THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.
Form 10-K
June 16, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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FORM 10-K

X .

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

For the fiscal year ended December 31, 2014

OR

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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 X .

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 X .

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 X .

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 X .

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. X .

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 .	Accelerated filer .
Non-accelerated filer .	Smaller reporting company X .

(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 X .

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $1,213,989 based on a closing price of $0.0064 as of June 7, 2016.

As of June 7, 2016, 681,951,000 shares of the registrant s common stock, par value of $0.001 per share, were outstanding.

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THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

PART I.

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.

EXPLANATORY NOTE

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:

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Need for additional capital;

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Limited operating history in our new business model;

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Limited experience introducing new products;

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

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Difficulty in managing our growth and expansion;

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Dilutive effects of any raising of additional capital;

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

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Material weaknesses reported in our internal control over financial reporting;

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

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The potential for product liability claims against us;

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Our dependence on third party manufacturers to manufacture our products;

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Our common stock is currently classified as a penny stock;

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Our stock price may experience future volatility;

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The illiquidity of our common stock; and

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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 Sol 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. 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 its annual report for the fiscal year ended December 31, 2015, nor any of the quarterly reports for the periods ending, March 31, 2015, June 30, 2015, September 30, 2015 and March 31, 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, 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. TSI has created several subsidiaries and divisions to focus on each of these programs:

Nutraceutical Division TSI has been producing high quality nutraceuticals. Its flagship product, ProJuvenol®, is a proprietary mixture containing pterostilbene one of the most potent antioxidants known. TSOI filed a patent application for ProJuvenol® on 07-08-2015 titled: Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions .

OmniBiome, Inc. - is a 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.

MolecuVax, Inc. is a subsidiary of TSI, incorporated in the State of Delaware on October 28, 2015, where the intellectual property surrounding immune-oncology is housed. The programs within MolecuVax include using exosomes derived from various immune cells to attack cancers as well as developing a cancer vaccine against cancers that express a certain protein unique to them.

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[1]. 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[2]. 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[3], as well as being published in the peer-reviewed literature in this area[4],[5].

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[1] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC551593/

[2] http://www.therapeuticsolutionsint.com/index.php/2015-04-19-16-05-26/228-therapeutic-solutions-international-files-patent-on

[3] http://www.google.com/patents/US8288172

[4] 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/

[5] 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.

ProJuvenol© includes:

Pterostilbene (trans-3,5-dimethoxy-4-hydroxystilbene) is a natural dietary compound and the primary antioxidant component of blueberries. It has increased bioavailability in comparison to other stilbene compounds, which may enhance its dietary benefit and possibly contribute to a valuable clinical effect. Multiple studies have demonstrated the antioxidant activity of pterostilbene in both in vitro and in vivo models illustrating both preventative and therapeutic benefits. The antioxidant activity of pterostilbene has been implicated in anticarcinogenesis, modulation of neurological disease, anti-inflammation, attenuation of vascular disease, and amelioration of diabetes.

Alpha lipoic acid (ALA), a coenzyme that is essential for producing cellular energy, assists in deactivating cell-damaging free radicals and renewing the body's antioxidant defense system. ALA supports a healthy liver function and enhanced insulin sensitivities.

Superoxide dismutase (SOD), an essential enzyme found in all living cells, it is a powerful cellular protector which helps break down potentially harmful oxygen molecules in cells, assisting in the prevention of damage to tissues. Green coffee bean extract, which contains antioxidant polyphenols and plant compounds that help support a variety of biological processes including fat and glucose metabolism. Projuvenol uses the only known, patented coated source of Superoxide dismutase, to ensure that your body has the ability to absorb and utilize this ingredient. Uncoated versions of SOD have not been shown to be effective when taken orally.

DMAE, 2-dimethylaminoethanol, an ingredient known to help promote choline production, which is required for healthy neurological and cognitive function. DMAE has been shown to have the ability to scavenge specific types of free radicals, it is also has been shown to assist in improving memory and mood; boosting thinking skills and intelligence; and increasing physical energy, oxygen efficiency, athletic performance, and muscle reflexes.

Piperine for bio-enhanced nutrient absorption. Piperine has been clinically tested in the United States. Piperine significantly enhances the bioavailability of various supplement nutrients through increased absorption. We have included this in ProJuvenol because we believe that it significantly increases the absorption of the amazing active ingredients found in ProJuvenol.

