

**TNI BioTech, Inc.**  
**Quarter Disclosure Statement**  
**For the quarter ending March 31, 2013**

**General Company Information**

**Item I The exact name of the issuer and its predecessors:**

**TNI BioTech, Inc. (OTC Pink Markets: "TNIB")**  
Formerly:  
Galliano International, Ltd. From May 27, 1998 until November 10, 2004  
Resorts Clubs International Inc., until March 1, 2012  
pH Environmental Inc until May 14, 2012

**Item II The address of its principal executive offices:**

6701 Democracy Boulevard, Suite 300  
Bethesda, Maryland 20817  
Phone: 888-613-8802

**IR Contact:**

Global Investment Media, LLC  
553 N Pacific Coast Highway #276  
Redondo Beach, California 90277  
Phone: 310-353-6277

**Item III Security Information:**

Trading Symbol:	TNIB
Common Stock:	500,000,000 shares authorized
CUSIP	872608104
Par Value of Common Stock:	\$.001 per share

**For the Period ending March 31, 2012:**

Common Stock Outstanding as of the date of this filing (May 15, 2013): 53,896,535

**Transfer Agent:**

Direct Transfer, LLC  
500 Perimeter Park Drive, Suite D  
Morrisville, North Carolina 27560

The Transfer Agent is registered under the Exchange Act.

**Item IV Issuance History**

**See the Financial Statements and the Notes to the Financial Statements attached hereto.**

**Item V Financial Statements**

The Issuer's unaudited Financial Statements are attached herein.

**Item VI Issuer's Business, Products and Services**

## **A. Business Operations**

TNI BioTech is a biopharmaceutical company focused on developing and commercializing therapeutics to treat cancer, HIV/AIDS and autoimmune diseases by combating these chronic and often life-threatening diseases through the activation and rebalancing of the body's immune system. The Company has been developing active and adoptive forms of immunotherapies through the acquisition of patents, INDs (investigational new drug) and clinical data and all proprietary technical information, know-how, procedures, protocols, methods, prototypes, designs, data and reports, which are not readily available to others through public means, and which are owned, generated or developed through experiments or testing by Dr. Plotnikoff, Professor Shan, Dr. Bernard Bihari, Dr. Ian Zagon, Dr. Jill Smith, Dr. Patricia J. McLaughlin and Moshe Rogosnitzky.

Our products, technologies and patents are designed to harness the power of the immune system to improve the treatment of cancer, autoimmune disease such as HIV/AIDS and, infections such as Crohn's disease or irritable bowel syndrome. We have been developing active and adoptive forms of immunotherapies.

Our most advanced clinical programs involve immunotherapy using Met-enkephalin (MENK) and low dose naltrexone, which both work by triggering opioid receptors on immune cells, leading to an activation and expansion of various cells of the immune system.

TNI BioTech's first acquisition was the patents and intellectual property of Dr. Nicholas P. Plotnikoff and Professor Fengping Shan. While Dr. Plotnikoff was with Oral Roberts University, he was a member of the team that developed and patented the specific application of Met-enkephalin ("MENK") as a treatment for cancer, HIV/AIDS, and infectious diseases. MENK is a member of the body of hormones known as cytokines, which are produced by the immune system. MENK plays an essential role in influencing all components of the immune system. The most important participant in the immune response is a class of white blood cells known as lymphocytes. These cells develop in the bone marrow and are released into general circulation.

Dr. Plotnikoff is the inventor behind a number of patents granted for cancer treatments and an adjunct to patents for autoimmune diseases including: European Patents in the United Kingdom, Germany, France, and Ireland number 1627/KOLNP/2003 and number 220265, an enkephalin peptide composition; a Russian Federation Patent, patent number 2313364 EP 1401471 covering BI Methods for inducing sustained immune response; The Patent Office of the People's Republic of China, application No.: 200810165784.8 China Patent CN101513407 A The Patent Office of the People's Republic of China ISSN: 1006-2858 CN 21-1349/R.; Government of India Patent, application number 1627/KOLNP/2003, patent number 220265 for an enkephalin peptide composition; the United States Patent is pending, US PCT patent Application Number 10/146.999. The Patent Cooperation Treaty ("PCT") enables a U.S. applicant to file a single application, known as "an international application," in a standardized format in English in the U.S. Receiving Office (the U.S. Patent and Trademark Office), that is acknowledged as a regular national or regional filing in any state or region that is party to the PCT.

In addition to the above patents, TNIB also signed an exclusive licensing agreement for all of the intellectual property developed at Pennsylvania State University by Dr. Ian S. Zagon, Dr. Patricia J. McLaughlin and Dr. Jill P. Smith for the treatment of cancer. The patents cover methods and formulations related to the treatment and prevention of cancers, particularly gastrointestinal cancer. More specifically, the present inventions describe the use of drugs that interact with opioid receptors (naltrexone, naloxone and the pentapeptide Met-enkephalin) to inhibit and arrest the growth of cancer. Such efficacy has been discovered to be partially due to the functional manipulation of the zeta opioid receptor through exogenous and endogenous Met-enkephalin. This receptor has been determined to be present in a variety of cancers,

including pancreatic and colon cancer. US Patent Numbers 6,737,397, CA 2,557,504, [US 20010046968](#), [US 6737397](#), [US 6136780](#), [US 20080015211](#), [US 20070053838](#), [US 8003630](#), [US 20110123437](#), [US 7807368](#), [US 7576180](#), [US 7517649](#), [US 20080146512](#), [US 7122651](#), [US 20060073565](#), [US 20050191241](#), Patent No 8,003,630.

As part of the agreement with TNIB, Dr. Jill Smith has agreed to arrange with the FDA the transfer of the Orphan Drug Designation for the use of MENK / OGF which are related to the therapeutic efficacy and action mechanism of Met-enkephalin, referred to as opioid growth factor in the treatment of pancreatic cancer to TNI BioTech. Dr. Smith will also make arrangements to transfer the IND to TNI BioTech, as well as the relevant clinical data set.

TNIB also acquired the licensing rights to the patent portfolio and intellectual property developed by Dr. Bernard Bihari relating to treatments with drugs that interact with opioid receptors such as low dose naltrexone and MENK for a variety of diseases and conditions including malignant lymphoma, chronic lymphocytic leukemia, Hodgkin's lymphoma and non-Hodgkin's lymphoma, chronic herpes virus infections and chronic infections due to the Epstein-Barr virus and a treatment method for humans infected with HTLV-III (AIDS) virus including patients clinically diagnosed as suffering from HIV/AIDS and those suffering from HIV/AIDS-related complex (ARC). The licensed rights include all reissues or modifications, reexaminations or other related U.S. patent filings directed to the same subject matter and the use of U.S. Patent No. [U.S. Patent Number 6,586,443](#), [U.S. Patent Number 6,384,044](#), [U.S. Patent Number 6,288,074](#), [U.S. Patent Number 5,356,900](#), [U.S. Patent Number 5,013,739](#), [U.S. Patent Number 4,888,346](#).

Once the Company had acquired the above patents it then was able to sign a licensing agreement to acquire the exclusive patent rights for the intellectual property of Dr. Jill Smith and LDN Research LLC whose members are Dr. Ian S. Zagon, Dr. Patricia J. McLaughlin and Moshe Rogosnitzky. The patent covers methods and formulations for the treatment of the inflammatory and ulcerative diseases of the bowel, using naltrexone in low dose as an opioid antagonist. Endogenous opioids and opioid antagonists at low doses have been shown to play a role in stimulating and rebalancing the immune system and the healing and repair of tissues. US Patent No. 6,136,780, Patent No. US 7879870.

TNIB then negotiated with Dr. Jill Smith who agreed to arrange with the FDA the transfer of the Orphan Drug Designation for the use of naltrexone for the treatment of pediatric Crohn's Disease. Dr. Smith will also make arrangements to transfer the IND to TNI BioTech, as well as the relevant clinical data set.

