

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

Form 10-K/A

January 25, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

---

**FORM 10-K/A**

**(Amendment No. 1)**

X .

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2015**

**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from to**

Commission File Number: **000-54554**

---

**Therapeutic Solutions International, Inc.**

(Exact name of registrant as specified in its charter)

**Nevada**

**45-1226465**

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

**4093 Oceanside Boulevard, Suite B**

**Oceanside, California 92056**

(Address of principal executive offices, including zip code)

**(760) 295-7208**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

**None**

Securities registered pursuant to Section 12(g) of the Act:

Title of class  
**Common Stock, \$0.001 par value per share**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  . No  .

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  . No  .

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  . No  .

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  . No  .

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.  .



Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates was \$389,268 based on a closing price of \$0.0028 as of June 30, 2015.

As of October 25, 2016, 740,251,000 shares of the registrant's common stock, par value of \$0.001 per share, were outstanding.

**INDEX**

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

	<b>PAGE NO</b>
<b>PART I</b>	
ITEM 1	BUSINESS 6
ITEM 1A	RISK FACTORS 12
ITEM 1B	UNRESOLVED STAFF COMMENTS 17
7ITEM 2	PROPERTIES 17
ITEM 3	LEGAL PROCEEDINGS 17
ITEM 4	MINE SAFETY DISCLOSURES 17
<b>PART II</b>	
ITEM 5	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES 18
ITEM 6	SELECTED FINANCIAL DATA 20
ITEM 7	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS 20
ITEM 7A	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 25
ITEM 8	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA 26
ITEM 9	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE 26
ITEM 9A	CONTROLS AND PROCEDURES 26
ITEM 9B	OTHER INFORMATION 27
<b>PART III</b>	
ITEM 10	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE 27
ITEM 11	EXECUTIVE COMPENSATION 31
ITEM 12	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS 32
ITEM 13	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR 32

ITEM 14	INDEPENDENCE PRINCIPAL ACCOUNTANT FEES AND SERVICES	32
<b>PART IV</b>		
ITEM 15	EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	33
SIGNATURES		35

## **PART I.**

### **Explanatory Note**

Theapeutic Solutions International, Inc. (the Company) is filing this Amendment No. 1 on Form 10-K/A (the Amended Form 10-K) to its Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (the Original Form 10-K), which was originally filed with the Securities and Exchange Commission (SEC) on October 31, 2016 (the Original Filing Date), to amend and restate management's conclusions regarding the effectiveness of disclosure controls and procedures and internal control over financial reporting as of December 31, 2015.

Management has concluded that its disclosure controls and procedures and internal control over financial reporting were not effective as of December 31, 2015 due to a material weakness in its internal control over financial reporting.

The Company's consolidated financial statements as of and for the year ended December 31, 2015, which were included in the Original Filing, have not changed as a result of the material weakness. See Item 9A., Controls and Procedures, for discussion of management's disclosure controls and procedures, management's restated, annual report on internal control over financial reporting, changes in internal control over financial reporting. Accordingly, the Company hereby amends and replaces in its entirety Items 9A and adds a Risk Factor related to Internal Control in the Original Filing.

As required by Rule 12b-15, the Company's principal executive officer and principal financial officer are providing new currently dated certifications. In addition, the Company is filing a new consent of PLS CPA, A Professional Corp. Accordingly, the Company hereby amends Item 15 in the Original Filing to reflect the filing of the new certifications and consent.

Except as described above, this Amended Filing does not amend, update or change any other items or disclosures in the Original Filing and does not purport to reflect any information or events subsequent to the filing date of the Original Filing. As such, the Company's consolidated financial statements as of and for the year ended December 31, 2015, which were included in the Original Filing, have not changed as a result of the material weakness. This Amended Filing speaks only as of the date the Original Filing was filed, and the Company has not undertaken herein to amend, supplement or update any information contained in the Original Filing to give effect to any subsequent events. Accordingly, this Amended Filing should be read in conjunction with the Company's filings made with the Securities and Exchange Commission subsequent to the filing of the Original Filing.



**IMPORTANT PREFATORY NOTE**

On April 28, 2014, we received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated. The ostensible reason Mr. Jaczko gave was our failure to make certain unspecified payments due under the license agreement to his clients. We disputed the termination, but believed that the costs involved with litigating the termination of the license was not in the best interest of the Company and its shareholders. Therefore, the Company decided to move in new direction.

**MolecuVax, Inc.**

The Company previously announced that MolecuVax, Inc. (MVAX) was a partially-owned subsidiary of TSOI. On September 30, 2016, Mr. Gerry Berg, and Mr. Timothy Dixon resigned as Officers and Directors of MVAX and cancelled any and all equity in MVAX and have asserted certain contractual rights of our licensed patent to MVAX dated February 5<sup>th</sup>, 2016. Our departure and subsequent cancellation of stock was due to an attempt at a hostile take-over of the Board of Directors of MVAX by other board members. In addition, on October 12, 2016, Dr. Thomas Ichim also resigned from MVAX as CEO and Director.

**Capo Therapeutics, Inc.**

The Company previously announced that TSOI held an equity stake in Capo Therapeutics, Inc. (CAPO). On September 30, 2016, Mr. Gerry Berg, and Mr. Timothy Dixon resigned as Officers and Directors of CAPO and cancelled any and all equity in CAPO. Our departure and subsequent cancellation of stock was due to an attempt at a hostile take-over of the Board of Directors of CAPO by other board members.

## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements, including statements about our business strategy, uncertainty regarding our future operating results and our profitability, anticipated sources of funds and all plans, objectives, expectations and intentions and any statements regarding future potential revenue, gross margins and our prospects for fiscal 2014 and thereafter. These statements may appear in a number of places and can be identified by the use of forward-looking terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "future," "intend," or "certain" or the negative of these terms or other variations or comparable terminology, or by discussions of strategy.

The following factors are among those that may cause actual results to differ materially from our forward-looking statements:

.

Need for additional capital;

.

Limited operating history in our new business model;

.

Limited experience introducing new products;

.

Our ability to successfully expand our operations and manage our future growth;

.

Difficulty in managing our growth and expansion;

.

Dilutive effects of any raising of additional capital;

.

The deterioration of global economic conditions and the decline of consumer confidence and spending;

.

Material weaknesses reported in our internal control over financial reporting;

.

Our ability to protect intellectual property rights and the value of our products;

.

The potential for product liability claims against us;

.

Our dependence on third party manufacturers to manufacture our products;

.

Our common stock is currently classified as a penny stock;

.

Our stock price may experience future volatility;

.

The illiquidity of our common stock; and

.

Substantial sales of shares of our common stock.

Actual results may vary materially from those in such forward-looking statements as a result of various factors, including those identified in "Item 1A. Risk Factors" and elsewhere in this document. No assurance can be given that the risk factors described in this Annual Report on Form 10-K are all of the factors that could cause actual results to vary materially from the forward-looking statements. Forward-looking statements are not guarantees of future performance. They involve risks, uncertainties, and assumptions. The Company's future results and shareholder values may differ materially from those expressed in these forward-looking statements. Readers are cautioned not to put undue reliance on any forward-looking statements. Forward-looking statements also include statements in which words such as expect, anticipate, intend, plan, believe, estimate, consider, or similar expressions are used in this Annual Report on Form 10-K to the Company, TSOI, we, our, and us refer to Therapeutic Solutions International, Inc.

## **ITEM 1**

### **BUSINESS.**

#### **Corporate History**

Therapeutic Solutions International, Inc. is a Nevada corporation which was incorporated on August 6, 2007 under the name Friendly Auto Dealers, Inc. In the first quarter of 2011, we acquired Splint Decisions Inc., and changed our name from Friendly Auto Dealers, Inc., to Therapeutic Solutions International, Inc. and our ticker symbol from FYAD to TSOI. This Annual Report on Form 10-K, and the financial statements included herein, reflect the treatment of Splint Decisions Inc., as the accounting acquirer in the transaction. Our principal executive office is located at 4093 Oceanside Blvd., Suite B, Oceanside, California 92056, our telephone number is (760) 295-7208 and our website is [www.therapeuticsolutionsint.com](http://www.therapeuticsolutionsint.com). The reference to our website does not constitute incorporation by reference of the information contained on our website.

Our common stock is currently quoted on the Pink Sheets under the symbol TSOI. There currently is a limited public market for our common stock. A limited public market for our stock could make it difficult to sell your shares in our stock. The Company is currently delinquent in its reporting obligations with the Securities and Exchange Commission ( SEC ). The Company has not filed quarterly reports for the periods ending, March 31, 2016 and June 30, 2016. The Company's common stock listing on the Pink Sheets currently has a Yield symbol affiliated with it indicating that there is limited public information available about the Company. The Yield affiliation also serves as a warning to potential investors that the Company may not be publishing adequate public information and only has published limited financial information and is delinquent in its SEC filings.

We file our quarterly and annual reports with the Securities and Exchange Commission ( SEC ), which the public may view and copy at the SEC's Public Reference Room at 100 F Street, N.E. Washington D.C. 20549, on official business days during the hours of 10 a.m. to 3 p.m. The public may obtain information on the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site, the address of which is [www.sec.gov](http://www.sec.gov), which contains reports, proxy and information statements, and other information regarding issuers which file electronically with the SEC. The periodic and current reports that we file with the SEC can also be obtained from us free of charge by directing a request to Therapeutic Solutions International, Inc., 4093 Oceanside Blvd, Suite B, Oceanside, California 92056, Attn: Corporate Secretary.

#### **Description of Business until April 28, 2014**

Until April 28, 2014 the Company sold (directly and through distributors and sublicensees), in non-US countries, plastic intraoral devices known as Anterior Midpoint Stop Appliances ( AMPSA Products ). Our customers were dentists and doctors. The AMPSA Products, which are used for the treatment and prevention of common neurological and temporomandibular disorders including migraine headaches, migraine pain and bruxism.

On April 28, 2014, we received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated. The ostensible reason Mr. Jaczko gave was our failure to make certain unspecified payments due under the license agreement to his clients. We disputed the termination, but believed that the costs involved with litigating the termination of the New License was not in the best interest of the Company and its shareholders. Therefore, the Company decided to move in new direction.

## **CURRENT BUSINESS DESCRIPTION**

Therapeutic Solutions International, Inc. ( TSI ), is a public company (OTC:TSOI) focused on immune modulation for the treatment of several specific diseases. Immune modulation refers to the ability to upregulate (make more active) or downregulate (make less active) one s immune system.

Activating one s immune system is now a well-accepted method to cure certain cancers, reduce recovery time from viral or bacterial infections and to prevent illness. On the other hand, inhibiting one s immune system is vital for reducing inflammation, autoimmune disorders and allergic reactions.

TSI is developing a range of immune-modulatory agents to target certain cancers, improve maternal and fetal health, fight periodontal disease, and for daily health. The following discusses the focus of TSI on each of these programs:

**Nutraceutical Division** TSI has been producing high quality nutraceuticals. Its flagship product, ProJuvenol<sup>®</sup>, is a proprietary mixture containing pterostilbene – one of the most potent antioxidants known. TSOI filed a patent application for ProJuvenol<sup>®</sup> on 07-08-2015 titled: Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions as well as a second patent application filed 04-27-2016 titled Augmentation Of Stem Cell Activity Using Pterostilbene And Compositions Containing Pterostilbene . In addition we recently introduced a line of oncologist friendly nutraceuticals in liposome formula. These include CoQ10, Curcumin, Glutathione, and Vitamin-C in 16oz bottles.

**OmniBiome, Inc.** - is a partially-owned subsidiary of TSI, incorporated in the State of Delaware on October 20, 2015, where the intellectual property surrounding probiotics is housed. Current programs focus on the use of probiotics to prevent pre-term labor and on using probiotics to reverse periodontal disease. Mr. Dixon and Mr. Berg, of the Company, are also officers and Directors of Omni. As of October 25, 2016, TSI owns approximately 73.75% of the outstanding shares of OmniBiome. Website: <http://omnibiomeinc.com>

## Summary

TSI has assembled a first-rate scientific advisory board that is leading the company into the most exciting and potentially profitable fields of medicine – immune modulation. TSI expects to launch several products that improve people's health and well-being over the next several months.

## Principle Products and Services

### Clinical Stage Dexosome

TSOI recently licensed in 2016 a Dexosome Clinical Stage Cancer Immunotherapy Product from Gustave Roussy European Cancer Centre. Planning is still underway as to next steps.

Dexosomes are exosome nanoparticles generated by dendritic cells, which have previously been used by investigators at Anosys, Inc., in collaboration with researchers at Duke University, for treatment of cancer patients as part of an FDA-cleared Phase I clinical trial<sup>1</sup>. The licensed patent was invented by internationally-renowned immunologists Sebastian Amigorena, Doctor at the Curie Institute, and Laurence Zitvogel, Professor at Gustave Roussy. The patent covers means of generating therapeutically-effective dexosomes, which can act as a platform for loading any tumor antigen desired.

In the area of drug development, much of the risk is taking the technology from the lab to the patient. We are fortunate that the current technology has already been utilized in patients under FDA jurisdiction, and has demonstrated safety with signs of efficacy.

The in-licensing of the current patent augments previously filed patent applications by TSOI, including one filed in November 2015, covering uses of exosomes to stimulate both innate and adaptive arms of the immune response<sup>2</sup>. The Company plans to leverage the experience of its newest Board Member, Dr. Thomas Ichim, to lead the Dexosome program back into clinical trials. Dr. Ichim has previously patented the manipulation of exosomes in the area of cancer therapy for alleviation of immune suppression<sup>3</sup>, as well as being published in the peer-reviewed literature in this area<sup>4,5</sup>.

<sup>1</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC551593/>

<sup>2</sup> <http://www.therapeuticsolutionsint.com/index.php/2015-04-19-16-05-26/228-therapeutic-solutions-international-files-patent-or>

<sup>3</sup> <http://www.google.com/patents/US8288172>

<sup>4</sup> Ichim et al. Exosomes as a tumor immune escape mechanism: possible therapeutic implications. *J Transl Med.* 2008 Jul 22;6:37. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504474/>

<sup>5</sup> Abusamra et al. Tumor exosomes expressing Fas ligand mediate CD8+ T-cell apoptosis. *Blood Cells Mol Dis.* 2005 Sep-Oct;35(2):169-73. <http://www.ncbi.nlm.nih.gov/pubmed/16081306>

### **Nutraceutical Division (TSOI)**

**ProJuvenol®** is a powerful synergistic blend of complex anti-aging ingredients inspired by nature to help promote cellular rejuvenation and healthy functionality for everyday living, based upon pterostilbene, one of nature's unique and intelligent antioxidants/anti-inflammatories. ProJuvenol includes a scientifically valid blend of interactive ingredients with anti-aging and cellular protective properties to help support optimal health and provide the benefits of mental alertness and physical well-being.



Pterostilbene (pronounced "tero-STILL-bean") has created a buzz in the world of nutrition research. Scientists discovered this powerful antioxidant several decades ago and have since found that it rivals its cousin resveratrol's multi-functional abilities, and may actually exceed its anti-aging and health promoting potential. Found naturally in blueberries, pterostilbene has been shown in emerging experimental studies to exhibit up to 7 times greater bioavailability than resveratrol as well as better metabolic stability. This translates to potentially higher levels of pterostilbene in the blood upon ingestion, and longer lasting effects in the body compared to resveratrol. More simply put, it remains active in your body for a much greater period of time and during this enhanced bio-available period your body has the opportunity to allow it to utilize this powerful antioxidant molecule.