Curcumin is an anti-inflammatory molecule in the turmeric root, a relative of ginger.

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[1]' 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[2],[3], antioxidant[4], and anti-inflammatory activities[5]. Through the filing of the recent patent, the company is exploring whether its lead product, ProJuvenol®, 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[6]. Accordingly, we are seeking through the current work to identify whether our currently marketed product, ProJuvenol®, may be utilized as part of an integrative approach to building up the immune response of cancer patients.

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

[2] 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/

[3] 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/

[4] 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/

[5] 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/

[6] 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© and its active ingredient pterostilbene for augmentation of stem cell activity. Diseases such as diabetes[1], cardiovascular disease[2], and neurodegenerative diseases[3] 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[4] and undergo accelerated neurological recovery after stroke[5] as compared to patients with lower numbers of such stem cells.

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

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

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

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

[5] 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®, a testosterone booster, and Vital® Female, an estrogen booster and has plans to introduce a line of oncologist friendly nutraceuticals in liposome formula.

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 one of nature's unique and intelligent anti- oxidants/anti-inflammatories.

T-Rx® - 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® - 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.

Fetal-Maternal Health

OmniBiome, Inc.

OmniBiome, Inc. 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.

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.

Immune-Oncology

MolecuVax, Inc.

MolecuVax is a subsidiary of the Company where the intellectual property surrounding immune-oncology is housed. The programs within MolecuVax include using exosomes derived from various immune cells to attack cancers as well as developing a cancer vaccine against cancers that express a certain protein unique to them.

On February 08, 2016 TSOI licensed its exosome patent filed on 11-20-2015 to MolecuVax titled Exosome Mediated Innate and Adaptive Immune Stimulation for Treatment of Cancer as part of a future generation of immune cell derived nanoparticles, as a means of selectively stimulating the body's own natural defense mechanisms to seek and destroy cancer cells by company collaborators. The patent is focused on a means of manufacturing exosomes that

possess high concentrations of proteins found on tumors, which are specifically optimized to stimulate the immune system of cancer patients as a new form of immunotherapy.

This patent was collaboration between Dr. Michael Agadjanyan, Head of the Department of Immunology at the Institute for Molecular Medicine, and Dr. Santosh Kesari, Head of Neuro-Oncology at the John Wayne Cancer Center, both of whom are members of the Scientific Advisory Board of TSOI.

Exosomes are one of the means by which immune system cells communicate with each other. In the current patent we disclose means of generating exosomes in the laboratory, which can be utilized as a nanoparticle-based cancer vaccine to stimulate immune response to tumors in patients suffering from cancer.

Immunotherapy of cancer offers the possibility of selectively treating cancer without the side effects of radiation and chemotherapy. The recent FDA approval of immune stimulatory drugs such as checkpoint inhibitors strongly supports the advancement of this natural means of using the body's own immune system to treat the cancer. Immunotherapy offers possibility to help patients in which chemotherapy and radiotherapy no longer work, without the side effects of these approaches.

On April 11, 2016 the Company announced the signing of an agreement between its subsidiary, MolecuVax, Inc., (MVAX) and the Pan Am Cancer Treatment Center covering production and clinical implementation of a novel cancer immunotherapy based around MVAX s proprietary BORISome (Brother of the Regulator of Imprinted Sites (BORIS)) peptide/exosome technology.

In November of last year, the Company filed a patent on technologies covering novel means of stimulating the immune system to kill cancer using naturally made nanoparticles termed exosomes[1], which was subsequently licensed to MVAX[2]. In contrast to previous exosome-based cancer therapeutic approaches, the strategy being pursued by MVAX involves focusing the immune system to attack the protein BORIS, which is selectively found on cancer stem cells[3].

BORIS represents a unique target in the fight against cancer because it is only found on cancer cells and not healthy tissues. Additionally, because it is selectively found on cancer stem cells, we possess the possibility of inducing an immune response that would strike cancer at its roots, which are the cancer stem cells. By leveraging dendritic cell technology to generate BORIS-expressing exosomes in vivo, we believe the current therapeutic approach possesses a possibility of inducing a potent and selective immune response against cancer.

The Pan Am Cancer Treatment Center is a clinical research and treatment facility, which has been offering dendritic cell therapy for treatment of cancer patients. The current collaboration will leverage existing cellular therapy manufacturing expertise to develop, and clinically apply, the BORIS-peptide loaded dendritic cell therapy to patients.