The Company acquired these patents and intellectual property because Management believes clinical trials involving low-dose naltrexone ("LDN") hold great promise for the millions of people worldwide with autoimmune diseases, central nervous system disorders or who face a deadly cancer. Management also believes it could be the first low-cost, easy to administer, and side-effect-free therapy for HIV/AIDS and other autoimmune diseases. TNIB intends to market these therapies under the names IRT-101, IRT-102 and IRT-103 (LDN).

### **Business Strategy**

The Company's business strategy focuses on Four (4) key areas:

- The establishment of treatment facilities throughout Africa, the Caribbean and South America for cancer, HIV/AIDS and other autoimmune diseases that can benefit from IRT-101, IRT-102 and IRT-103 patented technology and therapies;
- The large scale treatment of HIV/AIDS and immune-enhancing therapy using IRT-103;

- The large scale manufacturing and distribution of IRT-103 LDN, either in pill form, or cream for those unable to handle the medication in pill form, throughout Africa and expanding to other developing nations; and
- The Joint Venture with the Hubei Qianjiang Pharmaceutical Company that will provide the funding required for the phase III trials in China in exchange for TNIB providing exclusive licensing rights in China. TNIB will also receive a percentage of the gross revenue from sales in China.

TNIB, in conjunction with GB Energie LLC, under the leadership of Dr. Gloria B. Herndon, established GB Oncology and Imagining Group LTD (“GBOIB”) to meet the demands for oncological and infectious diseases expertise. Dr. Herndon has been involved in healthcare related issues in Africa since the mid 1990’s and is a consulting resource for the National Institute of Health (“NIH”) regarding the impact of the HIV/AIDS pandemic on the insurance industry and the dissemination of AIDS-related information to the United States Department of State. The goal of TNIB/GBOIG, together with the ministries of health across Africa, is to provide better access to and public awareness of the prevention, diagnosis and treatment of cancer and chronic infectious diseases.

### **Our Approach**

The purpose of TNI BioTech’s immunotherapy is to increase the production of the immune system by increasing production of DC cells, Macrophages, CD4+T Cells (CD4), CD8+T cells, NK cells, NKT cells and Gammadelta T cells and inhibiting Treg cells to allow the body to recognize cancer cells as a foreign invader and thereby remove these cancer cells, to control infection with various microbial agents and to control the inflammation and destruction of normal tissues by autoimmune diseases.

The treatment modality focused on using MENK has been demonstrated to be effective while avoiding certain deleterious effects on the body, as is often the case with traditional chemotherapy. The costs are reasonable, making this an attractive complement for a large number of cancer patients. The adaptive cell immunity of the immune system consists of Three (3) different arms:

1. Helper T Cells (Th1/Th2) (CD4+), Cytotoxic T Cells (CTL)(CD8+) and CD4+CD25+T cells (Treg). Th1 cells help the regulation of cellular immunity via secreting cytokines such as Gamma Interferon (IFN- $\gamma$ ), Interleukin-2 (IL-2) and tumor necrosis factor (TNF), playing a role in anti-infection like antiviral (anti-HIV) and anti-cancer. Th2 cells help B cells produce antibodies. CTL mediates in killing tumor cells. Treg cells balance immunity through negative feedback regulation;
2. Cytotoxic or Killer T-Cells (CD8) attach to and destroy viruses (HIV, for example) and tumor cells; and
3. Th2 cells produce specific antibodies that recognize foreign invaders, including viruses, bacteria and parasites and thereby control infections.

Our research results indicate that MENK, at suitable doses, boosts the immune system through:

1. Increasing proliferation and functional activities of CD4+T cells and CD8+T cells which will play a role in anti-virus and anti-tumor activities;
2. Increasing maturation and differentiation of dendritic cells and macrophages, which will selectively present foreign antigens to Th1 cells and lead to generation of CTLs;

3. Increasing secretion of cytokines such as IL-2, TNF, IL-12 and IFN- $\gamma$  which will amplify the T cell response and mediate interaction among immune cells, forming a balanced and more robust immunity; and

4. Increasing activity of natural killer (NK) cells, which can recognize and kill cancer cells, virus-infected cells and some fungi and parasites.

Based on these findings we have developed new therapies. Our therapies are especially important when the patient's immune system is compromised due to treatment or diseases that can initially prevent an adequate cellular response.

Two (2) of the most important compounds to come out of current research are Low Dose Naltrexone ("LDN") and met-enkephalin ("MENK"). Both LDN and MENK are immune-enhancing drugs. They boost the immune system by increasing the T and NK cells in the body, thereby activating the body's own immune defenses.

**B. Date and State of Incorporation**

May 27, 1998, State of Florida

**C. SIC Codes**

2834 – Pharmaceutical Preparations

**D. Fiscal Year End**

December 31

**E. Principal Product, Services and Markets**

**The Products**

IRT-101 is an active immunotherapy with MENK for patients with deficient functioning of the immune system, which works by restoring immune functions and by activating a patient's lymphocytes to attack cancer cells and also infectious diseases, including HIV/AIDS.

IRT-102 is an adaptive immunotherapy which involves isolation and enrichment of a patient's own immune cells and exposing them to MENK in the laboratory. After a few days of culture, the activated lymphocytes are infused back into the patient to boost the ability of the immune system to control cancer cells or infected cells.

IRT-103 is an active immunotherapy with low dose naltrexone (LDN), an oral medication that works by activating a patient's immune system against HIV/AIDS and cancer cells, or by rebalancing the immune system of patients with autoimmune diseases, for example inflammatory bowel diseases such as Crohn's Disease or Multiple Sclerosis.

Management considers any condition that results in altered-immune response a target for investigation; however, the Company will most likely pursue additional investigations for MENK as a valuable candidate in the treatment of the following:

- Autoimmune diseases such as Rheumatoid Arthritis and Multiple Sclerosis;
- Infectious diseases, as an adjunct to antibiotics; and
- Cancer, as an alternative or a complement to surgery, chemotherapy and/or radiation treatments.

**Clinical Trials and Potential Treatment Focus**

Clinical trials have produced significant evidence that LDN/MENK stimulates the immune system and is effective in the treatment of some immune-suppressed diseases. The treatment modality has been demonstrated to be effective while avoiding certain deleterious effects on the body, as is often the case with traditional chemotherapy. The costs are reasonable, making this an attractive complement for a large number of cancer patients.

## **Other Information**

### **Form 10 Registration Statement**

The Company filed a Form 10 Registration Statement with the Securities and Exchange Commission on April 22, 2013. The Registration Statement is available at [sec.gov](http://sec.gov).

### **African Contracts**

In the African countries where the Company currently has contracts, international laws require the exporting company provide a certificate of Free Sale. It has taken TNI BioTech longer than anticipated to obtain the certificate of Free Sale.

### **Confirmation of Transfer of IND Application and Orphan Drug Designation**

In confirmation letters dated April 3, 2013, the Company 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.

### **Meeting with FDA Regarding LDN**

In May 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.

### **Manufacturing**

In March 2013, the Company decided that it would be better to outsource our manufacturing, rather than manufacture ourselves. This decision was made when the joint venture partner was unable to provide a facility that met international standards for manufacturing and canceled the contract. The Company at the same time entered into discussions with an existing facility in Managua, Nicaragua that has excess capacity. The Company believes that between the facility in Nicaragua and the Qianjiang Pharmaceutical GMP facility located in China, the Company should be able to begin delivering LDN by July 1, 2013.

## **Item VII Issuer's Facilities**

The Company leases office space in Bethesda, Maryland and Orlando, Florida on a month-to-month basis.