A large body of experimental research has now documented a wide range of potential health effects associated with pterostilbene. In fact, the more researchers study pterostilbene, the greater its human health potential becomes. In addition to being a powerful antioxidant, emerging experimental research suggests this plant compound may also help regulate cell growth, promote fat metabolism, support glucose utilization, influence brain function, and improve the body's natural detoxification enzymes that are required to help protect cells against potentially damaging compounds from the environment.

#### **Patents:**

TSOI filed a patent covering the use of its ProJuvenol<sup>®</sup> product, as well as various pterostilbene compositions, for use in augmenting efficacy of existing immuno-oncology drugs that are currently on the market. The patent is based on the ability of pterostilbene, one of the major ingredients of ProJuvenol<sup>®</sup>, to reduce oxidative stress produced by cancer cells, which in turn protects the immune system from cancer mediated immune suppression.

Immuno-Oncology, described by Science Magazine as 'Breakthrough of the Year'<sup>1</sup> offers the possibility of not only killing tumor cells in a non-toxic manner, but also establishing immunological memory, which patrols the body and destroys recurrent tumor cells. While great progress has been made in developing drugs that stimulate the immune system to recognize and kill tumors, a major pitfall of current approaches is that tumors produce chemicals and oxidative stress that suppresses the immune system, thus limiting efficacy of immune therapies.

Pterostilbene, which is chemically related to resveratrol, has been published to possess anticancer<sup>2,3</sup>, antioxidant<sup>4</sup>, and anti-inflammatory activities<sup>5</sup>. Through the filing of the recent patent, the company is exploring whether its lead product, ProJuvenol<sup>®</sup>, may be useful as a nutraceutical adjuvant to conventional cancer immunotherapies.

The importance of proper nutrition in the context of immunotherapy cannot be overstated. Studies on one of the original cancer immunotherapies, interleukin-2, demonstrated that efficacy was related to anti-oxidant content in the patients at time of therapy<sup>6</sup>. Accordingly, we are seeking through the current work to identify whether our currently marketed product, ProJuvenol<sup>®</sup>, may be utilized as part of an integrative approach to building up the immune

response of cancer patients.

<sup>1</sup> Couzin-Frankel J. Breakthrough of the year 2013. Cancer immunotherapy. *Science*. 2013;342:1432-3. <https://www.sciencemag.org/content/342/6165/1432.summary>

<sup>2</sup> Yang et al. Pterostilbene exerts antitumor activity via the Notch1 signaling pathway in human lung adenocarcinoma cells. *PLoS One*. 2013 May 3;8(5):e62652. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3643961/>

<sup>3</sup> Li et al. Pterostilbene acts through metastasis-associated protein 1 to inhibit tumor growth, progression and metastasis in prostate cancer. *PLoS One*. 2013;8(3):e57542. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3586048/>

<sup>4</sup> McCormack and McFadden. A review of pterostilbene antioxidant activity and disease modification. *Oxid Med Cell Longev*. 2013;2013:575482. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3649683/>

<sup>5</sup> Qureshi et al. Inhibition of nitric oxide and inflammatory cytokines in LPS-stimulated murine macrophages by resveratrol, a potent proteasome inhibitor. *Lipids Health Dis*. 2012 Jul 10;11:76. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393619/>

<sup>6</sup> Marcus et al. Severe hypovitaminosis C occurring as the result of adoptive immunotherapy with high-dose interleukin 2 and lymphokine-activated killer cells. *Cancer Res*. 1987 Aug 1;47(15):4208-12.

In addition on April 28, 2016 the Company filed a patent application covering the use of ProJuvenol<sup>®</sup> and its active ingredient pterostilbene for augmentation of stem cell activity. Diseases such as diabetes<sup>1</sup>, cardiovascular disease<sup>2</sup>, and neurodegenerative diseases<sup>3</sup> are characterized by deficient stem cell activity. The patent covers the stimulation of stem cells that already exist in the patient's body, as well as stem cells that are administered therapeutically.

Studies have shown that patients who have higher levels of endogenous stem cell activity have reduced cardiovascular disease risk<sup>4</sup> and undergo accelerated neurological recovery after stroke<sup>5</sup> as compared to patients with lower numbers of such stem cells.

<sup>1</sup> Moon et al. *Circ J*. 2012;76(9):2273-9. <http://www.ncbi.nlm.nih.gov/pubmed/22664650>

<sup>2</sup> Hill et al. *N Engl J Med*. 2003 Feb 13;348(7):593-600. <http://www.ncbi.nlm.nih.gov/pubmed/12584367>

<sup>3</sup> Lee et al. *Neurology*. 2009 May 26;72(21):1858-63 <http://www.ncbi.nlm.nih.gov/pubmed/19470969>

<sup>4</sup> Hill et al. *N Engl J Med*. 2003 Feb 13;348(7):593-600. <http://www.ncbi.nlm.nih.gov/pubmed/12584367>

<sup>5</sup> Sobrino et al. *Stroke*. 2007 Oct;38(10):2759-64. <https://www.ncbi.nlm.nih.gov/pubmed/17761925>



TSOI markets currently two other nutraceuticals, T-Rx<sup>®</sup>, a testosterone booster, and Vital<sup>®</sup> Female, an estrogen booster and has just introduced a line of oncologist friendly nutraceuticals in liposome formula. These include CoQ10, Curcumin, Glutathione, and Vitamin-C in 16oz bottles. Website: [www.youcanordernow.com](http://www.youcanordernow.com)

**ProJuvenol<sup>®</sup>** - Is a powerful synergistic blend of complex anti-aging ingredients inspired by nature to help promote cellular rejuvenation and healthy functionality for everyday living. Based upon one of nature's unique and intelligent anti-oxidants/anti-inflammatories.

**T-Rx<sup>®</sup>** - Is specifically designed just for men and is formulated to assist in increasing testosterone levels and keeping them high. The result is a significant increase in testosterone levels, which assist in adding lean muscle mass, bone density, increased energy and the reduction of fat.

**VITAL<sup>®</sup>** - Is specifically formulated for women and is designed to increase energy, increase bone density, reduce fat and improve muscle tone. Additionally this supplement will also optimize hormone levels, increase libido, and decrease symptoms of stress and anxiety.

**Coenzyme Q10 (CoQ10)** is a substance similar to a vitamin. It is found in every cell of the body. Your body makes CoQ10, and your cells use it to produce energy your body needs for cell growth and maintenance. It also functions as an antioxidant, which protects the body from damage caused by harmful molecules.

**Curcumin** is an anti-inflammatory molecule in the turmeric root, a relative of ginger. The properties of curcumin can best be summarized as protective of the integrity of bio molecules in the body by being both a fabulous antioxidant and anti-inflammatory all rolled up in one.

**Glutathione** is one of the most powerful antioxidants that the body produces and is used to bind and remove toxins, including heavy metals such as mercury and lead from the body. Levels may drop as result of oxidative stress due to disease, drugs, aging, toxic chemicals, inflammation and stress. Adequate levels of glutathione are necessary to provide important antioxidant protection.

**Vitamin-C** is absorbed at approximately 19%, the balance remains in the gastrointestinal tract to attract water and loosen the bowels. Liposomalized vitamin C is absorbed much more efficiently than traditional delivery methods. A huge advance in both efficiency and effectiveness of supplemental nutrients.

### **Fetal-Maternal Health**

OmniBiome, Inc. a partially-owned subsidiary is focused on therapeutic / Rx approaches to either utilize or intervene with the systemic effects of the vaginal, lactal-duct and oral microbiomes for improving maternal healthcare and resulting birth outcomes. Mr. Dixon and Mr. Berg, of the Company, are also officers and Directors of Omni. As of October 25, 2016, TSI owns approximately 73.75% of the outstanding shares of OmniBiome. Website: [www.omnibiomeinc.com](http://www.omnibiomeinc.com)

The Company will focus initially on developing CLIA Dx services for both pre-pregnancy-associated and pregnancy-associated conditions or diseases where there is a substantive link with microbiome dysbiosis (disruption or imbalance), as well as on restoring eubiosis (proper balance).

In parallel OmniBiome will build a database of aggregated patient data that will later inform development of Rx / therapeutic and medical device & drug-device combination approaches for treating the same conditions or diseases.

### **MicroBiome Targets**

Certain microbiome target markets offer immediate revenue-generating business opportunities such as vaginal and lactal-duct microbiome banking & transplants from mother to child in the case of C-section-born babies, babies of non-nursing mothers, and children under 5 years of age receiving broad-spectrum antibiotics

OmniBiome's main focus will be on developing Dx / Rx products & services for pregnancy-associated conditions or diseases where there is a documented or substantive putative link with microbiome dysbiosis and resulting inflammatory cascades

In parallel the Company will look to create alliances and/or out-license its Medical Device / Drug Device Combinations patent portfolio.

The Company also plans to in-license microbiome - and pregnancy-related Rx & Dx innovations from universities and research institutes with several having been identified.

### **The Human Microbiome Link**

The following microbiomes combined recapitulate approximately 75 - 80 % of the gut microbiome, hence OmniBiome sees no need to focus on the gut microbiome

***The Vaginal Microbiome*** comprises approximately 300 - 600 species of bacteria. 100s of species are transferred to the newborn child orally as the baby passes thru the birth canal. C-section-born children miss this important microbiome transfer

***The Breast Milk Microbiome*** contains between 200 - 700 species of bacteria and is transferred to the child via nursing. Babies of non-nursing mothers miss this equally important transfer.

***The Oral Microbiome*** diversity spectrum also covers 600 species shared with the baby via kissing and sharing eating utensils with both the mother & the father.

### **Licensed Patents**

Patent titled "Prevention of Pregnancy Complications by Probiotic Administration." Press Release of 7/22/2015.

Patent titled "Preventative Methods and Therapeutic or Pharmaceutical Compositions for the Treatment or Prevention of Pregnancy Complications" covers utility of vaccines and various agents to alter pathological conditions in which the maternal immune system induces a process of inflammation that culminates in placental alterations leading to either fetal loss or preterm labor. Press Release of 9/8/2015.

Patent titled "Diagnostic Methods For The Assessment Of Pregnancy Complications" a cytokine-based diagnostic kit aimed at stratifying risk of preterm labor and other pregnancy associated complications. Press Release of 9/21/2015.

Patent titled "A Medical Device For Reducing The Risk Of Preterm-Labor And Preterm-Birth" covering various medical devices aimed at immune modulating the cervical microenvironment in order to prevent preterm labor. Press Release of 9/29/2015.

### **E-COMMERCE WEBSITE**

The Company's current e-commerce website, [www.youcanordernow.com](http://www.youcanordernow.com), seeks to speak directly and clearly to the user with the Company's established brand platform and function as a tactical extension of the Company's sales message.

In developing and implementing the Company's website, the Company will continue to:

.

Establish and integrate an enterprise solution that allows it to sell products securely over the Internet, [www.youcanordernow.com](http://www.youcanordernow.com);

.

Provide a mobile interface that allows customers and medical professionals to acquire product data and purchase from a mobile device such as an iPhone;

.

Publish articles, news and white papers containing relevant information;

.

Allow customers and medical professionals accessing the website to create a contact form with database capture; and,

.

Provide for links to other Social Media websites where the Company will establish its brand identity, including Face Book, Twitter, et al.



## **OTHER MARKETING EFFORTS**

The Company currently uses a number of other marketing efforts using the growing social media channels, FaceBook, YouTube, Twitter, Instagram, etc, which currently are becoming increasing more relevant for our marketing strategy.

## **MANUFACTURING AND ORDER FULLFILLMENT**

The Company has located and vetted redundant Certified Good Manufacturing Practices (cGMP) manufacturing and production facilities and the Company's initial products will be produced, warehoused and shipped through its existing corporate offices.

## **GOVERNMENT REGULATION**

The Company's business is subject to varying degrees of regulation by a number of government authorities in the United States, including the United States Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and the Consumer Product Safety Commission. The Company will be subject to additional agencies and regulations if it enters the manufacturing business. Various agencies of the state and localities in which we operate and in which our products are sold also regulate our business, such as the California Department of Health Services, Food and Drug Branch. The areas of our business that these and other authorities regulate include, among others:

- .
- product claims and advertising;
- .
- product labels;
- .
- product ingredients; and
- .
- how we package, distribute, import, export, sell and store our products.

The FDA, in particular, regulates the formulation, manufacturing, packaging, storage, labeling, promotion, distribution and sale of vitamins and other nutritional supplements in the United States, while the FTC regulates marketing and advertising claims. The FDA issued a final rule called Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, which includes regulations requiring companies, their suppliers and manufacturers to meet Good Manufacturing Practices in the preparation, packaging, storage and shipment of their products. Management is committed to meeting or exceeding the standards set by the FDA.

The FDA has also issued regulations governing the labeling and marketing of dietary and nutritional supplement products. They include:

.

the identification of dietary or nutritional supplements and their nutrition and ingredient labeling;

.

requirements related to the wording used for claims about nutrients, health claims, and statements of nutritional support;

.

labeling requirements for dietary or nutritional supplements for which high potency and antioxidant claims are made;

.

notification procedures for statements on dietary and nutritional supplements; and

.

pre-market notification procedures for new dietary ingredients in nutritional supplements.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) revised the existing provisions of the Federal Food, Drug and Cosmetic Act concerning the composition and labeling of dietary supplements and defined dietary supplements to include vitamins, minerals, herbs, amino acids and other dietary substances used to supplement diets. DSHEA generally provides a regulatory framework to help ensure safe, quality dietary supplements and the dissemination of accurate information about such products. The FDA is generally prohibited from regulating active ingredients in dietary supplements as drugs unless product claims, such as claims that a product may heal, mitigate, cure or prevent an illness, disease or malady, trigger drug status.

The Company is also subject to a variety of other regulations in the United States, including those relating to taxes, labor and employment, import and export, and intellectual property.

## **Employees**

As of December 31, 2015, we had three full-time employees, all non-union. We believe that our relations with our employees are good.

## ITEM 1A

### RISK FACTORS

As a smaller reporting company we are not required to provide a statement of risk factors. However, we believe this information may be valuable to our shareholders for this filing. We reserve the right to not provide risk factors in our future filings. Our primary risk factors and other considerations include:

This Annual Report on Form 10-K contains forward-looking statements concerning our future programs, expenses, revenue, liquidity and cash needs as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information, except as required by applicable laws and regulations. Numerous factors could cause actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors.

#### **Internal Control**

*Our management has concluded that our internal control over financial reporting is not effective. Material weaknesses in our internal control over financial reporting could cause our financial reporting to be unreliable and could lead to misinformation being disseminated to the public.*

Our management concluded that as of December 31, 2015 our internal control over financial reporting was not effective, and that material weaknesses existed in the following areas as of December 31, 2015:

(1)

we do not employ full time in-house personnel with the technical knowledge to identify and address some of the reporting issues surrounding certain complex or non-routine transactions. With respect to material, complex and non-routine transactions, management has and will continue to seek guidance from third-party experts and/or consultants to gain a thorough understanding of these transactions;

(2)

we have inadequate segregation of duties consistent with the control objectives including but not limited to the disbursement process, transaction or account changes, and the performance of account reconciliations and approval;

(3)

we have ineffective controls over the period end financial disclosure and reporting process caused by reliance on third-party experts and/or consultants and insufficient accounting staff; and

(4)

we do not have a functioning audit committee of the Board of Directors and our Board of Directors, in its performance of the functions generally associated with audit committees, lacks a majority of (indeed, lacks any) independent members and lacks a majority of (indeed, lacks any) outside directors, resulting in ineffective oversight in the establishment and monitoring of required internal controls, approvals and procedures.