Thomas Ichim, Ph.D, Board Member of TSOI co-authored three of the scientific peer reviewed papers demonstrating efficacy of BORIS-targeting immunotherapy in animal models, some of the papers together with scientists from the National Institutes of Health[4],[5],[6].

The importance of BORIS is difficult to overstate, not only is it a marker that is found on cancer stem cells, but when the protein is blocked from expressing by using gene silencing, we have previously published that cancer cells die[7]. Accordingly, there is a possibility that it will be difficult for tumors to become resistant to BORIS-based immunotherapies.

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[1] http://therapeuticsolutionsint.com/?page_id=60

[2] http://therapeuticsolutionsint.com/?page_id=39

[3] Asano et al. Oncotarget. 2016 Feb 3. https://www.ncbi.nlm.nih.gov/pubmed/?term=26849232

[4] Loukinov et al. J Cell Biochem. 2006 Aug 1;98(5):1037-43. https://www.ncbi.nlm.nih.gov/pubmed/16741971

[5] Ghochikyan et al. J Immunol. 2007 Jan 1;178(1):566-73. https://www.ncbi.nlm.nih.gov/pubmed/17182597

[6] Mkrtichyan et al. Gene Ther. 2008 Jan;15(1):61-4. https://www.ncbi.nlm.nih.gov/pubmed/17972923

[7] Dougherty et al. Biochem Biophys Res Commun. 2008 May 23;370(1):109-12. https://www.ncbi.nlm.nih.gov/pubmed/18355444

On May 09, 2016 the Company announced the signing of an exclusive license agreement between its subsidiary, MolecuVax, Inc., (MVAX) and UniVax, LLC covering composition of matter of a new cancer vaccine that targets a molecule found in cancer stem cells of a variety of types of cancers. The vaccine target, termed CTCFL or Brother of the Regulator of Imprinted Sites (BORIS), was discovered by researchers at the National Institutes of Health (NIH)[1], and has been shown in numerous peer-reviewed studies to be essential for cancer survival and progression[2],[3],[4].

The patent covers vaccines that stimulate the immune system to selectively kill tumor cells that are expressing this universal cancer specific protein. In contrast to other vaccines, our vaccine is targeting BORIS protein that is critical for the growth of histologically different cancers. This possesses important implications in that if a cancer cell mutates to lose expression of the target, then the cancer cell will no longer be cancerous.

The technology licensed positions MolecuVax in an ideal situation given the rapidly expanding interest in cancer immunotherapy clinical trials. The great successes of CAR-T cells and checkpoint inhibitors have already saved many lives and are testimony to the efficacy of this approach to cancer. We aim to utilize the licensed technology to enter clinical trials, in part through our existing collaboration with the Pan Am Cancer Treatment Center[5], as well as our planned FDA Investigational New Drug (IND) submission.

This vaccine was developed at the Institute for Molecular Medicine in Huntington Beach, California by Michael Agadjanyan, Ph.D. D.Sc., Head of the Cancer Vaccines Laboratory and member of TSI s Scientific Advisory Board, and Anahit Ghochikyan, Ph.D., Head of the Alzheimer s Disease Vaccines Laboratory. The vaccine is important because it not only prevents onset of cancer, but can also be used in patients that have cancer, thus it is termed a therapeutic vaccine . Additionally, the vaccine can be used as part of dendritic cell immunotherapy, which the inventors previously published as being extremely effective against breast cancer in animal models[6]

Our collaborators have been working on the concept of selectively killing cancer by immunologically targeting BORIS / CTCFL for over a decade. This work is now translated from a scientific hypothesis, to issued US and International patents, and now on the road to commercialization and to patients. Thomas Ichim, Ph.D, Board Member of TSOI has co-authored publications on BORIS / CTCFL with Dr. Agadjanyan and researchers at the NIH on this technology[7],[8],[9].

