LLP the power to insert on this Assignment any further identification that may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office for recordation of this document.

IN TESTIMONY WHEREOF, said Assignor has hereunto set its seal this 5th day of August, 2014.

/s/Fengping Shan
Fengping Shan Ph.D. (signed August 6, 2014)