**Our liquidity and capital resources are very limited.**

Our ability to fund operating activities is also dependent upon our ability to access external sources of financing and our ability to effectively manage our expenses in relation to revenues. Our ability to fund working capital and anticipated capital expenditures will depend on our future performance, which is subject to general economic conditions specific to the health, supplements and nutrition products industries, consumer demand for our products, competition and other factors that are beyond our control. There can be no assurance that our operations and access to external sources of financing will continue to provide resources sufficient to satisfy our liabilities arising in the ordinary course of business.

**We will require significant additional external financing to implement our business plan.**

We will require external financing to sustain our operations, support our expansion, achieve or maintain profitability, or, should we become subject to unforeseen events or circumstances, continue as a going concern. There can be no assurance that we will be able to secure any such external financing, or, if we are able to secure such external financing, that it will be on terms favorable, or even acceptable, to us. Any inability to achieve or sustain profitability or otherwise secure external financing would have a material adverse effect on our business, financial condition, and results of operations, raising substantial doubts as to our ability to continue as a going concern, and we may ultimately be forced to seek protection from creditors under the bankruptcy laws or cease operations, which may result in a substantial or complete loss of invested capital.



**We may not be able to effectively manage our potential growth and the execution of our business plan.**

Our potential growth and the execution of our business plan together are likely to place significant strain on our managerial, operational and financial resources. To effectively manage our potential growth and execute our business plan, we will need to, among other things:

- .  
retain additional personnel across several departments in the Company;
- .  
develop strong customer loyalty for new products in a crowded competitive marketplace;
- .  
continue to establish and continue to increase awareness of our brands;
- .  
price our products and services at points which will allow us to maximize sales while at the same time maximizing gross profit margins;
- .  
establish, maintain, expand and manage multiple relationships with various vendors, strategic partners, licensees and other third parties, including suppliers of the products we sell on our website and elsewhere, warehousing distributors, shipping companies and others;
- .  
rapidly respond to competitive developments, particularly when new high-demand products become available;
- .  
build an operations structure to support our business and provide efficient and effective customer service and support;
- .  
expand our IT infrastructure to respond to increasing customer traffic to our website, demand for content from site users and to manage growing e-commerce transactions;
- .  
establish and maintain effective financial and management controls, reporting systems and procedures;

control our expenses;

provide competitive employee salaries and benefit packages; and,

avoid lawsuits and other adverse claims.

There can be no assurance that we will be able to accomplish any or all of the above goals. If we prove unable to effectively execute our business plan or manage our growth, it is likely to have a material adverse effect on our business, financial condition, including liquidity and profitability, and our results of operations.

**If our proposed product sales model does not successfully operate at a profit our growth strategy may be impeded.**

To effectively expand and meet our growth objectives our products sales model must be executed upon in a profitable manner. Profitability is dependent upon a variety of factors, some beyond our control, including, but not limited to the amount of traffic we can consistently attract to our brand, to retail sales in brick and mortar retailers, to our website, and our ability to stock or otherwise make available products that our customers purchase, our ability to stock or otherwise make available the best new products as they enter the market, our ability to provide consistent and superior customer service, the general economic conditions, particularly in the U.S., that could impact the amount of money customers spend collectively on the products we sell, and/or that could reduce the amount of money our average customer spends, and/or could reduce the number or frequency of repeat orders for products, and/or could result in customers finding products in other venues if they can find those products for a lower price. Other factors that could impact our ability to execute on our business model in a profitable manner include, but are not limited to, competition in our markets, recruiting, training and retaining qualified personnel and management, maintenance of required local, state and federal governmental approvals and permits, costs associated with principal component products and supplies, delivery shortages or interruptions, consumer trends, our ability to finance operations externally, changes in supply or prices of the products we sell and disruptions or business failures among our product suppliers, distributors, warehouses or shippers. Any failure to operate in a profitable manner could hurt our ability to meet our growth objectives by attracting licensees, and our business, financial condition, including liquidity and profitability, and our results of operations would be negatively affected.

**If we cannot stock, warehouse or otherwise provide product to customers in a consistent, reliable and cost-effective manner our growth strategy may be impeded.**

As our growth strategy depends to a large extent on our ability to sell various products to consumers on our website and in traditional brick and mortar retailers, if we cannot supply those products in a consistent, reliable and



cost-effective manner, we may lose customers. To accomplish a consistent, reliable and cost-effective method for supplying product to customers, we must successfully engage with suppliers at a number of levels, including warehousing agreements, stocking agreements and other forms of distribution. Our ability to conclude such arrangements with specific product suppliers may involve the need for trade finance, purchasing agreement finance and other capital. In addition, we may encounter problems in fulfilling orders due to business conditions among the products companies themselves, many of which problems are beyond our control. If we are unable to establish and continue such agreements and structures with products companies, our growth strategy may be impeded, which could negatively affect our business, financial condition, including liquidity and profitability, and our results of operations.

**We face significant competition for our products.**

The markets in which we operate are intensely competitive, continually evolving and, in some cases, subject to rapid change. Our competitors include:

·  
traditional and well established companies with recognized and well patronized brands in the nutritional supplements and health products industry segment;

·  
entrenched nutritional supplements and health products companies with well known customer on-line services and portals and other high-traffic web sites that provide sales access to healthcare and nutritional supplements and related products; and

·  
companies that focus on providing on-line and/or off-line healthcare related content, including some that promote competitor brands.

Many of our competitors have greater financial, technical, product development, marketing and other resources than we do. These companies may be better known than we are and have more customers than we do. We cannot provide assurance that we will be able to compete successfully against these companies or any alliances they have formed or may form. If we are unable to compete with one or more of our competitors, our growth strategy may be impeded, which could negatively affect our business, financial condition, including liquidity and profitability, and our results of operations.

**Government regulation could adversely affect our business.**

Our products and their associated component ingredients are subject to existing and potential government regulation. Our failure, or the failure of our business partners or third party providers, to accurately anticipate the application of laws and regulations affecting our products and the manner in which we deliver them, or any failure to comply, could create liability for us, result in adverse publicity, or negatively affect our business. In addition, new laws and regulations, or new interpretations of existing laws and regulations, may be adopted with respect to consumer protection and other issues, including pricing, products liability, copyrights and patents, distribution and characteristics and quality of products and services. We cannot predict whether these laws or regulations will change or how such changes will affect our business. Any of this government regulation could impact our growth strategy, which could negatively affect our business, financial condition, including liquidity and profitability, and our results of

operations.

**Third parties may claim that we are infringing their intellectual property, and we could suffer significant litigation or licensing expense or be prevented from providing certain services, and which may otherwise harm our business.**

We could be subject to claims that we are misappropriating or infringing intellectual property, trade secrets or other proprietary rights of others. These claims, even if not meritorious, could be expensive to defend and divert management's attention from our operations. If we become liable to third parties for infringing these rights, we could be required to pay substantial damage awards and to develop non-infringing products, obtain a license or cease selling the products that use or contain the infringing intellectual property. We may be unable to develop non-infringing products or obtain a license on commercially reasonable terms, or at all. Any claims against our company for infringement could impede our growth strategy, which could negatively affect our business, financial condition, including liquidity and profitability, and our results of operations.

**We may be subject to claims brought against us as a result of product associated content we provide.**

Consumers are reasonably expected to access health-related information regarding our products through our on-line web site. If our content, or content we obtain from third parties, contains inaccuracies, it is possible that consumers or others may sue us for various causes of action. Although our planned web site contains terms and conditions, including disclaimers of liability, that are intended to reduce or eliminate our liability, the law governing the validity and enforceability of on-line agreements with consumers that provide the terms and conditions for use of our public or private portals are unenforceable. A finding by a court that these agreements are invalid and that we are subject to liability could harm our business and require costly changes to our business. We have planned editorial procedures in place to provide quality control of the information that we publish or provide. However, we cannot assure you that our editorial and other quality control procedures will be sufficient to ensure that there are no errors or omissions in particular content. Even if potential claims do not result in liability to us, the fact that we would need to investigate and defend against these claims could be expensive and time consuming and could divert management's attention away from our operations. In addition, our business is in part based on establishing a reputation amongst consumers that our portals as trustworthy and dependable sources of healthcare information. Allegations of impropriety or inaccuracy, even if unfounded, could therefore harm our reputation and business, which could negatively affect our business, financial condition, including liquidity and profitability, and our results of operations.

**Changes in commodity and other operating costs or supply chain and business disruptions could adversely affect our results of operations.**

Changes in product costs are a part of our business; any increase in the prices that suppliers charge for their products could adversely affect our operating results. We remain susceptible to increases in prices as a result of factors beyond our control, such as general economic conditions, seasonal fluctuations, weather conditions, demand, safety concerns, product recalls, labor disputes and government regulations. We rely on third-party distribution companies to deliver ingredients to our manufacturers and ultimately our products to customers. Interruption of distribution services due to financial distress or other issues could adversely affect our operations.

**We face substantial competition in attracting and retaining qualified senior management and key personnel and may be unable to develop and grow our business if we cannot attract and retain such senior management and key personnel.**

As an early stage company, our ability to develop and grow our business, to a large extent, depends upon our ability to attract, hire and retain highly qualified and knowledgeable senior management and key personnel who possess the skills and experience necessary to satisfy our business needs. Our ability to attract and retain such senior management and key personnel will depend on numerous factors, including our ability to offer salaries, benefits and professional growth opportunities that are comparable with and competitive to those offered by more established companies operating in our marketplace. We may be required to invest significant time and resources in attracting and retaining additional senior management and key personnel as needed. Moreover, many of the companies with which we will compete for any such individuals have greater financial and other resources, affording them the ability to undertake more extensive and aggressive hiring campaigns, than we can. The normal running of our operations may be interrupted, and our financial condition and results of operations negatively affected, as a result of any inability on our part to attract or retain the services of qualified and experienced senior management and key personnel, or should our prospective key personnel refuse to serve, or, once appointed, leave prior to a suitable replacement being found.

### **Risks Associated With Our Restricted Securities**

**Because there is currently a limited public trading market for our common stock, investor may not be able to resell stock.**

Our stock is now traded in OTC Markets under the stock symbol TSOI, which results in a very illiquid and limited market for our common stock.

**The Company is currently delinquent in its reporting obligations with the Securities and Exchange Commission ( SEC ). The Company has not filed quarterly reports for the periods ending March 31, 2016 and June 30, 2016. The Company s common stock listing on the Pink Sheets currently has a Yield symbol affiliated with it indicating that there is limited public information available about the Company. The Yield affiliation also serves as a warning to potential investors that the Company may not be publishing adequate public information and only has published limited financial information and is delinquent in its SEC filings.**

**We have identified material weaknesses in our internal control over financial reporting.**

We are required to comply with the provisions of Section 404 of the Sarbanes-Oxley Act of 2002, which require us to maintain an ongoing evaluation and integration of the internal controls of our business.

We evaluated our existing controls as of December 31, 2015. Our Chief Executive Officer and Chief Financial Officer identified material weaknesses in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected. Readers are directed to review that portion of this Form 10-K entitled Item 9A Controls and Procedures for a detailed disclosure.

Under Section 404 and the SEC s rules, a company cannot find that its internal control over financial reporting is effective if any material weaknesses exist in its controls over financial reporting.

**Our business changed materially on April 28, 2014 when we lost the right to sell AMPSA Products.**

Boyd Research Inc. gave notice to TSOI that we were in default on amounts owed for International Patent Maintenance Fees on April 28, 2014.

Section 8.2(a) of the License Agreement provides that if TSOI fails to cure [its] default within the applicable cure period, Licensor shall have the right to immediately terminate this Agreement.

TSOI disputed the amounts owed but ultimately was unable to cure this default and Boyd Research Inc. exercised their contractual rights under the August 24, 2012 MDRA and terminated our license agreement to market AMPSA products Internationally.

**There is currently no liquid trading market for our common stock and we cannot ensure that one will ever develop or be sustained.**

The trading market for our common stock is currently not liquid. We cannot predict how liquid the market for our common stock might become. Our common stock is quoted in OTC Markets under the symbol TSOI.

**Our common stock may be deemed a penny stock , which would make it more difficult for investors to sell their shares.**

Our common stock is subject to the penny stock rules adopted under the Exchange Act. The penny stock rules apply to companies whose common stock is not listed on the NASDAQ Stock Market or other national securities exchange and trades at less than \$4.00 per share, other than companies that have had average revenue of at least \$6,000,000 for the last three years or that have tangible net worth of at least \$5,000,000 (\$2,000,000 if the company has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than established customers complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities and investors may find it more difficult to dispose of our securities.

**Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.**

If our stockholders have the right to sell substantial amounts of common stock in the public market, e.g. upon the expiration of any statutory holding period under Rule 144, it could create a circumstance commonly referred to as an overhang and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make our ability to raise additional financing through the sale of equity or equity-related securities in the future, at a time and price that we deem reasonable or appropriate, more difficult.

**The elimination of monetary liability against our directors and officers under the Company's Articles of Incorporation and Nevada law, and the existence of indemnification rights to our directors, officers and employees, may result in substantial expenditures by the Company.**

Article 6 of our Articles of Incorporation exculpates our directors and officers from certain monetary liabilities. Article 7 of our Articles of Incorporation provides that we shall indemnify all directors (and all persons serving at our request as a director or officer of another corporation) to the fullest extent permitted by Nevada law.

Further pursuant to Article 7, the expenses of the indemnified person incurred in defending a civil suit or proceeding must be paid by us as incurred and in advance of the final disposition of the action, suit, or proceeding under receipt of an undertaking by or on behalf of the indemnified person to repay the amount if it is ultimately determined by a court of competent jurisdiction that he or she is not entitled to be indemnified by us.

The foregoing indemnification obligations could result in us incurring substantial expenditures, which we may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against directors and officers for breaches of their fiduciary duties even though such actions, if successful, might otherwise benefit us and our stockholders.

**Public company compliance may make it more difficult to attract and retain officers and directors.**

The Sarbanes-Oxley Act and related rules implemented by the SEC have required changes in corporate governance practices of public companies. As a public entity, these rules and regulations increase compliance costs and make certain activities more time consuming and costly. As a public entity, these rules and regulations also make it more difficult and expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve as directors or as executive officers.

*We do not plan to pay any cash or stock dividends in the foreseeable future.*

The payment of dividends upon our capital stock is solely within the discretion of our future board of directors and is dependent upon our financial condition, results of operations, capital requirements, restrictions contained in our future financing instruments and any other factors our board of directors may deem relevant. We have never declared or paid any cash or stock dividends on our capital stock and we currently anticipate that we will retain earnings, if any, to finance the development and expansion of our business and, as such, do not intend on paying any cash or stock dividends in the foreseeable future.

## **ITEM 1B**

### **UNRESOLVED STAFF COMMENTS**

No disclosure required.

## **ITEM 2**

### **PROPERTIES.**

We do not own any real-estate property or manufacturing equipment. Our business is conducted in approximately 1,300 square feet of rented offices and warehouse space located at 4093 Oceanside Blvd., Suite B, Oceanside, CA 92056.

## **ITEM 3**

### **LEGAL PROCEEDINGS.**

None.



**ITEM 4**

**MINE SAFETY DISCLOSURES.**

No disclosure required.

## PART II

### ITEM 5

#### MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our stock is now traded in OTC Markets under the stock symbol TSOI, which results in a very illiquid and limited market for our common stock. As of the date of Annual Report on Form 10-K there are approximately 137 stockholders of record of our common stock.

The following table sets forth the quarterly high and low closing sales prices for our common stock from January 1, 2014 through December 31, 2015.