## **Item VIII Officers, Directors and Control Persons**

Noreen Griffin, Founder, Chief Executive Officer and Director

Dr. Eugene Youkilis, Director and President

Dr. Fengping Shan, Director and Chief Science Officer

Christopher Pearce, Director and Chief Operating Officer

Peter Aronstam, Chief Financial Officer

Dr. Ronald B. Herberman, Chief Medical Officer and Director of Research and Development

Dr. Nicholas Plotnikoff, Non-Executive Chairman of the Board

**The Advisory Board**

Professor Angus Dalglish MD, FRACP, FRCP, FRCPath, FMedSci

Dr. Gloria B. Herndon

Dr. Ndiouga Dieng, PD

Dr. Henry A. Lenz, PHARM.D. F.A.S.C.P.

Philip Giordano R.Ph. C.Ph

**Item IX Third Party Providers**

**Legal Counsel:**

Brinen & Associates, LLC  
7 Dey Street, Suite 1503  
New York, New York 10007  
Phone: 212-330-8151  
Email: corporateaction@brinenlaw.com

**Accountant or Auditor**

Peter Aronstam, Chief Financial Officer  
6701 Democracy Boulevard, Suite 300  
Bethesda, Maryland 20817  
Phone: 888-613-8802  
Email: peter.aronstam@tnibiotech.com

**Investor Relations Consultant**

Global Investment Media, LLC  
553 N Pacific Coast Highway #276  
Redondo Beach, California 90277  
Phone: 310-353-6277

**Item X Certifications:**

**I, Noreen Griffin, hereby certify that:**

1. I have reviewed this Quarter Disclosure Statement of TNI BioTech, Inc.;
2. Based on my knowledge, this disclosure statement does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under

which such statements were made, not misleading with respect to the period covered by this disclosure statement; and

3. Based on my knowledge, the financial statements, and other financial information included or incorporated by reference in this disclosure statement, fairly present in all material respects the financial condition, results of operations and balance sheets of the issuer as of, and for the periods presented in this disclosure statement.

Date: May 15, 2013

/s/ Noreen Griffin

Noreen Griffin, Chief Executive Officer

**I, Peter Aronstam, hereby certify that:**

1. I have reviewed this Quarter Disclosure Statement of TNI BioTech, Inc.;
2. Based on my knowledge, this disclosure statement does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this disclosure statement; and
3. Based on my knowledge, the financial statements, and other financial information included or incorporated by reference in this disclosure statement, fairly present in all material respects the financial condition, results of operations and balance sheets of the issuer as of, and for the periods presented in this disclosure statement.

Date: May 15, 2013

/s/ Peter Aronstam

Peter Aronstam, Chief Financial Officer

#### **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This following information specifies certain forward-looking statements of management of the Company. Forward-looking statements are statements that estimate the happening of future events and are not based on historical fact. Forward-looking statements may be identified by the use of forward-looking terminology, such as may, shall, could, expect, estimate, anticipate, predict, probable, possible, should, continue, or similar terms, variations of those terms or the negative of those terms. The forward-looking statements specified in the following information have been compiled by our management on the basis of assumptions made by management and considered by management to be reasonable. Our future operating results, however, are impossible to predict and no representation, guaranty, or warranty is to be inferred from those forward-looking statements.

The assumptions used for purposes of the forward-looking statements specified in the following information represent estimates of future events and are subject to uncertainty as to possible changes in economic, legislative, industry, and other circumstances. As a result, the identification and interpretation of data and other information and their use in developing and selecting assumptions from and among reasonable alternatives require the exercise of judgment. To the extent that the assumed events do not occur, the outcome may vary substantially from anticipated or projected results, and, accordingly, no opinion is expressed on the achievability of those forward-looking statements. We cannot guaranty that any of the assumptions relating to the forward-looking statements specified in the following information are accurate, and we assume no obligation to update any such forward-looking statements.

**TNI BIOTECH, INC.**  
**BALANCE SHEET**  
**Unaudited**

	<u>March 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 176,246	\$ 313,095
Prepays and Other Current assets	130,000	-
Total current assets	<u>306,246</u>	<u>313,095</u>
Fixed Assets:		
Computer equipment, net of accumulated depreciation of \$238 and \$118 respectively	1,994	944
Intangible Assets:		
Patents and licenses, net of amortization of \$2,266,238 and \$1,570,114, respectively	20,702,685	18,688,270
Deposits	10,528	24,928
Total assets	<u>\$ 21,021,453</u>	<u>\$ 19,027,237</u>

**LIABILITIES AND STOCKHOLDERS' EQUITY**

Current Liabilities:		
Accounts payable	\$ 362,374	\$ 286,698
Payable to officer	76,000	76,000
Accrued liabilities	559,388	427,211
Current portion patent liability	200,000	200,000
Notes payable	619,697	432,363
Total current liabilities	<u>1,817,459</u>	<u>1,422,272</u>
Non-current Liabilities:		
Notes payable related party	121,128	121,128
Long-term portion patent liability	<u>68,333</u>	<u>140,000</u>
Total non-current liabilities	<u>189,461</u>	<u>261,128</u>
Total Liabilities	<u>2,006,920</u>	<u>1,683,400</u>
Stockholders' Equity:		
Common stock - par value \$0.001; 500,000,000 shares authorized; 53,508,635 and 45,489,368 shares issued and outstanding as of March 31, 2013 and December 31, 2012 respectively	53,508	45,489
Additional paid in capital	247,558,786	196,632,775
Stock issuances due	1,120,960	3,690,960
Prepaid services	(38,086,431)	(6,082,771)
Accumulated deficit	<u>(191,632,290)</u>	<u>(176,942,616)</u>
Total stockholders' equity	<u>19,014,533</u>	<u>17,343,837</u>
Total liabilities and stockholders' equity	<u>\$21,021,453</u>	<u>\$19,027,237</u>

The accompanying notes are an integral part of these condensed financial statements.

**TNI BIOTECH, INC.**  
**STATEMENTS OF OPERATIONS**  
(Unaudited)

	<b>THREE MONTHS ENDED</b>	
	<b><u>March 31, 2013</u></b>	<b><u>March 31, 2012</u></b>
Revenues, net	\$ -	\$ -
<b>Operating expenses:</b>		
Selling, general and administrative	1,676,961	-
Research and development expense	380,427	-
Depreciation and amortization expense	696,244	-
Amortization of stock issued for prepaid services	7,561,740	-
Stock warrant expense	1,065,894	-
Total operating expenses	<u>11,381,266</u>	<u>-</u>
Loss from operations	<u>(11,381,266)</u>	<u>-</u>
<b>Other income (expense):</b>		
Interest expense	(239,912)	(6,751)
Loss on settlement of debt	(3,068,496)	-
Total other income (expense)	<u>(3,308,408)</u>	<u>(6,751)</u>
Loss from continuing operations	<u>(14,689,674)</u>	<u>(6,751)</u>
Gain (loss) from discontinued operations	-	7,348
Net Income (loss)	<u>\$ (14,689,674)</u>	<u>\$ 597</u>
<b>Basic and diluted loss per share:</b>		
Loss from continuing operations	\$ (0.29)	\$ (0.06)
Gain (loss) from discontinued operations	<u>-</u>	<u>0.07</u>
	<u>\$ (0.29)</u>	<u>\$ 0.01</u>
Weighted average number of shares outstanding	49,983,416	113,644

The accompanying notes are an integral part of these condensed financial statements.