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[5] http://cancerimmunotherapy.mx/web/

[6] Mkrtichyan et al. Cell Immunol. 2011;270(2):188-97. http://www.ncbi.nlm.nih.gov/pubmed/21641588

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[8] Ghochikyan et al. J Immunol. 2007 Jan 1;178(1):566-73. http://www.ncbi.nlm.nih.gov/pubmed/17182597

[9] Mkrtichyan et al. Gene Ther. 2008 Jan;15(1):61-4. http://www.ncbi.nlm.nih.gov/pubmed/17972923

On May 2, 2016 TSOI retired to the treasury of MVAX 62,500,000 common shares of our holdings in MVAX. After this retirement, we now own 37,500,000 common shares of MVAX. On May 3, 2016 MVAX issued 37,500,000 of its common shares to UNIVAX, LLC in conjunction with the licensing agreement.

E-COMMERCE WEBSITE

The Company s current e-commerce website 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:

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Establish and integrate an enterprise solution that allows it to sell products securely over the Internet, www.youcanordernow.com;

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

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Publish articles, news and white papers containing relevant information;

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

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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:

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product claims and advertising;

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product labels;

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product ingredients; and

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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:

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

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

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

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notification procedures for statements on dietary and nutritional supplements; and

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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.

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:

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retain additional personnel across several departments in the Company;

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develop strong customer loyalty for new products in a crowded competitive marketplace;

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continue to establish and continue to increase awareness of our brands;

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price our products and services at points which will allow us to maximize sales while at the same time maximizing gross profit margins;

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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;

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rapidly respond to competitive developments, particularly when new high-demand products become available;

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build an operations structure to support our business and provide efficient and effective customer service and support;

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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;

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establish and maintain effective financial and management controls, reporting systems and procedures;

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control our expenses;

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provide competitive employee salaries and benefit packages; and,

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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:

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

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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

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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.

We initially and primarily depend on a single line of product for our revenue.

Although we intend and expect to develop and introduce new nutraceutical products, we currently market and sell Projuvenol©, a pterostilbene based system, T-Rx© and Vital©. We currently do not have a broad portfolio of other products completed that we could rely on to support our operations if we were to experience any difficulty with the manufacture, marketing, sale, or distribution of our current products.

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 its annual report for the fiscal year ended December 31, 2014 and December 31, 2015, nor any of the quarterly reports for the periods ending March 31, 2014, June 30, 2014, September 30, 2014, March 31, 2015, June 30, 2015, September 30, 2015 and March 31, 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.

Section8.2(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, 2013 through December 31, 2014.

Quarter Ended	High	Low
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
December 31, 2013	$0.009	$0.003
September 30, 2013	$0.009	$0.003
June 30, 2013	$0.025	$0.005
March 31, 2013	$0.07	$0.01

Dividends

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

Issuances of Unregistered Securities

On July 10, 2013, we issued 2,000,000 shares of common stock, valued at $.006 per shares, for legal services.

On July 15, 2013, we issued 4,000,000 shares of common stock, valued at $.006 per share, for consulting services.

On November 15, 2013, we issued 5,000,000 shares of common stock, valued at $.005 per share, for consulting services.

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 21,476,435shares 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 April 1, 2015, we issued 10,000,000 shares of common stock, valued at $.0025 per share, for consulting services.

On April 11, 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 April 11, 2015, we issued 2,000,000 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 $.0025 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 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 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 16, 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 November 17, 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 17, 2015, we issued 31,500,000 shares of common stock, valued at $.0025 per share, for consulting services.

On November 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 November 30, 2015, we issued 5,000,000 shares of common stock, valued at $.0025 per share, for consulting services.

On November 30, 2015, we issued 2,500,000 shares of common stock, valued at $.0025 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 $.0025 per share, for consulting services.

On February 1, 2016, we issued 2,500,000 shares of common stock, valued at $.0025 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 100,000,000 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.

Repurchases/Cancellation of Securities

We made no repurchases of our securities for the years ended 2013-2015.

On January 18, 2013 James Boyd surrendered 223,991,933 shares of common stock to us for cancellation of the license to use the international patents for the AMPSA device pursuant to the terms of a MDRA, and upon satisfaction of the conditions specified in an Escrow Agreement.

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, 2014.

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. 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 its annual report for the fiscal year ended December 31, 2015, nor any of the quarterly reports for the periods ending, March 31, 2015, June 30, 2015, September 30, 2015 and March 31, 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, 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®, is a proprietary mixture containing pterostilbene one of the most potent antioxidants known. TSOI filed a patent application for ProJuvenol® on 07-08-2015 titled: Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions .

OmniBiome, Inc. - is a 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.