Quarter Ended	High	Low
December 31, 2015	\$0.011	\$0.0025
September 30, 2015	\$0.023	\$0.0026
June 30, 2015	\$0.0043	\$0.0018
March 31, 2015	\$0.0063	\$0.0011
December 31, 2014	\$0.004	\$0.002
September 30, 2014	\$0.0033	\$0.0019
June 30, 2014	\$0.0045	\$0.0023
March 31, 2014	\$0.0055	\$0.0026

#### Dividends

We did not declare or pay dividends during 2014 to 2015.

#### Issuances of Unregistered Securities

Edgar Filing: THERAPEUTIC SOLUTIONS INTERNATIONAL, INC. - Form 10-K/A

On March 31, 2014, we issued 2,500,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On March 31, 2014, we issued 2,500,000 shares of common stock, valued at \$.004 per share, for consulting services.

On March 31, 2014, we issued 2,000,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On March 31, 2014, we issued 5,000,000 shares of common stock, valued at \$.004 per share, for legal services.

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500, shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,476,435 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,250,000 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 7,682,165 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On December 9, 2014, we issued 100,000,000 shares of common stock, valued at \$.0021 per share, in regard to a Material Definitive Agreement (Form 8-K filed on December 10, 2014).

On March 27, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On February 27, 2015, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On April 1, 2015, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On April 17, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On June 1, 2015, we issued 3,000,000 shares of common stock, valued at \$.0026 per share, for consulting services.

On June 1, 2015, we issued 7,000,000 shares of common stock, valued at \$.0025 per share, for legal services

On June 8, 2015, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On July 15, 2015, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On August 31, 2015, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On September 25, 2015, we issued 10,000,000 shares of common stock, valued at \$.0046 per share, for consulting services.

On October 1, 2015, we issued 23,000,000 shares of common stock, valued at \$.0063 per share, for consulting services.

On October 13, 2015, we issued 2,500,000 shares of common stock, valued at \$.0060 per share, for consulting services.

On October 14, 2015, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On October 16, 2015, we issued 4,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 9, 2015, we issued 3,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 23, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 30, 2015, we issued 2,500,000 shares of common stock, valued at \$.01 per share, for legal services.

On January 4, 2016, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On January 22, 2016, we issued 2,500,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On February 1, 2016, we issued 2,500,000 shares of common stock, valued at \$.003 per share, for consulting services.

On February 5, 2016, we issued 8,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On February 22, 2016, we issued 5,451,000 shares of common stock, valued at \$.003 per share, in regard to a License Agreement (Form 8-K filed on February 25, 2016).

On February 26, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On March 7, 2016, we issued 10,000,000 shares of common stock, valued at \$.0004 per share, for consulting services.

On March 21, 2016, we issued 100,800,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 2, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement and 1,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On May 26, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for consulting services.

On May 26, 2016, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 31, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for legal services.

On July 27, 2016, we filed with the Nevada Secretary of State a Certificate of Amendment to Articles of Incorporation to effect an amendment (the Amendment) changing the number of authorized shares of our common stock to 990,000,000.

On September 16, 2016, we issued 12,500,000 shares of common stock, valued at \$.004 per share, for an investment in the Company's Private Placement.

On October 18, 2016, we issued 40,000,000 shares valued at \$.0045 to the officers and directors of the Company for services, and 5,000,000 shares valued at \$.0045 for consulting services.

### **Repurchases/Cancellation of Securities**

We made no repurchases of our securities for the years ended 2014-2015.



## **ITEM 6**

### **SELECTED FINANCIAL DATA.**

No disclosure required.

## **ITEM 7**

### **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

The following discussion is intended to assist in the understanding and assessment of significant changes and trends related to the results of operations and financial condition of the Company. The following discussion contains forward-looking statements that involve risks and uncertainties. See *Forward-Looking Statements* elsewhere in this Annual Report on Form 10-K. This discussion and analysis should be read in conjunction with our financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Therapeutic Solutions International, Inc. is a Nevada corporation which was incorporated on August 6, 2007 under the name *Friendly Auto Dealers, Inc.* In the first quarter of 2011, we acquired *Splint Decisions, Inc.*, and changed our name from *Friendly Auto Dealers, Inc.*, to *Therapeutic Solutions International, Inc.*, and our ticker symbol from *FYAD* to *TSOI*. This Annual Report on Form 10-K, and the financial statements included herein, reflect the treatment of *Splint Decisions, Inc.*, as the accounting acquirer in the transaction. Our principal executive office is located at 4093 Oceanside Blvd., Suite B, Oceanside, California 92056, our telephone number is (760) 295-7208 and our website is [www.therapeuticsolutionsint.com](http://www.therapeuticsolutionsint.com). The reference to our website does not constitute incorporation by reference of the information contained on our website.

Our common stock is currently quoted on the Pink Sheets under the symbol *TSOI*. There currently is a limited public market for our common stock. A limited public market for our stock could make it difficult to sell your shares in our stock. The Company is currently delinquent in its reporting obligations with the Securities and Exchange Commission (SEC). The Company has not filed quarterly reports for the periods ending, March 31, 2016 and June 30, 2016. The Company's common stock listing on the Pink Sheets currently has a *Yield* symbol affiliated with it indicating that there is limited public information available about the Company. The *Yield* affiliation also serves as a warning to potential investors that the Company may not be publishing adequate public information and only has published limited financial information and is delinquent in its SEC filings.



We file our quarterly and annual reports with the Securities and Exchange Commission ( SEC ), which the public may view and copy at the SEC's Public Reference Room at 100 F Street, N.E. Washington D.C. 20549, on official business days during the hours of 10 a.m. to 3 p.m. The public may obtain information on the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site, the address of which is [www.sec.gov](http://www.sec.gov), which contains reports, proxy and information statements, and other information regarding issuers which file electronically with the SEC. The periodic and current reports that we file with the SEC can also be obtained from us free of charge by directing a request to Therapeutic Solutions International, Inc., 4093 Oceanside Blvd, Suite B, Oceanside, California 92056, Attn: Corporate Secretary.

#### **Description of Business until April 28, 2014**

Until April 28, 2014 the Company sold (directly and through distributors and sublicensees), in non-US countries, plastic intraoral devices known as Anterior Midpoint Stop Appliances ( AMPSA Products ). Our customers were dentists and doctors. The AMPSA Products are used for the treatment and prevention of common neurological and temporomandibular disorders including migraine headaches, migraine pain and bruxism.

On April 28, 2014, we received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc., and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated. The ostensible reason Mr. Jaczko gave was our failure to make certain unspecified payments due under the license agreement to his clients. We disputed the termination, but believed that the costs involved with litigating the termination of the New License was not in the best interest of the Company and its shareholders. Therefore, the Company decided to move in new direction.

#### **CURRENT BUSINESS DESCRIPTION**

Therapeutic Solutions International is a public company (OTC:TSOI) focused on immune modulation for the treatment of several specific diseases. Immune modulation refers to the ability to upregulate (make more active) or downregulate (make less active) one's immune system.

Activating one's immune system is now a well-accepted method to cure certain cancers, reduce recovery time from viral or bacterial infections and to prevent illness. On the other hand, inhibiting one's immune system is vital for reducing inflammation, autoimmune disorders and allergic reactions.

TSI is developing a range of immune-modulatory agents to target certain cancers, improve maternal and fetal health, fight periodontal disease, and for daily health. TSI has created several subsidiaries and divisions to focus on each of these programs:

**Nutraceutical Division** TSI has been producing very high quality nutraceuticals. Its flagship product, ProJuvenol<sup>®</sup>, is a proprietary mixture containing pterostilbene – one of the most potent antioxidants known. TSOI filed a patent application for ProJuvenol<sup>®</sup> on 07-08-2015 titled: Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions as well as a second patent application filed 04-27-2016 titled Augmentation Of Stem Cell Activity Using Pterostilbene And Compositions Containing Pterostilbene . In addition we recently introduced a line of oncologist friendly nutraceuticals in liposome formula. These include CoQ10, Curcumin, Glutathione, and Vitamin-C in 16oz bottles..

**OmniBiome, Inc.** - is a partially-owned subsidiary of TSI where the intellectual property surrounding probiotics is housed. Current programs focus on the use of probiotics to prevent pre-term labor and on using probiotics to reverse periodontal disease. Mr. Dixon and Mr. Berg, of the Company, are also officers and Directors of Omni. As of October 25, 2016, TSI owns approximately 73.75% of the outstanding shares of OmniBiome. Website: <http://omnibiomeinc.com>

## Summary

TSI has assembled a first-rate scientific advisory board that is leading the company into the most exciting and potentially profitable fields of medicine – immune modulation. TSI expects to launch several products that improve people's health and well-being over the next several months.

### **Clinical Stage Dexosome**

TSOI recently licensed January 2016 a Dexosome Clinical Stage Cancer Immunotherapy Product from Gustave Roussy European Cancer Centre. Planning is still underway as to next steps.

Dexosomes are exosome nanoparticles generated by dendritic cells, which have previously been used by investigators at Anosys, Inc., in collaboration with researchers at Duke University, for treatment of cancer patients as part of an FDA-cleared Phase I clinical trial<sup>1</sup>. The licensed patent was invented by internationally-renowned immunologists Sebastian Amigorena, Doctor at the Curie Institute, and Laurence Zitvogel, Professor at Gustave Roussy. The patent covers means of generating therapeutically-effective dexosomes, which can act as a platform for loading any tumor antigen desired.

In the area of drug development, much of the risk is taking the technology from the lab to the patient. We are fortunate that the current technology has already been utilized in patients under FDA jurisdiction, and has demonstrated safety with signs of efficacy.

The in-licensing of the current patent augments previously filed patent applications by TSOI, including one filed in November 2015, covering uses of exosomes to stimulate both innate and adaptive arms of the immune response<sup>2</sup>. The Company plans to leverage the experience of its newest Board Member, Dr. Thomas Ichim, to lead the Dexosome program back into clinical trials. Dr. Ichim has previously patented the manipulation of exosomes in the area of cancer therapy for alleviation of immune suppression<sup>3</sup>, as well as being published in the peer-reviewed literature in this area<sup>4,5</sup>.

<sup>1</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC551593/>

<sup>2</sup> <http://www.therapeuticsolutionsint.com/index.php/2015-04-19-16-05-26/228-therapeutic-solutions-international-files-patent-or>

<sup>3</sup> <http://www.google.com/patents/US8288172>

<sup>4</sup> Ichim et al. Exosomes as a tumor immune escape mechanism: possible therapeutic implications. *J Transl Med.* 2008 Jul 22;6:37. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504474/>

<sup>5</sup> Abusamra et al. Tumor exosomes expressing Fas ligand mediate CD8+ T-cell apoptosis. *Blood Cells Mol Dis.* 2005 Sep-Oct;35(2):169-73. <http://www.ncbi.nlm.nih.gov/pubmed/16081306>

### **Nutraceutical Division (TSOI)**

**ProJuvenol®** is a powerful synergistic blend of complex anti-aging ingredients inspired by nature to help promote cellular rejuvenation and healthy functionality for everyday living. Based upon pterostilbene, one of nature's unique and intelligent antioxidants/anti-inflammatories. ProJuvenol includes a scientifically valid blend of interactive ingredients with anti-aging and cellular protective properties to help support optimal health and provide the benefits of mental alertness and physical well-being.

Pterostilbene (pronounced "tero-STILL-bean") has created a buzz in the world of nutrition research. Scientists discovered this powerful antioxidant several decades ago and have since found that it rivals its cousin resveratrol's multi-functional abilities, and may actually exceed its anti-aging and health promoting potential. Found naturally in blueberries, pterostilbene has been shown in emerging experimental studies to exhibit up to 7 times greater bioavailability than resveratrol as well as better metabolic stability. This translates to potentially higher levels of pterostilbene in the blood upon ingestion, and longer lasting effects in the body compared to resveratrol. More simply put, it remains active in your body for a much greater period of time and during this enhanced bio-available period your body has the opportunity to allow it to utilize this antioxidant molecule.

A large body of experimental research has now documented a wide range of potential health effects associated with pterostilbene. In fact, the more researchers study pterostilbene, the greater its human health potential becomes. In addition to being a powerful antioxidant, emerging experimental research suggests this plant compound may also help regulate cell growth, promote fat metabolism, support glucose utilization, influence brain function, and improve the body's natural detoxification enzymes that are required to help protect cells against potentially damaging compounds from the environment.

**Patents:**

TSOI filed a patent covering the use of its ProJuvenol® product, as well as various pterostilbene compositions, for use in augmenting efficacy of existing immuno-oncology drugs that are currently on the market. The patent is based on the ability of pterostilbene, one of the major ingredients of ProJuvenol®, to reduce oxidative stress produced by cancer cells, which in turn protects the immune system from cancer mediated immune suppression.

Immuno-Oncology, described by Science Magazine as 'Breakthrough of the Year'<sup>1</sup> offers the possibility of not only killing tumor cells in a non-toxic manner, but also establishing immunological memory, which patrols the body and destroys recurrent tumor cells. While great progress has been made in developing drugs that stimulate the immune system to recognize and kill tumors, a major pitfall of current approaches is that tumors produce chemicals and oxidative stress that suppresses the immune system, thus limiting efficacy of immune therapies.

Pterostilbene, which is chemically related to resveratrol, has been published to possess anticancer<sup>2,3</sup>, antioxidant<sup>4</sup>, and anti-inflammatory activities<sup>5</sup>. Through the filing of the recent patent, the company is exploring whether its lead product, ProJuvenol<sup>®</sup>, may be useful as a nutraceutical adjuvant to conventional cancer immunotherapies.

The importance of proper nutrition in the context of immunotherapy cannot be overstated. Studies on one of the original cancer immunotherapies, interleukin-2, demonstrated that efficacy was related to anti-oxidant content in the patients at time of therapy<sup>6</sup>. Accordingly, we are seeking through the current work to identify whether our currently marketed product, ProJuvenol<sup>®</sup>, may be utilized as part of an integrative approach to building up the immune response of cancer patients.

<sup>1</sup> Couzin-Frankel J. Breakthrough of the year 2013. Cancer immunotherapy. Science. 2013;342:1432-3. <https://www.sciencemag.org/content/342/6165/1432.summary>

<sup>2</sup> Yang et al. Pterostilbene exerts antitumor activity via the Notch1 signaling pathway in human lung adenocarcinoma cells. PLoS One. 2013 May 3;8(5):e62652. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3643961/>

<sup>3</sup> Li et al. Pterostilbene acts through metastasis-associated protein 1 to inhibit tumor growth, progression and metastasis in prostate cancer. PLoS One. 2013;8(3):e57542. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3586048/>

<sup>4</sup> McCormack and McFadden. A review of pterostilbene antioxidant activity and disease modification. Oxid Med Cell Longev. 2013;2013:575482. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3649683/>

<sup>5</sup> Qureshi et al. Inhibition of nitric oxide and inflammatory cytokines in LPS-stimulated murine macrophages by resveratrol, a potent proteasome inhibitor. Lipids Health Dis. 2012 Jul 10;11:76. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393619/>

<sup>6</sup> Marcus et al. Severe hypovitaminosis C occurring as the result of adoptive immunotherapy with high-dose interleukin 2 and lymphokine-activated killer cells. Cancer Res. 1987 Aug 1;47(15):4208-12.

In addition on April 28, 2016 the Company filed a patent application covering the use of ProJuvenol<sup>®</sup> and its active ingredient pterostilbene for augmentation of stem cell activity. Diseases such as diabetes<sup>1</sup>, cardiovascular disease<sup>2</sup>, and neurodegenerative diseases<sup>3</sup> are characterized by deficient stem cell activity. The patent covers the stimulation of stem cells that already exist in the patient's body, as well as stem cells that are administered therapeutically.