**TNI BIOTECH, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE QUARTER ENDED MARCH 31, 2013 AND THE YEARS ENDED DECEMBER 31, 2012, and 2011**  
**(Unaudited)**

	<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Stock to Be Issued</u>	<u>Prepaid Services</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>					
Balance, December 31, 2010 as originally reported	113,644,000	\$ 113,644	\$ 892,073	\$ -	\$ -	\$ (1,827,471)	\$ (821,754)
Effect of reverse stock split	(113,530,356)	(113,530)	113,530	-	-	-	-
Adjusted balance, December 31, 2010	113,644	114	1,005,603	-	-	(1,827,471)	(821,754)
Net loss	-	-	-	-	-	(125,655)	(125,655)
Balance, December 31, 2011	113,644	114	1,005,603	-	-	(1,953,126)	(947,409)
Issuance of common stock for services	6,966,800	6,967	9,150,053	-	-	-	9,157,020
Issuance of common stock - dividend	1,182,474	1,182	(1,182)	-	-	-	-
Issuance of common stock in exchange for debt	2,901,450	2,901	22,472,407	-	-	-	22,475,308
Issuance of common stock for Acquisition of TNI Biotech IP	12,250,000	12,250	97,987,750	-	-	-	98,000,000
Issuance of common stock issued for Dr. Plotnikoff Patents	8,000,000	8,000	15,998,000	-	-	-	16,006,000
Issuance of common stock for prepaid services	6,790,000	6,790	23,080,460	-	(23,087,250)	-	-
Amortization of prepaid services	-	-	-	-	17,004,479	-	17,004,479
Issuance of common stock for cash	7,285,000	7,285	1,129,215	-	-	-	1,136,500
Issuance of warrants for common stock	-	-	25,810,469	-	-	-	25,810,469
Shares to be issued for patents and licenses	-	-	-	3,687,000	-	-	3,687,000
Shares to be issued for services	-	-	-	3,960	-	-	3,960
Net loss	-	-	-	-	-	(174,989,490)	(174,989,490)
Balance, December 31, 2012	45,489,368	45,489	196,632,775	3,690,960	(6,082,771)	(176,942,616)	17,343,837
Issuance of common stock for prepaid services	5,533,000	5,533	39,559,867	-	(39,565,400)	-	-
Amortization of prepaid services	-	-	-	-	7,561,740	-	7,561,740
Issuance of common stock for Jill Smith/LDN license	300,000	300	2,714,700	(2,715,000)	-	-	-
Issuance of common stock for Penn State License	300,000	300	2,549,700	-	-	-	2,550,000

Issuance of common stock issued for charitable donation	100,000	100	749,900	-	-	-	750,000
Issuance of common stock in exchange for debt	545,833	546	3,129,616	-	-	-	3,130,162
Issuance of common stock for loan expenses	60,000	60	272,190	-	-	-	272,250
Issuance of common stock for cash	1,180,434	1,180	884,144	-	-	-	885,324
Common stock to be issued for cash	-	-	-	145,000	-	-	145,000
Issuance of warrants for common stock	-	-	1,065,894	-	-	-	1,065,894
Net loss	-	-	-	-	-	(14,689,674)	(14,689,674)
Balance, March 31, 2013	53,508,635	\$ 53,508	\$ 247,558,786	\$ 1,120,960	\$ (38,086,431)	\$ (191,632,290)	\$ 19,014,533

The accompanying notes are an integral part of these condensed financial statements.

**TNI BIOTECH, INC.**  
**STATEMENTS OF CASH FLOWS**  
(Unaudited)

THREE MONTHS ENDED  
March 31, 2013    March 31, 2012

**CASH FLOWS FROM OPERATING ACTIVITIES**

Net income (loss)	\$ (14,689,674)	\$ 597
(Gain) loss from discontinued operations	-	(7,348)
Loss from continuing operations	(14,689,674)	(6,751)

Adjustments to reconcile loss from continuing operations to net cash flows used in operating activities:

Depreciation	120	-
Amortization	696,124	-
Stock issued for services	7,561,740	-
Loss on settlement of debt	3,068,496	-
Stock warrant expense	1,065,894	-
Stock issued for donation	750,000	-
Stock issued for interest	232,250	-
Changes in operating assets and liabilities:		
Accrued liabilities	132,177	6,751
Prepaid expenses and deposits	(75,600)	-
Accounts payable	75,676	-

Net cash used in operating activities from continuing operations	(1,182,797)	-
--	-------------	---

**CASH FLOWS FROM INVESTING ACTIVITIES**

Purchase of computer equipment	(1,170)	-
Purchase of Penn State License	(160,539)	-

Net cash used in investing activities from continuing operations	(161,709)	-
--	-----------	---

**CASH FLOWS FROM FINANCING ACTIVITIES**

Proceeds from exercise of stock options	735,326	-
Proceeds from sale of stock	294,998	-
Proceeds from notes payable	249,000	-
Payments made on patent liability	(71,667)	-

Net cash provided by financing activities from continuing operations	1,207,657	-
--	-----------	---

**CASH FLOWS FROM DISCONTINUED OPERATIONS**

Net cash provided by operating activities	-	-
---	---	---

Increase (decrease) in cash	(136,849)	-
Cash, beginning of period	313,095	12

Cash, end of period	<u>\$ 176,246</u>	<u>\$ 12</u>
---------------------	-------------------	--------------

The accompanying notes are an integral part of these condensed financial statements.

**TNI BIOTECH, INC.**  
**STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

THREE MONTHS ENDED  
March 31, 2013      March 31, 2012

**SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:**

Cash paid for interest	\$	-	\$	-
------------------------	----	---	----	---

**SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:**

Conversion of debt and accrued interest to common stock	\$	61,666	\$	-
Common Shares issued for Penn State License	\$	2,550,000	\$	-
Common shares issued for prepaid services	\$	39,565,400	\$	-

The accompanying notes are an integral part of these condensed financial statements.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

**1. Organization and Description of Business**

TNI BioTech, Inc. (the "Company" or "TNIB") was initially incorporated in Florida on December 2, 1993 as Resorts Clubs International, Inc. ("Resorts Club"). It was formed to manage and market golf course properties in resort markets throughout the United States. Galliano International Ltd. ("Galliano") was incorporated in Delaware on June 27, 1998. The Company began trading in November 1999 through the filing of a 15C-211. On November 3, 2004, Galliano merged with Resorts Club International, Inc. Resorts Club was the surviving corporation. On August 10, 2010, Resorts Club changed its name to pH Environmental Inc ("pH Environmental"). On April 23, 2012, pH Environmental completed a name change to TNI BioTech, Inc., and on April 24, 2012 pH Environmental executed a share exchange agreement for the acquisition of all of the outstanding shares of TNI BioTech, Inc.

TNI BioTech is a biopharmaceutical company focused on developing and commercializing therapeutics to treat cancer, HIV/AIDS and autoimmune diseases by combating these chronic and often life-threatening diseases through the activation and rebalancing of the body's immune system. The Company has been developing active and adoptive forms of immunotherapies through the acquisition of patents, INDs (investigational new drug) and clinical data and all proprietary technical information, know-how, procedures, protocols, methods, prototypes, designs, data and reports, which are not readily available to others through public means, and which are owned, generated or developed through experiments or testing by Dr. Plotnikoff, Professor Shan, Dr. Bernard Bihari, Dr. Ian Zagon, Dr. Jill Smith, Dr. Patricia J. McLaughlin and Moshe Rogosnitzky. The Company currently has offices in Bethesda, Maryland and Orlando, Florida.

**Going Concern**

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through private equity financings. Management expects operating losses and negative cash flows to continue at more significant levels in the future. As the Company continues to incur losses, transition to profitability is dependent upon the successful development, approval, and commercialization of its product candidate and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional cash. Management intends to fund future operations through additional private or public debt or equity offerings, and may seek additional capital through arrangements with strategic partners or from other sources. Based on the Company's operating plan, existing working capital at March 31, 2013 was not sufficient to meet the cash requirements to fund planned operations through March 31, 2014 without additional sources of cash. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business.

The Company has experienced a net loss from operations of \$14,689,674 and has used cash and cash equivalents for operations in the amount of \$1,182,797 during the three months ended March 31, 2013, resulting in stockholders' equity of \$19,014,533.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"), as amended for interim financial information.