MolecuVax, Inc. is a subsidiary of TSI where the intellectual property surrounding immune-oncology is housed. The programs within MolecuVax include using exosomes derived from various immune cells to attack cancers as well as developing a cancer vaccine against cancers that express a certain protein unique to them.

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[1]. 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[2]. 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[3], as well as being published in the peer-reviewed literature in this area[4],[5].

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[1] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC551593/

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

[3] http://www.google.com/patents/US8288172

[4] 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/

[5] 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.

ProJuvenol© includes:

Pterostilbene (trans-3,5-dimethoxy-4-hydroxystilbene) is a natural dietary compound and the primary antioxidant component of blueberries. It has increased bioavailability in comparison to other stilbene compounds, which may enhance its dietary benefit and possibly contribute to a valuable clinical effect. Multiple studies have demonstrated the antioxidant activity of pterostilbene in both in vitro and in vivo models illustrating both preventative and therapeutic benefits. The antioxidant activity of pterostilbene has been implicated in anticarcinogenesis, modulation of neurological disease, anti-inflammation, attenuation of vascular disease, and amelioration of diabetes.

Alpha lipoic acid (ALA), a coenzyme that is essential for producing cellular energy, assists in deactivating cell-damaging free radicals and renewing the body's antioxidant defense system. ALA supports a healthy liver function and enhanced insulin sensitivities.

Superoxide dismutase (SOD), an essential enzyme found in all living cells, it is a powerful cellular protector which helps break down potentially harmful oxygen molecules in cells, assisting in the prevention of damage to tissues. Green coffee bean extract, which contains antioxidant polyphenols and plant compounds that help support a variety of biological processes including fat and glucose metabolism. Projuvenol uses the only known, patented coated source of Superoxide dismutase, to ensure that your body has the ability to absorb and utilize this ingredient. Uncoated versions of SOD have not been shown to be effective when taken orally, ProJuvenol does not include ingredients that are not shown to possess the ability to convey the benefits attributable to that ingredient.

DMAE, 2-dimethylaminoethanol, an ingredient known to help promote choline production, which is required for healthy neurological and cognitive function. DMAE has been shown to have the ability to scavenge specific types of free radicals, it is also has been shown to assist in improving memory and mood; boosting thinking skills and intelligence; and increasing physical energy, oxygen efficiency, athletic performance, and muscle reflexes.

Piperine for bio-enhanced nutrient absorption. Piperine has been clinically tested in the United States. Piperine significantly enhances the bioavailability of various supplement nutrients through increased absorption. We have included this in ProJuvenol because we believe that it significantly increases the absorption of the active ingredients found in ProJuvenol.

Curcumin is an anti-inflammatory molecule in the turmeric root, a relative of ginger.

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[1]' 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[2],[3], antioxidant[4], and anti-inflammatory activities[5]. Through the filing of the recent patent, the company is exploring whether its lead product, ProJuvenol®, 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[6]. Accordingly, we are seeking through the current work to identify whether our currently marketed product, ProJuvenol®, may be utilized as part of an integrative approach to building up the immune response of cancer patients.

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

[2] 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/

[3] 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/

[4] 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/

[5] 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/

[6] 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© and its active ingredient pterostilbene for augmentation of stem cell activity. Diseases such as diabetes[1], cardiovascular disease[2], and neurodegenerative diseases[3] 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[4] and undergo accelerated neurological recovery after stroke[5] as compared to patients with lower numbers of such stem cells.

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

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

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

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

[5] 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®, a testosterone booster, and Vital® 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. 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.

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.

Immune-Oncology

MolecuVax, Inc.

MolecuVax is a subsidiary of TSI where the intellectual property surrounding immune-oncology is housed. The programs within MolecuVax include using exosomes derived from various immune cells to attack cancers as well as developing a cancer vaccine against cancers that express a certain protein unique to them.

On February 08, 2016 TSOI licensed its exosome patent filed on 11-20-2015 to MolecuVax titled Exosome Mediated Innate and Adaptive Immune Stimulation for Treatment of Cancer as part of a future generation of immune cell derived nanoparticles, as a means of selectively stimulating the body's own natural defense mechanisms to seek and destroy cancer cells by company collaborators. The patent is focused on a means of manufacturing exosomes that possess high concentrations of proteins found on tumors, which are specifically optimized to stimulate the immune system of cancer patients as a new form of immunotherapy.