Studies have shown that patients who have higher levels of endogenous stem cell activity have reduced cardiovascular disease risk<sup>4</sup> and undergo accelerated neurological recovery after stroke<sup>5</sup> as compared to patients with lower numbers of such stem cells.

<sup>1</sup> Moon et al. Circ J. 2012;76(9):2273-9. <http://www.ncbi.nlm.nih.gov/pubmed/22664650>

<sup>2</sup> Hill et al. N Engl J Med. 2003 Feb 13;348(7):593-600. <http://www.ncbi.nlm.nih.gov/pubmed/12584367>

<sup>3</sup> Lee et al. Neurology. 2009 May 26;72(21):1858-63 <http://www.ncbi.nlm.nih.gov/pubmed/19470969>

<sup>4</sup> Hill et al. N Engl J Med. 2003 Feb 13;348(7):593-600. <http://www.ncbi.nlm.nih.gov/pubmed/12584367>

<sup>5</sup> Sobrino et al. Stroke. 2007 Oct;38(10):2759-64. <https://www.ncbi.nlm.nih.gov/pubmed/17761925>

TSOI markets currently two other nutraceuticals, T-Rx<sup>®</sup>, a testosterone booster, and Vital<sup>®</sup> Female, an estrogen booster and has plans to introduce a line of oncologist friendly nutraceuticals in liposome formula.

### **Fetal-Maternal Health**

#### **OmniBiome, Inc.**

OmniBiome, Inc., a partially-owned subsidiary of TSI, is focused on therapeutic / Rx approaches to either utilize or intervene with the systemic effects of the vaginal, lactal-duct and oral microbiomes for improving maternal healthcare and resulting birth outcomes. Mr. Dixon and Mr. Berg, of the Company, are also officers and Directors of Omni. As of October 25, 2016, TSI owns approximately 73.75% of the outstanding shares of OmniBiome. Website: [www.omnibiomeinc.com](http://www.omnibiomeinc.com)

The Company will focus initially on developing CLIA Dx services for both pre-pregnancy-associated and pregnancy-associated conditions or diseases where there is a substantive link with microbiome dysbiosis (disruption or imbalance), as well as on restoring eubiosis (proper balance).

In parallel OmniBiome will build a database of aggregated patient data that will later inform development of Rx / therapeutic and medical device & drug-device combination approaches for treating the same conditions or diseases.





### **MicroBiome Targets**

Certain microbiome target markets offer immediate revenue-generating business opportunities such as vaginal and lactal-duct microbiome banking & transplants from mother to child in the case of C-section-born babies, babies of non-nursing mothers, and children under 5 years of age receiving broad-spectrum antibiotics

OmniBiome's main focus will be on developing Dx / Rx products & services for pregnancy-associated conditions or diseases where there is a documented or substantive putative link with microbiome dysbiosis and resulting inflammatory cascades

In parallel the Company will look to create alliances and/or out license its Medical Device / Drug Device Combinations patent portfolio.

The Company also plans to in-license microbiome- and pregnancy-related Rx & Dx innovations from universities and research institutes several have already been identified.

### **The Human Microbiome Link**

The following microbiomes combined recapitulate approximately 75 - 80 % of the gut microbiome, hence OmniBiome sees no need to focus on the gut microbiome

***The Vaginal Microbiome*** comprises approximately 300 - 600 species of bacteria. 100s of species are transferred to the newborn child orally as the baby passes thru the birth canal C-section-born children miss this important microbiome transfer

***The Breast Milk Microbiome*** contains between 200 - 700 species of bacteria and is transferred to the child via nursing. Babies of non-nursing mothers miss this equally important transfer.

***The Oral Microbiome*** diversity spectrum also covers 600 species shared with the baby via kissing and sharing eating utensils with both the mother & the father.

### **Licensed Patents**

Patent titled "Prevention of Pregnancy Complications by Probiotic Administration." Press Release of 7/22/2015.

Patent titled "Preventative Methods and Therapeutic or Pharmaceutical Compositions for the Treatment or Prevention of Pregnancy Complications" covers utility of vaccines and various agents to alter pathological conditions in which the maternal immune system induces a process of inflammation that culminates in placental alterations leading to either fetal loss or preterm labor. Press Release of 9/8/2015.

Patent titled "Diagnostic Methods For The Assessment Of Pregnancy Complications" a cytokine-based diagnostic kit aimed at stratifying risk of preterm labor and other pregnancy associated complications. Press Release of 9/21/2015.

Patent titled "A Medical Device For Reducing The Risk Of Preterm-Labor And Preterm-Birth" covering various medical devices aimed at immune modulating the cervical microenvironment in order to prevent preterm labor. Press Release of 9/29/2015.

### **Critical Accounting Policies**

The preparation of our consolidated financial statements and notes thereto requires management to make estimates and assumptions that affect the amounts and disclosures reported within those financial statements. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, contingencies, litigation and income taxes. Management bases its estimates and judgments on historical experiences and on various other factors believed to be reasonable under the circumstances. Actual results under circumstances and conditions different than those assumed could result in differences from the estimated amounts in the financial statements. There have been no material changes to these policies during 2015.

### **Results of Operations**

We had a net loss of approximately \$0.59 million in 2015 compared to a net loss of approximately \$0.29 million in 2014.

On April 28, 2014, we received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated. See Note 10, Discontinued Operation in Notes to the Financial Statements.

Net sales increased approximately \$1,911 in 2016 from \$0 in 2015. This increase was mainly due to the initial launch of the Company's new nutraceutical line of products.

Cost of Goods Sold increased approximately \$3,193 in 2016 from \$0 in 2015. This increase was mainly due to the initial launch of the Company's new nutraceutical line of products.

Operating expenses for the years ended December 31, 2015 and December 31, 2014 were approximately \$.57 million and \$.33 million, respectively, an increase of approximately \$.24 million. This increase was mainly due a combination of increased salaries, wages and related costs, an increase in consulting fees, and a decrease in legal and accounting fees.

General and administrative expenses increased approximately \$.022 million from \$.073 in 2015, as compared to \$.051 in 2014. This increase was mainly due to increased rent, marketing and insurance costs.

Salaries, wages and related costs increased approximately \$0.16 million from \$.27 million in 2015, as compared \$.11 in 2014. This increase was mainly due to an increased payroll and an increase in officer salary accruals.

Selling expenses increased approximately \$4 thousand in 2015 from \$0 in 2014. This increase was mainly due to a reclassification of all selling and marketing expenses for last year to discontinued operation.

Amortization and depreciation was \$0 for the year ended December 31, 2015 versus approximately \$.021 million for the year ended December 31, 2014.

Consulting fees increased approximately \$.146 million from \$.186 million in 2015, as compared to \$.040 million in 2014. This increase was mainly due to an increase in overall consulting services

Legal and professional fees decreased approximately \$.063 million from \$.040 million in 2015, as compared to \$.103 million in 2014. This decrease was mainly due to a reduction of overall legal services in 2015 vs. 2014.

Net other income/expense decreased approximately \$5 thousand from \$4 thousand in 2015, as compared to \$9 thousand in 2014.

This change was mainly due to fluctuations in quarterly seminar tuition and related expenses.

Impairment of intangible asset decreased by \$210 thousand from \$0 in 2015, as compared to \$210 thousand in 2014. This decrease was due to the Company unable to forecast future short term revenue from acquired intellectual property.

Net interest expense decreased approximately \$4 thousand from \$5 thousand in 2015, as compared to \$9 thousand in 2014. This change was mainly due to reductions in notes payable and changes in interest rates.

Net income from discontinued operation for 2015 and 2014 were \$(13,822) and \$249,002, a decrease of \$262,824. This decrease was primarily due to the final sales of inventory from the notification that our license to use the international patents for our AMPSA device, pursuant to our license agreement, that was terminated on April 28, 2014 and the write off of accounts receivable,

### **Liquidity and Capital Resources**

As of December 31, 2015, our cash and cash equivalents was \$2,183 and our current liabilities totaled \$488,992. Our current cash reserves are not adequate for our needs. The Company plans to continue to reduce costs and seek additional funding for operations.

There is no guarantee we will receive the required financing to complete our business strategies, and it is uncertain whether future financing will be available to us on acceptable terms. If financing is not available on satisfactory terms, we may be unable to continue, develop or expand our operations. Our auditor has stated in their opinion that there is substantial doubt about the Company's ability to continue as a going concern.

### **Off-Balance Sheet Arrangements.**

We currently do not have any off-balance sheet arrangements.

**ITEM 7A**

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

No disclosure required.

## **ITEM 8**

### **FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

Our financial statements and the accompanying notes that are filed as part of this Annual Report on Form 10-K are listed and set forth beginning on page F-1 immediately following the signature page of this Form 10-K.

## **ITEM 9**

### **CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

## **ITEM 9A**

### **CONTROLS AND PROCEDURES**

#### **Disclosure Controls and Procedures**

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

At the end of the period covered by this Annual Report on Form 10-K for the fiscal year ended December 31, 2015, an evaluation was carried out under the supervision of and with the participation of our management, including the Chief Executive Officer ( CEO ) and Chief Financial Officer ( CFO ), of the effectiveness of the design and operations of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act).



Based on that evaluation the CEO and the CFO have concluded that as of the end of the period covered by this Annual Report, our disclosure controls and procedures were not effective.

### **Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by a company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management, including the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making our assessment, we used the framework and criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") (2009) in Internal Control-Integrated Framework in 2015. Based on that assessment, our management has identified certain material weaknesses in our internal control over financial reporting.



Our management concluded that as of December 31, 2015 our internal control over financial reporting was not effective, and that material weaknesses existed in the following areas as of December 31, 2015:

(1)

we do not employ full time in-house personnel with the technical knowledge to identify and address some of the reporting issues surrounding certain complex or non-routine transactions. With respect to material, complex and non-routine transactions, management has and will continue to seek guidance from third-party experts and/or consultants to gain a thorough understanding of these transactions;

(2)

we have inadequate segregation of duties consistent with the control objectives including but not limited to the disbursement process, transaction or account changes, and the performance of account reconciliations and approval ;

(3)

we have ineffective controls over the period end financial disclosure and reporting process caused by reliance on third-party experts and/or consultants and insufficient accounting staff; and

(4)

we do not have a functioning audit committee of the Board of Directors and our Board of Directors, in its performance of the functions generally associated with audit committees, lacks a majority of (indeed, lacks any) independent members and lacks a majority of (indeed, lacks any) outside directors, resulting in ineffective oversight in the establishment and monitoring of required internal controls, approvals and procedures.

#### **Changes in Internal Control Over Financial Reporting**

No substantial changes in our internal control over financial reporting occurred during 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except that we have increased our use of external accounting services, adopted policies to improve timely reviews by management and coordination with accounting consultants, and engaged corporate and securities legal counsel with better capabilities than our previous provider's.

**ITEM 9B**

**OTHER INFORMATION.**

None

**PART III**

**ITEM 10**

**DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

The Company's executive officers and directors and their respective ages as of October 25, 2016 are as follows:

**Directors:**

<b>Name of Director</b>	<b>Age</b>
Timothy G. Dixon	58
Gerry B. Berg	70
Dr. Thomas E. Ichim	40

**Executive Officers:**

<b>Name of Officer</b>	<b>Age</b>	<b>Office</b>
Timothy G. Dixon	58	President & CEO
Gerry B. Berg	70	Vice President & CFO
Hong Ma	47	Chief Science Officer

The term of office for each director is one year, or until the next annual meeting of the stockholders.

\*Thomas E. Ichim, Ph.D was appointed to the Board of Directors on January 22, 2016.

## **Biographical Information**

### **Timothy G. Dixon**

Mr. Dixon currently serves as Chief Executive Officer, President, and Chairman of Therapeutic Solutions International, Inc. Mr. Dixon also serves as President and Chairman of OmniBiome, Inc. Mr. Dixon previously served as the President of TMD Courses, Inc. from 2006 to 2012 and; as the President of Splint Decisions Inc. from 2010 to 2011. Mr. Dixon has attended hundreds of hours of continuing medical/dental education throughout the years and has produced many educational DVD s used by dental professionals worldwide on the subject of parafunctional control, migraine prevention, therapeutic Botox injections, migraine pathophysiology, dental sleep medicine, and other therapeutic protocols. Mr. Dixon also has extensive experience in dealing with corporate compliance matters with the U.S. Food and Drug Administration, (FDA) as well as many international regulatory bodies.

### **Gerry B. Berg**

Gerry B. Berg has served as our Vice-President and Chief Financial Officer since April 20, 2011. Mr. Berg became a director of the Company on August 24, 2012. Mr. Berg also serves as Chief Financial Officer OmniBiome, Inc. Mr. Berg has over 30 years of senior management experience working with private and public companies. From May 2010 to March 2011, Mr. Berg served as President and Chairman of the Board of Directors of Friendly Auto Dealers, Inc., and also served in a consulting capacity from March 2009 to May 2010.

Mr. Berg holds a Bachelors of Science in Accounting from Walsh College where he graduated Cum Laude. Mr. Berg became a Certified Public Accountant in the State of Michigan in 1979 and in the State of California in 1984. Mr. Berg does not currently practice as a Certified Public Accountant.

### **Thomas E. Ichim, Ph.D**

Dr. Ichim was appointed to the Board of Directors on January 22, 2016. Dr. Ichim is a seasoned biotechnology entrepreneur with a track record of scientific excellence. He has founded/co-founded several companies including Batu Biologics, Inc., Medvax Pharma Corp, ToleroTech, Inc, bioRASI, and OncoMune LLC. To date he has published 99 peer-reviewed articles and is co-editor of the textbooks RNA Interference: From Bench to Clinical Translation and Immuno-Oncology Text Book.

Dr. Ichim is an ad-hoc editor and sits on several editorial boards. Dr. Ichim is inventor on over 50 patents and patent applications. Dr. Ichim has extensive experience with stem cell therapy and cellular product development through FDA regulatory pathways. Dr. Ichim spent over 7 years as the President and Chief Scientific Officer of Medistem, developing and commercializing a novel stem cell, the Endometrial Regenerative Cell, through drug discovery, optimization, preclinical testing, IND filing, and up through Phase II clinical trials with the FDA. Dr. Ichim has extensive experience in product development, regulatory filings, and business development.

Dr. Ichim has a BSc in Biology from the University of Waterloo, Waterloo, Ontario, Canada, a MSc in Microbiology and Immunology a University of Western Ontario, London, Ontario, Canada and a Ph.D in Immunology from the University of Sciences Arts and Technology, Olveston Monserrat.

**Hong Ma, MD, Ph.D, M.B.A.**

Dr. Ma has an extensive history in academic and translational research. Subsequent to completing her medical degree, she performed basic research in the area of molecular biology of endothelial-associated pathways in her doctorate and postdoctoral studies. She has been critical in establishing numerous ventures and collaborations in the area of biosciences. Dr. Ma has over 20 peer-reviewed publications and has worked with prestigious institutions in the USA, China, and Japan. She received her M.D. from Dalian Medical University, her Ph.D in Cardiovascular Pharmacology at Asahikawa Medical College, and has also earned her MBA at the Rady School of Management at the University of California San Diego.

**Information with Respect to Our Board of Directors**

The following is a brief description of the structure and certain functions of our Board of Directors. Each of the current directors is serving until his respective successor is duly elected, subject to earlier resignation. We do not have standing audit, compensation or nominating committees of our Board of Directors. However, the full Board of Directors performs all of the functions of a standing audit committee, compensation committee and nominating committee.

*Audit Committee Related Function*

We do not have a separately designated standing audit committee in place. Our full Board of Directors currently serves in that capacity. This is due to the small number of members of our Board of Directors, the small number of executive officers involved with our company, and the fact that we operate with few employees. Our Board of Directors will continue to evaluate, from time to time, whether a separately designated standing audit committee should be put in place. We do not have an audit committee charter.