The financial information as of December 31, 2012 is derived from the audited financial statements presented in the Company's Form 10 Registration Statement filed with the Commission on April 22, 2013 for the year ended December 31, 2012. The unaudited interim consolidated financial statements should be read in conjunction with the Company's Form 10 Registration Statement, which contains the audited financial statements and notes thereto, together with Management's Discussion and Analysis of Financial Condition and Results of Operations, for the years ended December 31, 2012 and 2011.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

Certain information or footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all the information and footnotes necessary for a comprehensive presentation of financial position, results of operations, or cash flows. It is management's opinion, however, that all material adjustments (consisting of normal recurring adjustments) have been made which are necessary for a fair financial statement presentation. The interim results for the three months ended March 31, 2013 are not necessarily indicative of results for the full fiscal year.

**Use of Estimates**

The preparation of the Company's financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from such estimates.

**Cash, Cash Equivalents, and Short-Term Investments**

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits, marketable securities with maturities of three months or less at purchase, and money market funds that invest primarily in certificates of deposits, commercial paper and U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Marketable securities with original maturities greater than three months and less than one year are considered to be short-term investments. Short-term investments are reported at fair market value and unrealized gains and losses are included as a separate component of stockholders' equity (deficit). Realized gains, realized losses, the amortization of premiums and discounts, interest earned and dividends earned are included in other income (expense). The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year are classified as long-term. A decline in the market value of a security below its cost value that is deemed to be other than temporary is charged to earnings, and results in the establishment of a new cost basis for the security.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company is exposed to credit risk, subject to federal deposit insurance, in the event of a default by the financial institutions holding its cash and cash equivalents to the extent of amounts recorded on the balance sheets.

**Segment and Geographic Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment and does not segment the business for internal reporting or decision making.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

**Fair Value of Financial Instruments**

In accordance with the reporting requirements of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 825, "*Financial Instruments*", the Company calculates the fair value of its assets and liabilities which qualify as financial instruments under this standard and includes this additional information in the notes to the financial statements when the fair value is different than the carrying value of those financial instruments. Cash, patents and licenses, accounts payable, payable to officer, patent liability and net liabilities of discontinued operations are accounted for at cost which approximates fair value due to the relatively short maturity of these instruments. The carrying value of notes payable and notes payable related party also approximate fair value since they bear market rates of interest and other terms. None of these instruments are held for trading purposes.

**Property and Equipment**

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is determined on a straight-line basis over the estimated useful lives of the assets, which generally range from three to five years. Leasehold improvements are amortized over the shorter of the useful life of the asset or the term of the related lease. Maintenance and repairs are charged against expense as incurred. Depreciation expense from continuing operations for the three months ended March 31, 2013 and 2012 was \$120 and \$0, respectively.

**Intangible Assets**

Costs incurred to acquire and/or develop the Company's product licenses and patents are capitalized and amortized by straight-line methods over estimated useful lives of seven to sixteen years. Intangible assets are stated at the lower of cost or estimated fair market value. During the three months ended March 31, 2013, the Company capitalized \$2,710,539 of such costs incurred for the acquisition of the Company's patents. (See Note 10 of the Company's Form 10 Registration Statement). Amortization expense for the three months ended March 31, 2013 and 2012 was \$696,124 and \$0, respectively. The Company estimates its amortized expense related to these assets will approximate \$2,600,000 each year for the next five years.

**Impairment of Long-Lived Assets**

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable as prescribed by ASC Topic 360-10-05, "*Property, Plant and Equipment*" (formerly SFAS No. 144 "Accounting for the Impairment of Long-Lived Assets"). If the carrying amount of the asset, including any intangible assets associated with that asset, exceeds its estimated undiscounted net cash flow, before interest, the Company will recognize an impairment loss equal to the difference between its carrying amount and its estimated fair value. No impairment losses were recognized for the three months ended March 31, 2013.

**Research and Development Costs**

Research and development costs are charged to expense as incurred and are typically comprised of salaries and benefits, pre-clinical studies, clinical trial activities, drug development and manufacturing, fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf and third-party service fees, including clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as operating expenses.

**Income Taxes**

The Company follows FASB ASC Topic 740, "*Income Taxes*", which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are based on the differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC Topic 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement. ASC Topic 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. At the date of adoption, and as of March 31, 2013, the Company does not have a liability for unrecognized tax uncertainties.

The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of March 31, 2013, the Company has no accrued interest or penalties related to uncertain tax positions.

**Stock-Based Compensation and Issuance of Stock for Non-Cash Consideration**

The Company measures and recognizes compensation expense for all share-based payment awards made to employees and directors, including employee stock options, based on estimated fair values equaling either the market value of the shares issued or the value of consideration received, whichever is more readily determinable. The majority of the non-cash consideration pertains to services rendered by consultants and others and has been valued at the estimated value of the services to be provided on the dates issued.

The Company's accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows the provisions of ASC Topic 505-50, "*Equity-Based Payments to Non-Employees*." The measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete.

**Net Loss per Share**

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method and the if-converted method. Dilutive common stock equivalents are comprised of common stock purchase warrants and options outstanding. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

**Recent Accounting Standards**

For the three months ended March 31, 2013, there were several new accounting pronouncements issued by the Financial Accounting Standards Board. Each of these pronouncements, as applicable, has been or will be adopted by the Company. Management does not believe the adoption of any of these accounting pronouncements has had or will have a material impact on the Company's financial statements.

**3. Promissory Notes**

On March 11, 2013 the Company issued four short-term promissory notes to third party investors totaling \$249,000. Under the terms of the notes, the Company was required to issue a total of 25,000 shares of restricted common stock to the note holders as loan origination fees. The notes matured on March 25, 2013. Under the terms of the notes, if the loans were not repaid, the note holders would collectively receive 25,000 shares of restricted common stock on the maturity date and every 30 days thereafter that the notes remain unpaid. On April 25, 2013 the Company issued a total 50,000 shares of its restricted common stock to the noteholders for the two defaults on March 25, 2013 and April 25, 2013.

The Company has an outstanding note payable to K-C Operations (an unrelated party) issued on October 15, 2009. The balance as of March 31, 2013 and December 31, 2012 was \$338,833 and \$398,000, respectively. The note matured on October 31, 2010 and accrues interest at a rate of 6% per annum and is convertible to shares of common stock at a rate of \$0.20 per share.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

The Company has an outstanding note payable to Robert Johnson (former officer and director) issued on September 30, 2006 with a balance as of March 31, 2013 and December 31, 2012 of \$21,547 and \$21,547, respectively. The note matured on September 30, 2007 and is convertible to shares of common stock at a rate of \$0.20 per share.

The Company has an outstanding note payable to Lexicon (an unrelated party) issued on January 15, 2009. The note is due upon demand. The balance as of March 31, 2013 and December 31, 2012 was \$10,317 and \$12,817, respectively. The note bears an interest rate of 6% per annum and is convertible to shares of common stock at a rate of \$0.01 per share.

During the quarter ending March 31, 2013, the Company issued 545,833 shares of common stock for the retirement of \$61,667 of promissory notes payable and accrued interest. The Company recognized a loss on conversion of the above debt of \$3,068,495 and \$0 in the three months ending March 31, 2013 and 2012 respectively.

#### **4. Capital Structure—Common Stock and Common Stock Purchase Warrants**

Each holder of common stock is entitled to vote on all matters and is entitled to one vote for each share held. No holder of shares of stock of any class shall be entitled as a matter of right to subscribe for or purchase or receive any part of any new or additional issue of shares of stock of any class, or of securities convertible into shares of stock or any class, whether now hereafter authorized or whether issued for money, for consideration other than money, or by way of dividend.

As of March 31, 2013 and March 31, 2012, the Company was authorized to issue 500,000,000 common shares at a par value of \$0.001 per share.