This patent was a collaboration between Dr. Michael Agadjanyan, Head of the Department of Immunology at the Institute for Molecular Medicine, and Dr. Santosh Kesari, Head of Neuro-Oncology at the John Wayne Cancer Center, both of whom are members of the Scientific Advisory Board of TSOI.

Exosomes are one of the means by which immune system cells communicate with each other. In the current patent we disclose means of generating exosomes in the laboratory, which can be utilized as a nanoparticle-based cancer vaccine to stimulate immune response to tumors in patients suffering from cancer.

Immunotherapy of cancer offers the possibility of selectively treating cancer without the side effects of radiation and chemotherapy. The recent FDA approval of immune stimulatory drugs such as checkpoint inhibitors strongly supports the advancement of this natural means of using the body's own immune system to treat the cancer. Immunotherapy offers possibility to help patients in which chemotherapy and radiotherapy no longer work, without the side effects of these approaches.

On April 11, 2016 the Company announced the signing of an agreement between its subsidiary, MolecuVax, Inc., (MVAX) and the Pan Am Cancer Treatment Center covering production and clinical implementation of a novel cancer immunotherapy based around MVAX s proprietary BORISome (Brother of the Regulator of Imprinted Sites (BORIS)) peptide/exosome technology.

In November of last year, the Company filed a patent on technologies covering novel means of stimulating the immune system to kill cancer using naturally made nanoparticles termed exosomes, which was subsequently licensed to MVAX[2]. In contrast to previous exosome-based cancer therapeutic approaches, the strategy being pursued by MVAX involves focusing the immune system to attack the protein BORIS, which is selectively found on cancer stem cells[3].

BORIS represents a unique target in the fight against cancer because it is only found on cancer cells and not healthy tissues. Additionally, because it is selectively found on cancer stem cells, we possess the possibility of inducing an immune response that would strike cancer at its roots, which are the cancer stem cells. By leveraging dendritic cell technology to generate BORIS-expressing exosomes in vivo, we believe the current therapeutic approach possesses a possibility of inducing a potent and selective immune response against cancer.

The Pan Am Cancer Treatment Center is a clinical research and treatment facility, which has been offering dendritic cell therapy for treatment of cancer patients. The current collaboration will leverage existing cellular therapy manufacturing expertise to develop, and clinically apply, the BORIS-peptide loaded dendritic cell therapy to patients.

Thomas Ichim, Ph.D, Board Member of TSOI co-authored three of the scientific peer reviewed papers demonstrating efficacy of BORIS-targeting immunotherapy in animal models, some of the papers together with scientists from the National Institutes of Health[4],[5],[6].

The importance of BORIS is difficult to overstate, not only is it a marker that is found on cancer stem cells, but when the protein is blocked from expressing by using gene silencing, we have previously published that cancer cells die[7]. Accordingly, there is a possibility that it will be difficult for tumors to become resistant to BORIS-based immunotherapies.

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[1] http://therapeuticsolutionsint.com/?page_id=60

[2] http://therapeuticsolutionsint.com/?page_id=39

[3] Asano et al. Oncotarget. 2016 Feb 3. https://www.ncbi.nlm.nih.gov/pubmed/?term=26849232

[4] Loukinov et al. J Cell Biochem. 2006 Aug 1;98(5):1037-43. https://www.ncbi.nlm.nih.gov/pubmed/16741971

[5] Ghochikyan et al. J Immunol. 2007 Jan 1;178(1):566-73. https://www.ncbi.nlm.nih.gov/pubmed/17182597

[6] Mkrtichyan et al. Gene Ther. 2008 Jan;15(1):61-4. https://www.ncbi.nlm.nih.gov/pubmed/17972923

[7] Dougherty et al. Biochem Biophys Res Commun. 2008 May 23;370(1):109-12. https://www.ncbi.nlm.nih.gov/pubmed/18355444

On May 09, 2016 the Company announced the signing of an exclusive license agreement between its subsidiary, MolecuVax, Inc., (MVAX) and UniVax, LLC covering composition of matter of a new cancer vaccine that targets a molecule found in cancer stem cells of a variety of types of cancers. The vaccine target, termed CTCFL or Brother of the Regulator of Imprinted Sites (BORIS), was discovered by researchers at the National Institutes of Health (NIH)[1], and has been shown in numerous peer-reviewed studies to be essential for cancer survival and progression[2],[3],[4].