The Board of Directors reviews with management and the Company's independent public accountants the Company's financial statements, the accounting principles applied in their preparation, the scope of the audit, any comments made by the independent accountants upon the financial condition of the Company and its accounting controls and procedures and such other matters as the Board of Directors deems appropriate. Because our common stock is traded on the OTC Markets Pink Sheet, we are not subject to the listing requirements of any securities exchange regarding audit committee related matters.

The Board of Directors consisted of two directors: Mr. Dixon and Mr. Berg, until January 22, 2016 when Thomas E. Ichim was elected to the Board of Directors. Because we do not have an audit committee at all, we disclose that we do not have any "audit committee financial expert" serving on an audit committee.

*Compensation Committee Related Function*

We do not currently have a standing compensation committee, and do not have a compensation committee charter. The full Board of Directors currently has the responsibility of reviewing and establishing compensation for executive officers and making policy decisions concerning salaries and incentive compensation for executive officers of the Company.

The Company's executive compensation program is administered by the Board of Directors, which determines the compensation of the Chief/Executive Officer/President and the Chief Financial Officer of the Company. In reviewing the compensation of the individual executive officers, the Board of Directors considers the recommendations of the Chief Executive Officer, other market information and current market conditions, as well as any existing employment agreements with them.



*Nominating Committee Related Function*

We do not currently have a standing nominating committee. We have not adopted procedures by which security holders may recommend nominees to serve on our board of directors.

**SCIENTIFIC ADVISORY BOARD**

The following are members of the Company's Scientific Advisory Board as of October 25, 2016:

**Dr. Michael G. Agadjanyan** is currently Research Professor of Immunology and Virology at the Institute for Molecular Medicine. He was formally a Visiting Professor at the University of Pennsylvania, Philadelphia, PA. He was also previously a Visiting Professor at the Wistar Institute in Philadelphia, and before that a Junior then Senior Scientist at the Gamaleya Institute of the USSR Academy of Science, Moscow. Dr. Agadjanyan has served on several committees and member of several international associations, He has over 120 publications in the areas of cellular immunology and virology.

Dr. Agadjanyan currently holds two grants from the National Institutes of Health on the immunology and biochemistry of HIV infection and HIV vaccines. His research interests are in the area of immune response to HIV infection and the development of HIV-1 vaccines based on DNA vaccine technology.

D.Sc., Immunology/Virology, Institute of Viral Preparation, USSR Academy of Science, 1989; Ph.D., Immunology, Institute of Epidemiology & Immunology, USSR Academy of Science, 1980; M.S., Biology, Moscow State University, Moscow, 1976; B.S., Biology, University of Yerevan, Armenia, 1972.

**Dr. Barry Glassman**, DMD, DAAPM, DAACP, FICCMO, Diplomate ABDSM, FADI, is a Diplomate of the American Academy of Craniofacial Pain and the American Academy of Pain Management, as well as a Fellow of the International College of Craniomandibular Orthopedics and the Academy of Dentistry International, he is also on staff at the Lehigh Valley Hospital where he serves as a resident instructor of Craniofacial Pain and Dysfunction and Dental Sleep Medicine.

Dr. Glassman is a Diplomate of the Academy of Dental Sleep Medicine. He is on the staff at the Sacred Heart Hospital Sleep Disorder Center, as well as serving as the Chief Dental Consultant to three other sleep centers in the

Lehigh Valley.

A popular and dynamic speaker, Dr. Glassman lectures internationally, as well as throughout the United States. In addition to his extensive schedule which includes guest lecture appearances and in-depth courses on joint dysfunction, chronic pain, headache, sleep disorders, and migraine headache, Dr. Glassman is a frequent speaker at major chronic pain and joint dysfunction professional conferences.

University of Pittsburgh: Bachelor of Science 1969, Pittsburgh, Pennsylvania

University of Pittsburgh School of Dental Medicine; D.M.D. 1973, Pittsburgh Pennsylvania

Post Graduate Hours in Craniomandibular Dysfunction and Sleep Disorders: Over 2500

**Dr. David P. Hajjar** is currently Professor of Biochemistry, at Weill Cornell Medical College and Professor of Pathology and Laboratory Medicine, Weill Cornell Medical College. Professor Hajjar was also a Frank H.T. Rhodes Distinguished Professor of Cardiovascular Biology and Genetics, Pathology and Laboratory Medicine, Weill Cornell Medical College from 1998 – 2014. Currently Dr. Hajjar is Dean Emeritus and was Executive Vice Provost at Cornell University.

The principal aim of Dr. Hajjar's work is to define the mechanisms by which Nitric Oxide (NO) and prostaglandin synthetic pathways interact to alter eicosanoid biosynthesis as well as to investigate the impact of these mediators on atherosclerosis and thrombosis.

Over the years, he has defined the roles and mechanisms of these complex signaling interactions in order to gain an understanding of the pathophysiological processes in atherosclerosis using animal models and the consequences of pharmacological interventions.

**Dr. Santosh Kesari** is a board-certified neurologist and neuro-oncologist and is currently Chair, Department of Translational Neuro-Oncology and Neurotherapeutics, John Wayne Cancer Institute. He is also Director of Neuro-Oncology, Providence Saint John's Health Center and Member, Los Angeles Biomedical Research Institute.

He is ranked among the top 1% of neuro-oncologists and neurologists in the nation, according to Castle Connolly Medical Ltd and an internationally recognized scientist and clinician.

Dr. Kesari is a winner of an Innovation Award by the San Diego Business Journal. He is on the advisory board of American Brain Tumor Association, San Diego Brain Tumor Foundation, Chris Elliott Fund, Nicolas Conor Institute, Voices Against Brain Cancer, and Philippine Brain Tumor Alliance. He has been the author of over 250 scientific

publications, reviews, or books. He is the inventor on several patents and patent applications, and founder and advisor to many cancer and neurosciences focused biotech startups.

**Dr. Harry M. Lander** was the Assistant Provost of Weill Cornell Medical College in New York City where, similarly, he oversaw the business of science from 2003 to 2013. From 1995-1999, Dr. Lander was an Assistant Professor of Biochemistry at Cornell University Medical College.

His National Institutes of Health-funded laboratory studied the role of reactive nitrogen on the activation of the Ras superfamily of proteins and its role in carcinogenesis. He served on the editorial board of Antioxidants and Redox Signaling and as a reviewer for a National Institutes of Health Study Section Special Emphasis Panel.

Dr. Lander received a B.S. in Biochemistry and a B.A. in Chemistry from State University at Stony Brook in 1987, a Ph.D. in Biochemistry from Cornell University Graduate School of Medical Sciences in 1992 and an MBA in Finance from the New York University Stern School of Business in 2001.

**Dr. Vijay Mahant** has been involved in Research and Development in the medical industry for close to 30 years. Working in the FDA regulated medical industry, he has headed R&D activities for several bio-medical companies as well as being the founder, CEO & Chairman of MediLite, Inc.

Dr. Mahant has specialized in the areas of assay development, has numerous patents to his credit and has published extensively. Dr. Mahant received his B.S. in Biochemistry from the University of Salford, UK; a M.S. in Medicinal Chemistry and a Ph.D. in Medical Biochemistry from Loughborough University of Technology, UK.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other of our equity securities. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.



To our knowledge, based solely on a review of the copies of such reports furnished to us during the fiscal year ended December 31, 2015, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with.

## Code of Ethics

We have adopted a Code of Ethics for our principal executive and financial officers. Our Code of Ethics was filed as an Exhibit to our Annual Report on Form 10-K for fiscal year 2010. We hereby undertake to provide a copy of this Code of Ethics to any person, without charge, upon request. Requests for a copy of this Code of Ethics may be made in writing addressed to: Therapeutic Solutions International, Inc., 4093 Oceanside Blvd, Suite B, Oceanside, California 92056, Attn: Corporate Secretary.

## ITEM 11

### EXECUTIVE COMPENSATION.

#### Summary Compensation Table

The following table summarizes the compensation paid, with respect to years ended December 31, 2015 and 2014 for services rendered to us in all capacities, to each person who served as an executive officer of the Company.

#### Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards	Nonequity	All Other Compensation	Total
						Incentive Plan Compensation		
	2015	(\$) 25,500	(\$) -	(\$) -	(\$) -	(\$) -	(\$) -	(\$) 25,500

Timothy G. Dixon*								
President and CEO	2014	10,192	-	-	-	-	-	10,192
Gerry B. Berg**	2015	25,500	-	-	-	-	-	25,500
Vice President, Chief Financial Officer	2014	10,192	-	-	-	-	-	10,192

**Outstanding Equity Awards**

None

**Employment Agreements**

We do not have any employment agreements as of December 31, 2015.

**Director Compensation**

When our employees serve on our Board of Directors, we do not give them any additional compensation in respect of such Board service. Directors currently serve without compensation.

**ITEM 12****SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The following table sets forth, as of October 25, 2016, information regarding the ownership of the Company's outstanding shares of common stock by (i) each person known to management to own, beneficially or of record, more than 5% of the outstanding shares of our common stock, (ii) each director of the Company, (iii) each executive officer of the Company, and (iv) all directors and executive officers as a group. As of October 20, 2016, a total of 740,751,000 shares of our common stock were outstanding.

Name of Beneficial Owners	Amount and Nature of Beneficial Ownership	Percent of Shares Outstanding
Timothy G. Dixon	121,475,671	16.41%
Gerry B. Berg	107,750,000	14.56%
Thomas E. Ichim*	44,500,000	6.01%
Robert F. Graham	102,500,000	15.01%
John Peck, Jr.	120,000,000	17.58%
All directors and executive officers as a group (3 persons) (2)(3)(4)	273,725,671	36.98%

\*Dr. Ichim was appointed to the Board of Directors on January 22, 2016.

(1)

Under SEC rules (i) a person is deemed to be the beneficial owner of shares if that person has, either alone or with others, the power to vote or dispose of those shares. The persons named in the table have sole voting and dispositive power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable.

**ITEM 13****CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.**



Our Board of Directors currently consists of three directors, two of whom are an employee director. As of December 31, 2015 we disclose that we had no independent directors. Thomas E. Ichim, Ph.D was appointed to the Board of Directors on January 22, 2016

In general, it is our policy to submit all proposed related party transactions (those of the kind and size that may require disclosure under Regulation S-K, Item 404) to the Board of Directors for approval. The Board of Directors only approves those transactions that are on terms comparable to, or more beneficial to us than, those that could be obtained in arm's length dealings with an unrelated third party. Examples of related party transactions covered by our policy are transactions in which any of the following individuals has or will have a direct or indirect material interest: any of our directors or executive officers, any person who is known to us to be the beneficial owner of more than 5% of our common stock, and any immediate family member of one of our directors or executive officers or person known to us to be the beneficial owner of more than 5% of our common stock.

## **ITEM 14**

### **PRINCIPAL ACCOUNTANT FEES AND SERVICES.**

#### *Audit Fees*

The aggregate fees billed to us by our principal accountants, PLS CPA, A Professional Corporation, for auditing and accounting services for fiscal year 2015 was \$24,000 (inclusive of the review of the quarterly reports on Form 10-Q).

The aggregate fees billed to us by our principal accountants, PLS CPA, A Professional Corporation, for auditing and accounting services for 2014 was \$24,000 (inclusive of the review of the quarterly reports on Form 10-Q).

#### *Audit-Related Fees, Tax Fees and All Other Fees*

There were no fees billed to us by our principal accountant for fiscal year 2015 for assurance and related services (audit-related fees), tax services or other products and services.

There were no fees billed to us by our principal accountant for fiscal year 2014 for assurance and related services (audit-related fees), tax services or other products and services.

*Audit Committee Matters*

We do not have an audit committee.

**PART IV**

**ITEM 15**

**EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.**

(a)

The following documents have been filed as a part of this Annual Report on Form 10-K.

1.

Financial Statements

Report of Independent Registered Public Accounting Firm	Page F-1
Balance Sheets	F-2
Statements of Operations	F-3
Statements of Stockholders' Equity	F-4
Statements of Cash Flows	F-5
Notes to Financial Statements	F-6

2.

Financial Statement Schedules.

All schedules are omitted because they are not applicable or not required or because the required information is included in the Financial Statements or the Notes thereto.



3.

Exhibits.

The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:

EXHIBIT

NUMBER DESCRIPTION

3.1	Articles of Incorporation
3.1.1	Certificate of Merger, filed February 22, 2011
3.1.2	Certificate of Amendment to Articles of Incorporation filed October 15, 2012 (incorporated herein by reference to Form 8-K, filed on October 17, 2012)
3.2	Bylaws (incorporated herein by reference to Form SB-2, filed on November 21, 2007)
3.2.1	Bylaws amendments adopted August 22, 2012, August 24, 2012 and September 26, 2012
10.1	2009 Stock Incentive Plan (as amended on August 31, 2011) (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.2	Common Stock Share Exchange Agreement dated November 16, 2010 (incorporated herein by reference to Exhibit E to Regulation 14C information statement filed on February 15, 2011)
10.3	Exclusive License Agreement between Boyd Research, Inc. and us, dated April 1, 2011 (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.4	Investor Relations Consulting Agreement, between us and Constellation Asset Advisors, Inc., dated June 17, 2011 (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.5	Employment Agreement between Timothy Dixon and us, dated November 15, 2011 (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.6	Employment Agreement between Gerry Berg and us, dated November 15, 2011 (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.7	Master Dispute Resolution Agreement, by and among us, James P. Boyd, Boyd Research, Inc., TMD Courses, Inc., Timothy G. Dixon and Gerry B. Berg, dated August 24, 2012 (incorporated herein by reference to Exhibit 10.1 to Form 8-K filed August 30, 2012)
10.8	License Agreement, by and among us, Boyd Research, Inc. and TMD Courses, Inc., dated August 24, 2012 (incorporated herein by reference to Exhibit 10.2 to Form 8-K filed August 30, 2012)
10.9	Escrow Agreement, by and among us and James P. Boyd and Chicago Title Company (as escrow agent), dated August 24, 2012 (incorporated herein by reference to Exhibit 10.3 to Form 8-K filed August 30, 2012)
10.10	Voting Agreement, by and between us and James P. Boyd, dated August 24, 2012 (incorporated herein by reference to Exhibit 10.4 to Form 8-K filed August 30, 2012)
10.11	License Agreement, by and among us, Innovative Supplements, Inc. and Robert F. Graham, dated December 9, 2014 (incorporated herein by reference to Form 8-K filed December 10, 2014)
10.12	License Agreement, by us and OmniBiome, Inc., a wholly owned subsidiary, dated November 18, 2015, 2015 (incorporated herein by reference to Form 8-K filed November 18, 2015)
10.13	License Agreement, by us and OmniBiome, Inc., a wholly owned subsidiary, dated December 4, 2015, 2015 (incorporated herein by reference to Form 8-K filed December 8, 2015)
10.14	

License Agreement, by us and MolecuVax, Inc., a wholly owned subsidiary, dated February 5, 2016, 2015 (incorporated herein by reference to Form 8-K filed February 8, 2015)

- 23.1 Consent of Independent Registered Public Accounting Firm
- 31.1 Rule 13a-14(a)/Section 302 Certification of Principal Executive Officer
- 31.2 Rule 13a-14(a)/Section 302 Certification of Principal Financial Officer
- 32.1 Certification pursuant to 18 U.S.C. Section 1350/Rule 13a-14(b)

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

*By: /s/ Timothy G. Dixon*  
Timothy G. Dixon  
Chief Executive Officer and President  
Date: January 25, 2017

*/s/ Timothy G. Dixon*  
Timothy G. Dixon  
Chief Executive Officer, President and Director (Principal  
Executive Officer)  
Date: January 25, 2017

*/s/ Gerry B. Berg*  
Gerry B. Berg  
Vice President, Chief Financial Officer and Director  
(Principal Financial and Accounting Officer)  
Date: January 25, 2017

*/s/ Thomas E. Ichim*  
Thomas E. Ichim  
Director  
Date: January 25, 2017

**PLS CPA, A Professional Corp.**

**t 4725 MERCURY STREET SUITE 210 t SAN DIEGO t CALIFORNIA 92111 t**

**t TELEPHONE (858)722-5953 t FAX (858) 761-0341 t FAX (858) 764-5480**

**t E-MAIL changgpark@gmail.com t**

**Report of Independent Registered Public Accounting Firm**

**To the Board of Directors and Stockholders**

**Therapeutic Solutions International, Inc.**

We have audited the accompanying consolidated balance sheets of Therapeutic Solutions International, Inc. (the Company ) as of December 31, 2015 and 2014 and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.