On March 18, 2012, the Company effected a 1 for 1000 reverse stock split of the Company's common stock, resulting in a reduction of the number of shares outstanding of the Company from approximately 113,644,000 to approximately 113,644. Persons holding less than 1000 shares of common stock received one share common stock. The rights and privileges of the holders of shares of common stock were substantially unaffected by the reverse stock split. All issued and outstanding options, warrants and convertible securities were appropriately adjusted for the reverse stock split automatically on the effective date of the reverse stock split, and have been presented retroactively in the financial statements.

As of March 31, 2013 and December 31, 2012 the Company had 53,508,635 and 45,489,368 shares of common stock outstanding respectively.

The Company on April 12, 2012 issued a one-time dividend of 1,182,474 shares to the existing shareholders of TNI BioTech, Inc., with a record date of April 23, 2012. No dividends were issued in the three months ending March 31, 2013.

The Company acquired TNI BioTech IP, Inc., for 20,250,000 shares as part of a share exchange agreement on April 24, 2012. There were no acquisitions for shares the three months ending March 31, 2013.

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 at exercise prices ranging from \$1.00 to \$1.50.

#### **Stock Warrants**

In the three months ended March 31, 2013, the Company issued common stock purchase warrants for the purchase of up to 295,109 shares of common stock of the Company at an exercise price \$15.00 per share. The warrants expire between January and March 2018.

Fair value of \$1,065,894 was calculated using the Black-Scholes Model. Variables used in the Black-Scholes option-pricing model during the three months ended March 31, 2013, include (1) 0.77% discount rate, (2) warrant life is the expected remaining life of the options as of each year end, (3) expected volatility recorded during the three months ended March 31, 2013, related to these options.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

The Company made an offer to the holders of Common Stock Purchase Warrants issued in the Company's 2012 Private Placement offering a reduced exercise price of \$0.75 per share if they exercised by the deadline, which was subsequently extended to March 22, 2013. During the first quarter of 2013, the Company issued 1,180,434 shares of its restricted common stock through common stock purchase warrant exercises. The warrants were exercised at a price of \$0.75 per share and the Company received proceeds of \$885,325 for equity from the exercise of the warrants.

Under the terms of the exercise, warrant holders exercising at the Reduced Warrant Price were issued new five-year Common Stock Purchase Warrants with an exercise price of \$15.00 per share (the "Series C Warrants"). The number of shares purchasable under the Series C Warrants equals 25% of the total number of shares exercised at the Reduced Warrant Price. The Company issued 295,109 Series C Warrants during the three months ended March 31, 2013.

Following is a summary of outstanding stock warrants at March 31, 2013 and December 31, 2012 and activity during the periods then ended:

	<u>Number of Shares</u>	<u>Exercise Price</u>	<u>Weighted Average Price</u>
Warrants as of December 31, 2012	7,260,000	\$ 1.00 – 1.50	\$ 1.02
Issued in 1 <sup>st</sup> quarter of 2013	295,109	\$ 15.00	\$ 15.00
Expired	-	-	-
Exercised	980,434	\$ 0.75	\$ 0.75
Warrants as of March 31, 2013	6,574,675	\$ 1.00 – 15.00	\$ 1.66

Summary of outstanding warrants as of March 31, 2013:

<u>Expiration Date</u>	<u>Number of Shares</u>	<u>Exercise Price</u>	<u>Remaining Life (years)</u>
2013	-	-	-
2014	-	-	-
2015	-	-	-
2016	-	-	-
September 2017	2,281,666	\$ 1.00-1.50	4.2
October 2017	2,265,000	\$ 1.00	4.3
November 2017	1,732,900	\$ 1.00 – 1.50	4.4
December 2017	-	-	-
January 2018	167,084	\$ 15.00	4.6
February 2018	127,275	\$ 15.00	4.7
March 2018	750	\$ 15.00	4.8

## 5. Stock Compensation

### Founders' Shares and Shares Issued for Services

During the three months ended March 31, 2013, the Company issued 5,533,000 shares of common stock for prepaid services, which included founder shares. The Company valued these shares based upon the fair market value of the common stock at the date of the agreements. The consulting fees are amortized over the contract periods, which are typically twelve months. The Company recognized an expense from common stock issued for services of \$39,565,400 and \$0 for the months ended March 31, 2013 and 2012, respectively. The amortization of prepaid services totaled \$7,561,740 and \$0 for the three months ended March 31, 2013 and 2012, respectively.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

**6. Income Taxes - Results of Operations**

There was no income tax expense reflected in the results of operations for the three months ended March 31, 2013.

Deferred tax assets reflect the net income tax effect of temporary differences between the carrying amounts of the assets and liabilities for financial reporting purposes and the amounts used for income taxes.

<b>Deferred tax assets:</b>	<b>As of March 31, 2013</b>	<b>As of December 31, 2012</b>
Net operating losses	\$ 31,218,000	\$ 26,223,000
Valuation allowance	<u>31,218,000</u>	<u>(26,223,000)</u>
<b>Total deferred tax assets</b>	<b>\$ -</b>	<b>\$ -</b>

The Company has recognized no tax benefit for the losses generated for the three months ended March 31, 2013 and the year ended December 31, 2012. ASC Topic 740 requires that a valuation allowance be provided if it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company's ability to realize the benefit of its deferred tax asset will depend on the generation of future taxable income. Because the Company has yet to recognize revenue, we believe that the full valuation allowance should be provided.

Our effective tax rate for fiscal years 2011 and 2012 was 0%. Our tax rate can be affected by recurring items, such as tax rates in foreign jurisdictions and the relative amount of income we earn in jurisdictions. It may also be affected by discrete items that may occur in any given year, but are not consistent from year to year.

As of December 31, 2012, we have estimated federal and state income tax net operating loss ("NOL") carry-forwards of \$98,700,000, which will expire in 2031-2032. \$32,897 of which is the allowable carry forward amount pursuant to 26 USC § 382.

	<b>March 31, 2013</b>		<b>March 31, 2012</b>	
	<b>Amount</b>	<b>Percent</b>	<b>Amount</b>	<b>Percent</b>
Benefits for income tax at federal statutory rate	\$ 4,995,000	34%	\$ 200	34%
Change in valuation allowance	(4,995,000)	(34)	-	-
Other	-		200	(34)
	<u>\$ -</u>	<u>-%</u>	<u>\$ -</u>	<u>-%</u>

**7. Discontinued Operations**

In April 2012, TNI BioTech, Inc., divested itself of certain assets and liabilities related to its previous activities in the hospitality business ("Resorts Club") by transferring them to Resorts Club International Corporation Georgia. Accordingly, the operations of that business have been reflected as discontinued operations the financial statements.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

The result of this transfer was a Gain from Discontinued Operations in 2012 of \$231,356. This transfer is not expected to affect the cash flow of the remaining operations.

These financial statements reflect the results of Resorts Club as a discontinued operation for all periods presented.

The net sales and earnings of discontinued operations were as follows:

	<b>Three Months Ended March 31, 2013</b>	<b>Three Months Ended March 31, 2012</b>
Net Sales	0	0
Earnings before Income Taxes	0	7,348
Income Taxes	0	0
Net Earnings from Discontinued Operations	0	7,348

Cash flows from operating and investing activities of discontinued operations for the three months ended March 31, 2013 and 2012 were \$0 and (\$6,751), respectively.

## **8. Licenses and Supply Agreements**

### **Patent and Subsidiary Acquisition**

The Company entered into a share exchange agreement April 24, 2012 to acquire all of the outstanding shares of TNI BioTech IP, Inc., (“TNI IP”) a biotechnology firm incorporated in Florida formed to acquire patents related to the treatment of cancer and HIV/AIDS and autoimmune diseases, using Met-enkephalin (“MENK”) and Naltrexone (“LDN”). The goal of TNI IP’s management is to enable mankind and civilization to combat fatal diseases by activating and mobilizing the body’s own immune system using TNI IP patented use of MENK.