The patent covers vaccines that stimulate the immune system to selectively kill tumor cells that are expressing this universal cancer specific protein. In contrast to other vaccines, our vaccine is targeting BORIS protein that is critical for the growth of histologically different cancers. This possesses important implications in that if a cancer cell mutates to lose expression of the target, then the cancer cell will no longer be cancerous.

The technology licensed positions MolecuVax in an ideal situation given the rapidly expanding interest in cancer immunotherapy clinical trials. The great successes of CAR-T cells and checkpoint inhibitors have already saved many lives and are testimony to the efficacy of this approach to cancer. We aim to utilize the licensed technology to enter clinical trials, in part through our existing collaboration with the Pan Am Cancer Treatment Center[5], as well as our planned FDA Investigational New Drug (IND) submission.

This vaccine was developed at the Institute for Molecular Medicine in Huntington Beach, California by Michael Agadjanyan, Ph.D. D.Sc., Head of the Cancer Vaccines Laboratory and member of TSI s Scientific Advisory Board, and Anahit Ghochikyan, Ph.D., Head of the Alzheimer s Disease Vaccines Laboratory. The vaccine is important because it not only prevents onset of cancer, but can also be used in patients that have cancer, thus it is termed a therapeutic vaccine . Additionally, the vaccine can be used as part of dendritic cell immunotherapy, which the inventors previously published as being extremely effective against breast cancer in animal models[6].

Our collaborators have been working on the concept of selectively killing cancer by immunologically targeting BORIS / CTCFL for over a decade. This work is now translated from a scientific hypothesis, to issued US and International patents, and now on the road to commercialization and to patients. Thomas Ichim, Ph.D, Board Member of TSOI has co-authored publications on BORIS / CTCFL with Dr. Agadjanyan and researchers at the NIH on this technology[7],[8],[9].

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[1] Loukinov et al. Proc Natl Acad Sci U S A. 2002 May 14;99(10):6806-11, http://www.ncbi.nlm.nih.gov/pubmed/12011441

[2] Asano et al. Oncotarget. 2016 Mar 8;7(10):11223-37. http://www.ncbi.nlm.nih.gov/pubmed/26849232

[3] Alberti et al. PLoS One. 2015 Jul 17;10(7):e0132977.

[4] Dougherty et al. Biochem Biophys Res Commun. 2008 May 23;370(1):109-12. http://www.ncbi.nlm.nih.gov/pubmed/18355444

[5] http://cancerimmunotherapy.mx/web/

[6] Mkrtichyan et al. Cell Immunol. 2011;270(2):188-97. http://www.ncbi.nlm.nih.gov/pubmed/21641588

[7] Loukinov et al. J Cell Biochem. 2006 Aug 1;98(5):1037-43. http://www.ncbi.nlm.nih.gov/pubmed/16741971

[8] Ghochikyan et al. J Immunol. 2007 Jan 1;178(1):566-73. http://www.ncbi.nlm.nih.gov/pubmed/17182597

[9] Mkrtichyan et al. Gene Ther. 2008 Jan;15(1):61-4. http://www.ncbi.nlm.nih.gov/pubmed/17972923

On May 2, 2016 TSOI retired to the treasury of MVAX 62,500,000 common shares of our holdings in MVAX. After this retirement, we now own 37,500,000 common shares of MVAX. On May 3, 2016 MVAX issued 37,500,000 of its

common shares to UNIVAX, LLC in conjunction with the licensing agreement.

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 2013.

Results of Operations

We had a net loss of approximately $0.29 million in 2014 compared to a net loss of approximately $0.55 million in 2013.

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 9, Discontinued Operation in Notes to the Financial Statements.

Operating expenses for the years ended December 31, 2014 and December 31, 2013 were approximately $0.33 million and $.85 million, respectively, a decrease of approximately $.52 million. This decrease was mainly due headcount and salary reductions, and the nonrecurrence of legal fees.

General and administrative expenses decreased approximately $.018 million for 2014 as compared to 2013. This decrease was mainly due to an overall reduction in overhead costs.

Salaries, wages and related costs decreased approximately $0.4 million for 2014 as compared to 2013. This decrease was due reduction in officers salaries and reduced employee headcount.