In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial positions of Therapeutic Solutions International, Inc. as of December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company's recurring losses over past years and working capital deficits raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*/s/ PLS CPA*

---

**PLS CPA, A Professional Corp.**

**October 31, 2016**

**San Diego, CA 92111**

**Registered with the Public Company Accounting Oversight Board**

F-1

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**  
**Condensed Consolidated Balance Sheets**  
**(Audited)**

	<b>December 31, 2015</b>	<b>December 31, 2014</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 2,183	\$ 2,894
Accounts Receivable, net	2,184	-
Inventories	29,675	-
Prepaid expenses and other current assets	213,444	139,016
Assets from discontinued operations	-	46,845
<b>Total current assets</b>	<b>247,488</b>	<b>188,756</b>
Other non-current assets	12,476	12,461
Property and equipment, net	-	-
<b>Total assets</b>	<b>\$ 259,964</b>	<b>\$ 201,217</b>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 277,342	\$ 290,554
Accrued expenses and other current liabilities	15,636	14,777
Due to related parties	196,014	27,174
<b>Total current liabilities</b>	<b>488,992</b>	<b>332,505</b>
<b>Shareholders' Equity</b>		
Preferred stock, \$.001 par value; 5,000,000 shares authorized	-	-
Common stock, \$.001 par value; 699,999,999 shares authorized, 541,000,000 issued and outstanding at December 31, 2015 and 699,999,999 shares authorized, 400,000,000 issued and outstanding at December 31, 2014	541,000	400,000
Capital in excess of par	2,440,709	2,093,009
Deficit accumulated	(3,210,737)	(2,624,296)
<b>Total shareholders' equity</b>	<b>(229,028)</b>	<b>(131,288)</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 259,964</b>	<b>\$ 201,217</b>

*See accompanying notes to financial statements.*

F-2

---

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**  
**Consolidated Statements of Operations**  
**(Audited)**

	<b>For the Year End December 31, 2015</b>	<b>For the Year End December 31, 2014</b>
<b>Net Sales</b>	\$ 1,911	\$ -
Cost of Goods Sold	3,193	-
<b>Gross Profit</b>	<b>(1,282)</b>	<b>-</b>
<b>Operating expenses:</b>		
General and administrative	73,353	50,868
Salaries, wages, and related costs	266,286	111,986
Selling expenses	3,894	-
Amortization and depreciation	-	21,133
Consulting fees	185,700	39,734
Legal and professional fees	40,420	103,384
<b>Total operating expenses</b>	<b>569,653</b>	<b>327,105</b>
<b>Loss from operations</b>	<b>(570,935)</b>	<b>(327,105)</b>
<b>Other income (expense):</b>		
Net other income (expense)	3,866	8,728
Impairment of intangible asset	-	(210,000)
Interest expense	(5,550)	(9,375)
<b>Total other income (expense)</b>	<b>(1,684)</b>	<b>(210,647)</b>
<b>Net income (loss) from continuing operations</b>	<b>\$ (572,619)</b>	<b>\$ (537,752)</b>
Net income (loss) from discontinued operations	(13,822)	249,002
<b>Net income (loss)</b>	<b>\$ (586,441)</b>	<b>\$ (288,750)</b>
<b>Basic and diluted loss per common share</b>		
Continuing operation	\$ (0.00)	\$ (0.00)
Discontinued operation.	\$ (0.00)	\$ 0.00
<b>Weighted average shares outstanding</b>	<b>461,967,123</b>	<b>196,385,920</b>

*See accompanying notes to financial statements.*

F-3

---

**Therapeutic Solutions International, Inc.**  
**Condensed Consolidated Statement of Changes in Shareholders' (Deficit)**  
**For the Period from December 31, 2013 to December 31, 2015**  
**(Audited)**

	Common Stock	Common Stock Amount	Additional Paid-in Capital	Earnings (Deficit) Accumulated	Total
<b>Balance, December 31, 2013</b>	<b>94,466,400</b>	<b>\$ 94,466</b>	<b>\$ 1,665,725</b>	<b>\$ (2,335,546)</b>	<b>\$ (575,355)</b>
Stock issued for service on March 31, 2014	12,000,000	12,000	33,750	-	45,750
Stock issued for note conversion on June 30, 2014	90,000,000	90,000	180,000	-	270,000
Stock issued for note conversion on September 30, 2014	103,533,600	103,534	103,534	-	207,067
Stock issued for a material definitive agreement	100,000,000	100,000	110,000	-	210,000
Net Loss, December 31, 2014	-	-	-	(288,750)	(288,750)
<b>Balance, December 31, 2014</b>	<b>400,000,000</b>	<b>\$ 400,000</b>	<b>\$ 2,093,009</b>	<b>\$ (2,624,296)</b>	<b>\$ (131,288)</b>
Stock issued on March 27, 2015	20,000,000	20,000	30,000	-	50,000
Stock issued on April 17, 2015	20,000,000	20,000	30,000	-	50,000
Stock issued on June 8, 2015	1,000,000	1,000	1,500	-	2,500
Stock issued on July 15, 2015	1,000,000	1,000	1,500	-	2,500
Stock issued on August 31, 2015	10,000,000	10,000	15,000	-	25,000
Stock issued on October 14, 2015	2,000,000	2,000	3,000	-	5,000
Stock issued on October 16, 2015	4,000,000	4,000	6,000	-	10,000
Stock issued on November 9, 2015	3,000,000	3,000	4,500	-	7,500
Stock issued on November 23, 2015	20,000,000	20,000	30,000	-	50,000
Stock issued for services on February 27, 2015	2,000,000	2,000	3,000	-	5,000
	10,000,000	10,000	15,000	-	25,000

Edgar Filing: THERAPEUTIC SOLUTIONS INTERNATIONAL, INC. - Form 10-K/A

Stock issued for services on April 1, 2015					
Stock issued for services on June 1, 2015	7,000,000	7,000	10,500		17,500
Stock issued for services on June 1, 2015	3,000,000	3,000	4,800	-	7,800
Stock issued for services on September 25, 2015	10,000,000	10,000	36,000	-	46,000
Stock issued for services on October 1, 2015	23,000,000	23,000	121,900	-	144,900
Stock issued for services on October 13, 2015	2,500,000	2,500	12,500	-	15,000
Stock issued for services on November 30, 2015	2,500,000	2,500	22,500	-	25,000
Net Loss, December 31, 2015	-	-	-	(586,441)	(586,441)
<b>Balance, December 31, 2015</b>	<b>541,000,000</b>	<b>\$ 541,000</b>	<b>\$ 2,440,709</b>	<b>\$ (3,210,737)</b>	<b>\$ (229,028)</b>

*See Accompanying Notes to Financial Statements*

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**  
**Condensed Consolidated Statement of Cash Flows**  
**(Audited)**

	<b>For the Year Ended December 31, 2015</b>	<b>For the Year Ended December 31, 2014</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (586,441)	\$ (288,750)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Non-cash expenses:		
Depreciation	-	21,132
Stock based compensation to consultants	286,200	45,750
Impairment of intangible asset	-	210,000
Gain from disposal of property and equipment	-	(7,000)
Changes in operating assets and liabilities:		
(Increase) decrease in inventory	(29,675)	-
(Increase) decrease in accounts receivable	(2,184)	-
(Increase) decrease in prepaid expenses and other current assets	(74,428)	(70,447)
(Increase) decrease in other assets	(15)	(20)
(Increase) decrease in bank overdraft	-	-
Increase (decrease) in accounts payable	(13,212)	(7,967)
Increase (decrease) in accrued expenses and other current liabilities	860	(236,577)
Cash used by operating activities-continuing operations	(418,895)	(333,879)
Cash provided (used) by operating activities-discontinued operations	46,845	1,343
<b>Net cash used by operating activities</b>	<b>(372,050)</b>	<b>(332,536)</b>
<b>Cash flows from investing activities</b>		
Disposal of fixed assets from discontinued operations	-	55,000
<b>Net cash used by by investing activities</b>	<b>-</b>	<b>55,000</b>
<b>Cash flows from financing activities</b>		
Related parties liabilities	168,840	272,917
Stock issuance	202,500	-
Repayments	-	(5,000)
<b>Net cash provided by financing activities</b>	<b>371,340</b>	<b>267,917</b>
Increase in cash	(711)	(9,619)



Edgar Filing: THERAPEUTIC SOLUTIONS INTERNATIONAL, INC. - Form 10-K/A

Cash at beginning of period		2,894		12,513
Cash at end of period	\$	2,183	\$	2,894
<b>Significant non-cash investing and financing activities:</b>				
Stock issuance for acquisition of intangible assets	\$	-	\$	210,000
Stock issuance for due to related parties	\$	-	\$	477,067
<b>Supplemental Cash Flow Information:</b>				
Cash paid for interest	\$	3,213	\$	2,812
Cash paid for income taxes	\$	800	\$	800

*See accompanying notes to financial statements.*

F-5

---

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**Notes to Financial Statements**

**December 31, 2015 and 2014**

**Note 1 Nature of Business**

Therapeutic Solutions International, Inc. (the Company) was organized August 6, 2007 under the name Friendly Auto Dealers, Inc., under the laws of the State of Nevada. In the first quarter of 2011 the Company changed its name from Friendly Auto Dealers, Inc. to Therapeutic Solutions International, Inc., and acquired Splint Decisions, Inc., a California corporation organized September 21, 2010 ( Splint ). Splint is treated as the accounting acquirer in the accompanying financial statements.

Until April 28, 2014 the Company sold (directly and through distributors and sublicensees), in non-US countries, plastic intraoral devices known as Anterior Midpoint Stop Appliances ( AMPSA Products ). Our customers were dentists and doctors. The AMPSA Products, which are used for the treatment and prevention of common neurological and temporomandibular disorders including migraine headaches, migraine pain and bruxism.

On April 28, 2014, we received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated. The ostensible reason Mr. Jaczko gave was our failure to make certain unspecified payments due under the license agreement to his clients. We disputed the termination, but believed that the costs involved with litigating the termination of the New License was not in the best interest of the Company and its shareholders. Therefore, the Company moved in a new direction.

Currently the Company is focused on immune modulation for the treatment of several specific diseases. Immune modulation refers to the ability to upregulate (make more active) or downregulate (make less active) one's immune system.

Activating one's immune system is now a well-accepted method to cure certain cancers, reduce recovery time from viral or bacterial infections and to prevent illness. On the other hand, inhibiting one's immune system is vital for reducing inflammation, autoimmune disorders and allergic reactions.

TSI is developing a range of immune-modulatory agents to target certain cancers, improve maternal and fetal health, fight periodontal disease, and for daily health. The following outlines our relationships and divisions to focus on each of these programs:

**Nutraceutical Division** TSI has been producing high quality nutraceuticals. Its flagship product, ProJuvenol<sup>®</sup>, is a proprietary mixture containing pterostilbene – one of the most potent antioxidants known. TSOI filed a patent application for ProJuvenol<sup>®</sup> on 07-08-2015 titled: Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions . . . In addition we recently introduced a line of oncologist friendly nutraceuticals in liposome formula. These include CoQ10, Curcumin, Glutathione, and Vitamin-C in 16oz bottles.

**OmniBiome, Inc.,** ( OMNI ) - is a partially-owned subsidiary of TSI, incorporated in the State of Delaware on October 20, 2015, where the intellectual property surrounding probiotics is housed. As of October 25, 2016, TSI owns approximately 73.75% of the outstanding shares of OmniBiome. Website: <http://omnibiomeinc.com>

On November 18, 2015 the Company licensed to OmniBiome, Inc. certain intellectually property. The License agreement in its entirety may be read as an exhibit filed with Form 8K:

[https://www.sec.gov/Archives/edgar/data/1419051/000107878215001890/f8k111715\\_ex10z1.htm](https://www.sec.gov/Archives/edgar/data/1419051/000107878215001890/f8k111715_ex10z1.htm)

Licensed Patent Rights: Shall mean:

- a. Patent Application Serial No. 62/213260 filed 9-02-2015 by Licensor.
- b. Patent Application Serial No. 62/219020 filed 9-15-2015 by Licensor.
- c. Patent Application Serial No. 62/232722 filed 9-25-2015 by Licensor.

1. Initial Payment and Royalty Rate. For the licensed herein granted:

(a) Licensee agrees to pay a sign-up fee of \$ 50,000.00. As of October 25, 2016 this fee has not been paid. OmniBiome did not have any operations as of December 31, 2015.

(b) Licensee shall pay on earned royalty of Five Percent (5 %) of Licensee's Gross Sales of Products and fifty percent (50%) of the sublicensing receipts.

F-6

---

(c) Licensee shall pay an annual minimum royalty fee of Fifteen Thousand Dollars (\$15,000.00) for each licensed Product.

On December 4, 2015 the Company licensed to OmniBiome, Inc. certain intellectually property. The License agreement in its entirety may be read as an exhibit filed with Form 8K:

[https://www.sec.gov/Archives/edgar/data/1419051/000107878215001971/f8k120815\\_ex10z2.htm](https://www.sec.gov/Archives/edgar/data/1419051/000107878215001971/f8k120815_ex10z2.htm)

1. Licensed Patent Rights: Shall mean:

a. Patent Application Serial No. 62/194990 filed 7-21-2015 by Licensor.

1. Initial Payment and Royalty Rate. For the licensed herein granted:

(a) Licensee agrees to pay a sign-up fee of \$ 50,000.00. As of October 25, 2016 this fee has not been paid.

(b) Licensee shall pay on earned royalty of Five Percent (5 %) of Licensee s Gross Sales of Products and fifty percent (50%) of the sublicensing receipts.

(c) Licensee shall pay an annual minimum royalty fee of Fifteen Thousand Dollars (\$15,000.00) for each licensed Product.

Current programs focus on the use of probiotics to prevent pre-term labor and on using probiotics to reverse periodontal disease. Mr. Dixon and Mr. Berg, of the Company, are also officers and Directors of Omni. As of October 25, 2016 TSI owns approximately 73.75% of the outstanding shares of Omni. Website: <http://omnibiomeinc.com>.

**Note 2 Significant Accounting Policies**

Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash

For the Statements of Cash Flows, all highly liquid investments with maturity of three months or less are considered to be cash equivalents. There were no cash equivalents as of December 31, 2015 and 2014. Other assets include restricted cash of \$10,000 that is used to secure a company credit card.

Depreciation and Amortization

Depreciation is calculated using the straight line method over the estimated useful lives of the assets. Amortization is computed using the straight line method over the term of the agreement.