The first patents acquired by TNI IP were acquired from Dr. Nicholas P. Plotnikoff and Professor Fengping Shan in 2012. 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. The primary cytokine, among many others currently being studied by TNI IP, is MENK. The Company is focused on the treatment of cancer, HIV/AIDS and other infectious diseases through the use of our lead compounds.

TNI IP changed its name from TNI BioTech, Inc., to TNI BioTech IP, Inc. on April 23, 2012. TNI BioTech IP, Inc., is the wholly-owned subsidiary of the Company. TNI IP was acquired in exchange for 20,250,000 shares of the Company’s common stock of which 8,000,000 shares were issued for the acquisition of the patent and the remaining 12,250,000 shares were issued to the founders of TNI IP in exchange for all of their right, title and interest in their TNI IP shares. The goodwill arising on the acquisition of TNI BioTech IP, Inc. was valued at \$98,000,000 and license agreements arising from the acquisition of TNI BioTech IP, Inc. was valued at \$16,006,000.

At the time of the acquisition, the valuation of goodwill and other intangible assets were determined using the fair market price for the Company’s common stock which were exchanged for shares of TNI BioTech IP, Inc. In the fourth quarter of 2012, the Company performed an annual valuation to determine whether any goodwill or intangible assets that had been acquired by the Company were impaired. The result of this valuation was that material impairments were identified. The Company recognized an impairment of the goodwill arising on the acquisition of TNI BioTech IP, Inc. of \$98,000,000.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

**Patent License Agreements**

On August 13, 2012, the Company signed a License Agreement with Ms. Jacqueline Young for the intellectual property developed by Dr. Bernard Bihari relating to treatments with opioid antagonists such as naltrexone and Met-enkephalin for a variety of diseases and conditions including malignant lymphoma, chronic lymphocytic leukemia, Hodgkin's lymphoma, and non-Hodgkin's lymphoma, chronic herpes virus infections, chronic herpes viral infections such as chronic genital herpes caused by the herpes simplex virus Type 2 and chronic infections due to the Epstein-Barr virus and a treatment method for humans infected with HTLV-III (AIDS) virus including patients clinically diagnosed as suffering from AIDS and those suffering from AIDS-related complex (ARC). The Bihari patents were acquired in exchange for 540,000 shares of the Company's common stock with a fair market value of \$972,000 and assumed liabilities of \$400,000 which is payable to Ms. Young over a twenty-four month period in equal installments to reimburse her for the costs of a New York city office in accordance with the patent license agreement. The patent liability at December 31, 2012 totaled \$340,000. The cost of the patent totaled \$1,372,000. Additionally, the Company will pay the licensor a royalty payment 1% of gross MENK sales and provide the licensor a position as non-executive chairman of the Company.

On December 24, 2012, the Company signed an agreement for the acquisition of patent rights for the intellectual property of Dr. Jill Smith and LDN Research Group LLC (the "Patent License Agreement"), 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. These patents were acquired in exchange for 300,000 shares of the Company's common stock with a fair market value of \$2,715,000 and expenses of \$165,384, which totaled \$2,880,384.

In partial consideration of the Patent License Agreement, the Company agreed to pay to the members the applicable milestone payments listed below after substantial achievement of each milestone event is achieved by the Company, its Affiliates or Sublicensees.

- A. Upon initiation of each phase III trial, the Company will pay \$350,000.
- B. Upon positive completion of each phase III clinical trial of the therapeutic use of an LDN compound in the field of Use, the Company will pay \$150,000.
- C. When an NDA is accepted for review by the FDA, the Company will pay \$250,000.
- D. When FDA approval to market the NDA is approved, the Company will pay \$750,000.
- E. Upon the first dosing of the first patient in a phase III clinical trial for each Licensed Product, the Company will pay 250,000 shares of the Company's common stock.
- F. Upon the first sale of each Licensed Product, the Company will issue 400,000 shares of the Company's common stock.
- G. Upon the achievement of \$20 Million USD in cumulative sales for each licensed product covered by NDAs, the Company will issue 500,000 shares of the Company's common stock.

As part of the Patent License Agreement, TNI BioTech has the right to apply to the Food and Drug Administration (FDA) for the transfer of the orphan drug status, the investigational new drug applications (INDs), and the right to acquire the relevant clinical data set from Dr. Smith. The FDA has designated orphan drug status for the use of low dose naltrexone in the treatment of pediatric patients with Crohn's disease and ulcerative colitis.

The Patent License Agreement calls for the formation of a Development Committee to monitor the clinical progress of the Licensed Products and will consist of independent scientific and technical leaders who are highly regarded by the scientific community in the Field of Use of each Licensed Product. The development committee consists of at least one representative from the Licensor Parties and one representative from the Company in addition to outside experts in the field.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

Naltrexone in low dose is a platform immunomodulatory technology that the Company expects to clinically test in the treatment of other immune-mediated or immune-deficient diseases for which it has previously acquired additional patents.

The Company signed an exclusive licensing agreement with The Penn State Research Foundation on January 18, 2013 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" (the "Licensing Agreement"). These licenses were acquired in exchange for 300,000 shares of the Company's common stock with a fair market value of \$2,550,000 and expenses of \$160,539 which totaled \$2,710,539.

The patent covers methods and formulations related to the treatment and prevention of different cancers. More specifically, the present inventions describe the use of drugs that interact with opioid receptors (naltrexone, naloxone and the pentapeptide growth factor Met-enkephalin) to inhibit and arrest the growth of cancer. 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. Such efficacy has been discovered to be partially due to the functional manipulation of the zeta opioid receptor through exogenous and endogenous Met-enkephalin. This receptor has been determined to be present in a variety of cancers, including pancreatic and colon cancer.

As part of the Licensing Agreement, TNI BioTech is working to acquire the orphan drug designation (IND) and clinical data set from Dr. Jill Smith.

The Licensing Agreement calls for TNI BioTech to (a) use commercially reasonable efforts to develop, commercialize, market and sell Licensed Products in a manner consistent with the Business Plan; (b) will expend a minimum of \$110,000 (per annum) to develop and commercialize Licensed Products as soon as practicable, consistent with sound business practices and judgment; (c) be responsible for obtaining all requisite regulatory approvals needed to use or sell Licensed Products in the Field of Use; and (d) make the first commercial sale of a Licensed Product by December 31, 2016.

The Licensing Agreement calls for the formation of a Development Committee to monitor the clinical progress of the Licensed Products, which will consist of independent scientific and technical leaders who are highly regarded by the scientific community in the Field of Use of each Licensed Product.

In confirmation letters dated April 3, 2013, the Company 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.

## **9. Commitments and Contingencies**

### **Malawi Treatment Facilities**

On July 14, 2012, GB Oncology and Imaging Group LTD ("GBOIG") in partnership with TNIB signed a letter of intent agreement to collaborate with the Government of Malawi to assist in expanding the treatment of cancer, HIV/AIDS and other infectious diseases.

The Company and GB will work in connection with the government of Malawi to open and operate clinics that provide treatments for HIV/AIDS, cancer and other infectious diseases. GBOIG and TNIB expect to have the oncology and infectious disease clinic fully operational within 12 months of the signing of the Agreement, and hope to begin treatment for HIV patients within 180 days. Under the letter of intent, TNIB and GBOIG will begin by providing HIV/AIDS treatment to 25,000 patients and hopefully expanding to 500,000 within 24 months.

GB Oncology and Imaging Group LTD., a subsidiary of GB Energie LLC is a Washington D.C. based minority woman-owned business managed by Dr. Gloria B. Herndon. Dr. Herndon is also a director of TNI BioTech, Inc.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

**Distribution Agreement in Nigeria**

Effective November 9, 2012, TNI BioTech, Inc., signed an exclusive Distribution Agreement with G-Ex Technologies/St. Maris Pharma and GB Pharma Holdings, LLC for the Federal Republic of Nigeria. Under the terms of the Distribution Agreement, G-Ex Technologies/St. Maris Pharma and GB Pharma Holdings LLC will have exclusive marketing and distribution rights to IRT-103 LDN and IRT-104 LDN cream in Nigeria. TNIB will be responsible for the manufacture and supply of IRT-103 LDN and IRT-104 LDN cream. As part of the Distribution Agreement, G-Ex Technologies/St. Maris Pharma will provide TNIB with a revolving letter of credit for the minimum purchase of 750,000 doses monthly of IRT-103 LDN or IRT-104 LDN cream priced at \$1.00 per dose.

The Distribution Agreement calls for G-Ex Technologies/St. Maris Pharma and GB Pharma Holdings, LLC to purchase a minimum of 15,000,000 doses monthly within 24 months to maintain the exclusivity of the Agreement. Once G-Ex Technologies/St. Maris Pharma and GB Pharma Holdings, LLC reach sales of 1,000,000 doses per day TNIB has agreed to joint venture a factory in the Federal Republic of Nigeria to meet local demands.

G-Ex Technologies/St. Maris Pharma is a consortium of companies organized under the laws of the Republic of Nigeria operated by management, consultant, general pharmaceutical, clinical pharmacy and marketing executives, each with over twenty-five years of industry experience and well versed in the changing dynamics of the prescription and over-the-counter drug international marketplace. G-Ex Technologies/St. Maris Pharma has been actively supported by medical practice professionals in business and academia who have been involved in the management of related drug therapies for many years.

**Strategic Framework Agreement with Zhongzhu Group**

On October 9, 2012, the Company signed a Strategic Framework Agreement for Cooperation with the Zhongzhu Group. Under the Strategic Framework Agreement, the parties will work together to further the development of new products and conduct research and development on TNI's licensed patented technology. Specifically, the parties aim to co-invest to develop and market products focusing on HIV, cancer and related autoimmune system therapies, develop co-ventured manufacturing facilities in China, and develop co-ventured distribution of the developed products in China and Africa.

**Commissioned Processing Contract, Addendum to Venture Cooperation and Strategic Framework Agreement**

The Company signed a Commissioned Processing Contract, Addendum to Venture Cooperation and Strategic Framework Agreement with Hubei Qianjiang Pharmaceutical Co., LTD ("HBQ") on February 24, 2013. Under the Commissioned Processing Contract, HBQ will manufacture low dose Naltrexone for TNI. The Addendum to Venture Cooperation expands the scope of the originally executed agreement in October to include clinical trials on pancreatic and liver cancer. Under the Strategic Framework Agreement, the parties will work together to further the research and development and marketing of new products. Specifically, the parties aim to co-invest to develop and market products focusing on HIV-AIDS and develop co-ventured distribution of the developed products in China, Central America, South America, Africa and the United States.

**Manufacturing**

In March 2013, the Company decided that it would be better to outsource our manufacturing, rather than manufacture ourselves. This decision was made when the joint venture partner was unable to provide a facility that meet international standards for manufacturing and canceled the contract. The Company at the same time entered into discussions with an existing facility in Managua, Nicaragua that has excess capacity. The Company believes that between the facility in Nicaragua and the Qianjiang Pharmaceutical GMP facility located in China, the Company should be able to begin delivering LDN by July 1, 2013.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

**African Contracts**

In the African countries where the Company currently has contracts, international laws require the exporting company provide a certificate of Free Sale. It has taken TNI BioTech longer than anticipated to obtain the certificate of Free Sale.

**Operating Leases**

The Company leases office space in Bethesda, Maryland and Orlando, Florida under a month-to-month lease agreement. Rental expense for the three months ended March 31, 2013 and the twelve months ended December 31, 2012 was \$16,259 and \$10,303, respectively.

**10. Related Party Transactions**

Effective September 15, 2012, TNI BioTech, Inc. entered into a one-year employment agreement with Joseph Griffin, the brother of the Company's Chief Executive Officer, in which base salary, the grant of a common stock, and health insurance coverage were defined. As a signing bonus, Mr. Griffin received 250,000 shares restricted common stock of the Company. During the quarter ended March 31, 2013, the Company paid cash compensation totaling \$18,702. During the year December 31, 2012, the Company paid cash compensation totaling \$11,146.

In 2012, Webfoot, Inc., provided financing to the Company and as of December 31, 2012, the Company owed Webfoot, Inc., \$121,128. Webfoot, Inc., is owned by the son of Noreen Griffin. On February 21, 2013, the Company entered into a formal loan agreement to evidence the amount owed on December 31, 2012. The loan accrues interest at an annual rate of 6%. The interest is repayable at maturity. The note matures on February 21, 2014.

In 2012, Noreen Griffin made payments on the Company's behalf covering the costs of incorporation and merger-related expenses. At December 31, 2012, the Company owed Ms. Griffin \$30,000. On February 13, 2013, the Company entered into a formal loan agreement to evidence repayment of the amount owed as of December 31, 2012. The loan bears interest at an annual rate of 6%. The interest is repayable at maturity.

In 2012, Griffin Enterprises, Inc. made payments on the Company's behalf covering the cost of incorporation and merger-related expenses. Griffin Enterprises, Inc. wholly-owned by Noreen Griffin. At December 31, 2012, the company owed Griffin Enterprises, Inc. \$46,000. On February 13, 2013, the Company entered into a formal loan agreement to evidence repayment of the amount owed on December 31, 2012. The loan bears interest at an annual rate of 6%. The interest is repayable maturity.

On January 3, 2013, the Company formalized the terms under which Kelly O'Brien Wilson, the daughter-in-law of the Company's Chief Executive Officer has been employed. Ms. Wilson had been working with the Company in 2012 and her three-year employment agreement is effective as of December 1, 2012. The terms of the agreement define her base salary, a grant of a common stock, and health insurance coverage. As a signing bonus, Ms. Wilson is entitled to receive 50,000 shares of restricted common stock of the Company. During the quarter ended March 31, 2013, the Company paid cash compensation totaling \$12,884. During the year ended December 31, 2012, the Company paid cash compensation totaling \$4,035. Ms. Wilson has not received the 50,000 shares of common stock that were part of her original agreement and previously disclosed in our Form 10 Registration Statement. The terms of Ms. Wilson's agreement are currently being renegotiated including the share issuance.

**TNI BioTech, Inc.**  
**Notes to the Financial Statements**  
**March 31, 2013 (Unaudited)**

**11. Subsequent Events**

On April 4, 2013, a warrant holder exercised its right to purchase 107,900 shares of restricted common stock of the Company. The Company received \$80,925 from the exercise of the warrants.

On April 5, 2013, the Company issued a \$100,000 short-term note to a third party investor that matures on April 19, 2013. Under the terms of the note, the Company was required to issue 10,000 shares of its restricted common stock as a loan origination fee. If the note was not repaid on the maturity date, then the Company must issue 10,000 shares and must issue an additional 10,000 shares for each 30 day period after the maturity date that the note remains unpaid. The Company issued 10,000 shares for the default on April 19, 2013.

In April 2013, the Company issued 60,000 shares of restricted common stock at a per share price of \$0.75 and 26,975 Series C Warrants to a holder of Common Stock Purchase Warrants issued in the Company's 2012 Private Placement.

The following is a schedule of shares issued subsequent to March 31, 2013.

	<u>Shares</u>
Shares issued for loan origination fee	10,000
Shares issued for default on promissory notes	35,000
Shares issued for warrant exercise	107,900
Shares issued to investor	60,000

**Meeting with FDA Regarding LDN**

In May 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.