Intangible Assets

Intangible assets consisted primarily of intellectual properties such as proprietary nutraceutical formulations. Intellectual assets are capitalized in accordance with ASC Topic 350 Intangibles Goodwill and Other.

Long-lived Assets

In accordance with ASC 360, Property, Plant and Equipment, the carrying value of intangible assets and other long-lived assets is reviewed on a regular basis for the existence of facts or circumstances that may suggest impairment. The Company recognizes impairment when the sum of the expected undiscounted future cash flows is less than the carrying amount of the asset. Impairment losses, if any, are measured as the excess of the carrying amount of the asset over its estimated fair value. During the year ended December 31, 2014, the Company recognized an impairment charge of \$210,000 for intangible assets.

F-7

---

### Income Taxes

The Company accounts for income taxes under ASC 740 "Income Taxes," which codified SFAS 109, "Accounting for Income Taxes" and FIN 48 *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109*. Under the asset and liability method of ASC 740, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. 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. Under ASC 740, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period the enactment occurs. A valuation allowance is provided for certain deferred tax assets if it is more likely than not that the Company will not realize tax assets through future operations.

### Going Concern

The Company's financial statements are prepared using accounting principles generally accepted in the United States of America applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has experienced recurring losses over the past years which have resulted in stockholders' accumulated deficits of approximately \$3.2 million at December 31 2015. These conditions raise uncertainty about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is contingent upon its ability to secure additional financing, increase sales of its products and attain profitable operations. It is the intent of management to continue to raise additional capital. However, there can be no assurance that the Company will be able to secure such additional funds or obtain such on terms satisfactory to the Company, if at all.

The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

### Share Based Expenses



ASC 718 "*Compensation - Stock Compensation*," which codified SFAS 123, prescribes accounting and reporting standards for all stock-based payments awarded to employees, including employee stock options, restricted stock, employee stock purchase plans and stock appreciation rights. Such payments may be classified as either equity or liabilities. The Company should determine if a present obligation to settle the share-based payment transaction in cash or other assets exists. A present obligation to settle in cash or other assets exists if: (a) the option to settle by issuing equity instruments lacks commercial substance or (b) the present obligation is implied because of an entity's past practices or stated policies. If a present obligation exists, the transaction should be recognized as a liability; otherwise, the transaction should be recognized as equity. See also Note 6 Equity Transactions.

The Company accounts for stock-based compensation issued to non-employees and consultants in accordance with the provisions of ASC 505-50 "*Equity-Based Payments to Non-Employees*," which codified SFAS 123, and the Emerging Issues Task Force consensus in Issue No. 96-18, "*Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods or Services*". Measurement of share-based payment transactions with non-employees shall be based on the fair value of whichever is more reliably measurable: (a) the goods or services received; or (b) the equity instruments issued. The fair value of the share-based payment transaction should be determined at the earlier of the performance commitment date or performance completion date. See also Note 6 Equity Transactions.

#### Recently Implemented Standards

The Company has implemented all new accounting pronouncements that are in effect that may impact its financial statements and does not believe that there are any new accounting pronouncements that have been issued that might have a material impact on its financial statements.

#### **Note 3 Restricted Cash**

Other non-current asset is a \$10,000 certificate of deposit with an annual interest rate of 0.6%. This certificate matures on June 17, 2017, and is used as collateral for a Company credit card, pursuant to a security agreement dated June 20, 2011.



**Note 4 Equipment**

The cost and accumulated depreciation of fixed assets and equipment at December 31, 2014 and 2013 are summarized below:

	December 31, 2015		December 31, 2014
Computer Hardware	\$ 10,747	\$	10,747
Office Furniture and Equipment	3,639		3,639
Shipping and Other Equipment	1,575		1,575
Total	15,961		15,961
Accumulated Depreciation	(15,961)		(15,961)
Property and Equipment, net	\$ -	\$	-

Depreciation is calculated using the straight line method over the estimated useful lives of the assets. Depreciation expenses for the years ended December 31, 2015 and 2014 were \$0 and \$21,132, respectively.

**Note 5 License Agreements**

The Company had a New License Agreement for the period from August 24, 2012 to December 31, 2012, an exclusive worldwide license with a 30% royalty on net sales (subject to reduction under certain conditions). Also, the New License Agreement granted the Company, for the period from January 1, 2013 forward, a royalty-free nonexclusive worldwide license to make and sell certain products, but excluding the United States market. On April 28, 2014, the Company received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated

**Note 6 - Intangible Asset**

On December 9, 2014 the Company contractually obtained the rights, title and interest in and to proprietary formulations for two nutritional supplement products known under the trade names: (a) T-Rx ; and, (b) Vital Female; and, (ii) the purchase of all legal right, title and interest, in and to intellectual property including, but not limited to, Innovative s nutritional supplement product known under the trade name: Projuvenol. The Company issued 100,000,000 shares for this rights, title and interest. The fair value of the 100,000,000 shares of common stock of \$210,000 was recorded as an intangible asset. On December 31, 2014, the Company performed an impairment test on the intellectual property. The Company recorded impairment of \$210,000.

#### Note 7 Notes Payable-related party

As of December 31, 2015 and 2015, the Notes Payable are as the following:

##### December 31, 2015

Noteholder	Issued Date	Original amounts	Addition	Repayment	Interest	Total Balance	Interest Rate
Gerry Berg	12/18/2015	80,000	-	-	-	80,000	8%
Barry Glassman	1/14/2013	15,000	-	-	1,147	13,574	10%
Timothy Dixon	1/16/2013	19,000	-	2,000	1,368	13,595	9.75%
Timothy Dixon	1/16/2013	15,000	7,300	-	1,190	20,069	10%
Timothy Dixon	12/18/2015	80,000	-	-	-	80,000	8%

##### December 31, 2014

Noteholder	Issued Date	Original amounts	Addition	Repayment	Interest	Total Balance	Interest Rate
Barry Glassman	1/14/2013	15,000	-	3,000	1,173	12,427	8%
Timothy Dixon	1/16/2013	19,000	4,000	5,005	1,540	15,946	9.75%
Timothy Dixon	1/16/2013	15,000	-	6,000	1,141	11,578	10%

## **Note 8 Equity Transactions**

### Preferred Stock

The Company is authorized to issue 5,000,000 shares of \$.001 par value preferred stock. The Company has not issued any preferred stock.

### Common Stock

As of July 27, 2016, the Company is authorized to issue 990,000,000 shares of \$.001 par value common stock. All shares have equal voting rights, are non-assessable, and have one vote per share. Voting rights are not cumulative and, therefore, the holders of more than 50% of the common stock could, if they choose to do so, elect all of the directors of the Company.

On March 31, 2014, we issued 2,500,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On March 31, 2014, we issued 2,500,000 shares of common stock, valued at \$.004 per share, for consulting services.

On March 31, 2014, we issued 2,000,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On March 31, 2014, we issued 5,000,000 shares of common stock, valued at \$.004 per share, for legal services.

Edgar Filing: THERAPEUTIC SOLUTIONS INTERNATIONAL, INC. - Form 10-K/A

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500, shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,476,435 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,250,000 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 7,682,165 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On December 9, 2014, we issued 100,000,000 shares of common stock, valued at \$.0021 per share, in regard to a Material Definitive Agreement (Form 8-K filed on December 10, 2014).

On March 27, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On February 27, 2015, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On April 1, 2015, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On April 17, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On June 1, 2015, we issued 3,000,000 shares of common stock, valued at \$.0026 per share, for consulting services.

On June 1, 2015, we issued 7,000,000 shares of common stock, valued at \$.0025 per share, for legal services

F-10

---

On June 8, 2015, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On July 15, 2015, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On August 31, 2015, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On September 25, 2015, we issued 10,000,000 shares of common stock, valued at \$.0046 per share, for consulting services.

On October 1, 2015, we issued 23,000,000 shares of common stock, valued at \$.0063 per share, for consulting services.

On October 13, 2015, we issued 2,500,000 shares of common stock, valued at \$.0060 per share, for consulting services.

On October 14, 2015, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On October 16, 2015, we issued 4,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 9, 2015, we issued 3,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.



Edgar Filing: THERAPEUTIC SOLUTIONS INTERNATIONAL, INC. - Form 10-K/A

On November 23, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 30, 2015, we issued 2,500,000 shares of common stock, valued at \$.01 per share, for legal services.

On January 4, 2016, we issued 2,500,000 shares of common stock, valued at \$.0004 per share, for consulting services.

On January 22, 2016, we issued 2,500,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On February 1, 2016, we issued 2,500,000 shares of common stock, valued at \$.003 per share, for consulting services.

On February 5, 2016, we issued 8,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On February 22, 2016, we issued 5,451,000 shares of common stock, valued at \$.003 per share, in regard to a License Agreement (Form 8-K filed on February 25, 2016).

On February 26, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On March 7, 2016, we issued 10,000,000 shares of common stock, valued at \$.004 per share, for consulting services.

On March 21, 2016, we issued 100,800,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 2, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement and 1,000,000 shares of common stock, valued at \$.0053 per share, for consulting services.

On May 26, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for consulting services.

On May 26, 2016, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 31, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for legal services.

F-11

---

On July 27, 2016, we filed with the Nevada Secretary of State a Certificate of Amendment to Articles of Incorporation to effect an amendment (the Amendment) changing the number of authorized shares of our common stock to 990,000,000.

On September 16, 2016, we issued 12,500,000 shares of common stock, valued at \$.004 per share, for an investment in the Company's Private Placement.

On October 18, 2016, we issued 40,000,000 shares valued at \$.0045 to the officers and directors of the Company for services, and 5,000,000 shares valued at \$.0045 for consulting services.

#### **Note 9 Related Party Transactions**

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500, shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,476,435 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,250,000 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 7,682,165 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

As of December 31, 2015, the Company has advanced approximately \$117,900 to the officers of the company. Additionally the officers of the Company waived their monthly salary accrual from July 1, 2014 to December 31, 2014. The Company accrued officers salary of \$20,384 in 2015 (\$43,675 in 2014).

On October 18, 2016, we issued 40,000,000 shares valued at \$.0045 to the officers and directors of the Company for services.

**Note 10 Income Taxes**

The Company has net operating losses carried forward of \$2,270,802 (2014 \$2,043,048) available to offset taxable income in future years which expire beginning in fiscal 2031.

The Company is subject to United States federal and state income taxes at an approximate rate of 45%. The reconciliation of the provision for income taxes at the United States federal statutory rate compared to the Company's income tax expense as reported is as follows:

	December 31, 2015	December 31, 2014
	\$	\$
Net loss before income taxes per financial statements	(586,441)	(288,750)
Income tax rate	45%	45%
Income tax recovery	(263,898)	(123,619)
Permanent differences	88,616	6,318
Change in valuation allowance	175,282	117,301

Provision for income taxes

F-12

---

The significant components of deferred income tax assets and liabilities at December 31, 2015 and 2014 are as follows:

	December 31, 2015	December 31, 2014
	\$	\$
Net operating loss carry-forward	1,021,679	846,397
Valuation allowance	(1,021,679)	(846,397)
Net deferred income tax asset		

#### Note 11 Discontinued Operation

On April 28, 2014, we received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated.

The following are the summarized results of discontinued operations for the years ended December 31, 2015 and 2014 and the Balance Sheet as of December 31, 2015 and 2014:

	<b>For the Year Ended December 31, 2015</b>	<b>For the Year Ended December 31, 2014</b>
Net international revenues	\$ -	\$ 268,892
Cost of goods sold	-	(26,798)
Selling expenses	-	(6,525)
Bad debt	(9,770)	-
Obsolete Inventory	(4,052)	-
Royalties	-	13,433
	\$ (13,822)	\$ 249,002
	<b>December 31, 2015</b>	<b>December 31, 2014</b>
Assets		
Accounts Receivable, net	\$ -	\$ 46,895

Total assets of discontinued operations	\$	-	\$	46,895
---	----	---	----	--------

## **Note 12   Litigation**

The Company previously reported, on April 29, 2013 a former employee of the Company, Reid Jilek, sued the Company, its two directors and its three officers in San Diego County (California) Superior Court for breach of contract, retaliation, constructive discharge, failure to pay wages, failure to reimburse, conversion and fraudulent inducement. The complaint related to his employment agreement with the Company and his resignation which was effective in January 2013.

The trial was held in September 2014. On September 26, 2014 the Court ruled in favor of the Company and against all of Jilek's claims, and ruled that the Company was the prevailing party, and therefore was entitled to recover its attorney's fees and costs from Jilek. The Company did not prevail in its cross-claims against Jilek. Jilek's claims against the Company's directors and officers had previously been dismissed.

## **Note 13   Subsequent Events**

On January 4, 2016, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On January 22, 2016, we issued 2,500,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On February 1, 2016, we issued 2,500,000 shares of common stock, valued at \$.003 per share, for consulting services.

On February 5, 2016, we issued 8,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On February 22, 2016, we issued 5,451,000 shares of common stock, valued at \$.003 per share, in regard to a License Agreement (Form 8-K filed on February 25, 2016).

On February 26, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On March 7, 2016, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On March 21, 2016, we issued 100,800,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 2, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement and 1,000,000 shares of common stock, valued at \$.0053 per share, for consulting services.

On May 26, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for consulting services.

On May 26, 2016, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 31, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for legal services.

On January 21, 2016, our Board of Directors elected Thomas E. Ichim, Ph.D, to fill a vacant seat on our Board of Directors.

On February 05, 2016, Therapeutic Solutions International, Inc. licensed certain intellectual property to MolecuVax, Inc., a wholly owned subsidiary of Therapeutic Solutions International, Inc., Application No. 62/258,007 titled



Exosome Mediated Innate and Adaptive Immune Stimulation for Treatment of Cancer.

On April 27, 2016, the United States Patent and Trademark Office (the USPTO ) accepted U.S. Application No. 62/327756 titled Augmentation Of Stem Cell Activity Using Pterostilbene And Compositions Containing Pterostilbene .

On July 27, 2016, we filed with the Nevada Secretary of State a Certificate of Amendment to Articles of Incorporation to effect an amendment (the Amendment ) changing the number of authorized shares of our common stock to 990,000,000.

On August 22, 2016, the Board of Directors deemed it to be in the best interest of the Company to affect a reverse stock-split of its common stock of one (1) new common share for each two (2) old common shares of stock, subject to approval by a majority of shareholders. If sufficient votes are not obtained from a majority of shareholders, this action will become cancelled as of October 31, 2016.

On September 16, 2016, we issued 12,500,000 shares of common stock, valued at \$.004 per share, for an investment in the Company s Private Placement.

The Company previously announced that MolecuVax, Inc. (MVAX) was a partially-owned subsidiary of TSOI. On September 30, 2016, Mr. Gerry Berg, and Mr. Timothy Dixon resigned as Officers and Directors of MVAX and cancelled any and all equity in MVAX and have asserted certain contractual rights of our licensed patent to MVAX dated February 5<sup>th</sup>, 2016. Our departure and subsequent cancellation of stock was due to an attempt at a hostile take-over of the Board of Directors of MVAX by other board members. In addition, on October 12, 2016, Dr. Thomas Ichim also resigned from MVAX as CEO and Director.

The Company previously announced that TSOI held an equity stake in Capo Therapeutics, Inc. (CAPO). On September 30, 2016, Mr. Gerry Berg, and Mr. Timothy Dixon resigned as Officers and Directors of CAPO and cancelled any and all equity in CAPO. Our departure and subsequent cancellation of stock was due to an attempt at a hostile take-over of the Board of Directors of CAPO by other board members.

On October 18, 2016, we issued 40,000,000 shares valued at \$.0045 to the officers and directors of the Company for services, and 5,000,000 shares valued at \$.0045 for consulting services.