Amortization and depreciation was approximately $0.021 million for the year ended December 31, 2014 versus approximately $0.023 million for the year ended December 31, 2013.

Consulting fees decreased approximately $0.046 million for 2014 as compared to 2013. This decrease was primarily due to a reduction in consulting agreements during the year.

Legal and professional fees decreased approximately $0.046 million for 2014 as compared to 2013. This decrease was mainly due to a reduction of overall legal services in 2014 vs. 2013.

Net other income/expense decreased approximately $14 thousand from $23 thousand in 2013 to $9 thousand in 2014 from a decrease in seminar tuition.

Impairment of intangible asset increase by $210 thousand in 2014 from $0 in 2013 due to the Company unable to forecast future short term revenue from acquired intellectual property.

Net interest expense decreased approximately $1 thousand from $10 thousand to $9 thousand from 2013 to 2014. This change was mainly due to reductions in notes payable and changes in interest rates.

Net income from discontinued operation for the year ended December 31, 2014 and 2013 were $249,002 and $284,088, a decrease of $35,086. 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.

Liquidity and Capital Resources

As of December 31, 2014, our cash and cash equivalents totaled only about $2,894 and our current liabilities totaled $333,000. 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

A.

Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act, our principal executive officer and principal financial officer evaluated our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act) for the period covered by this Annual Report on Form 10-K as of December 31, 2014. Based on this evaluation, these officers concluded that as of December 31, 2014, these disclosure controls and procedures were adequate to ensure that the information required to be disclosed by us in reports we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and include controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake.

B.

Management s Report on 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 a process designed to provide reasonable assurance to management and the board of directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions; (ii) provide reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; (iii) provide reasonable assurance that receipts and expenditures of company assets are made in accordance with management authorization; and (iv) provide reasonable assurance that unauthorized acquisition, use or disposition of company assets that could have a material effect on our financial statements would be prevented or detected on a timely basis.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect every misstatement. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because changes in conditions may occur or the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. This assessment was based on the criteria for effective internal control described in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO). Based on its assessment, management concluded that our internal control over financial reporting as of December 31, 2014 was not effective and was subject to material weaknesses.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

We identified the following material weaknesses in our internal control over financial reporting using the criteria established in the COSO framework:

.

There is a significant lack of definition and segregation of duties throughout our financial and financial reporting processes;

.

Currently we have no written policies or procedures that clearly define roles in the financial close and reporting process. The various roles and responsibilities related to this process need to be defined, assigned, documented, updated and communicated; and

.

We fail to have an audit committee or other independent committee that is independent of management to assess internal control over financial reporting.

C.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting that occurred during our fiscal year ended December 31, 2013 that materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

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 June 7, 2016 are as follows:

Directors:

Name of Director	Age
Timothy G. Dixon	57
Gerry B. Berg	69
Thomas E. Ichim*	40

Executive Officers:

Name of Officer	Age	Offices
Timothy G. Dixon	57	Chief Executive Officer and President
Gerry B. Berg	69	Vice President, Chief Financial Officer and Secretary

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 MolecuVax, Inc., President and Chairman of OmniBiome, Inc., and President and Chairman of Capo Therapeutics, 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 of MolecuVax, Inc., OmniBiome, Inc., and Capo Therapeutics, 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.

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 Sheept, 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.

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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 February 29, 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 Lougborough 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, 2014 and 2013 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 Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Timothy G. Dixon*	2014	10,192						10,192
President and CEO	2013	10,500					-	10,500
Gerry B. Berg**	2014	10,192						10,192
Vice President, Chief Financial Officer	2013	10,500					-	10,500

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 May 22, 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 May 22, 2016, a total of 674,951,000 shares of our common stock were outstanding.

Name of Beneficial Owners	Amount and Nature of Beneficial Ownership (1)	Percent of Shares Outstanding
Timothy G. Dixon (2)	106,475,671	15.61%
Gerry B. Berg (3)	97,750,000	14.33%
Thomas E. Ichim* (4)	34,500,000	5.06%
Robert F. Graham	102,500,000	15.03%
John Peck, Jr.	120,000,000	17.60%
All directors and executive officers as a group (3 persons) (2)(3)(4)	238,725,671	32.37%

*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 2014 was $nil (inclusive of the review of the quarterly reports on Form 10-Q). We had not filed any form 10-Q and Form 10-K in 2014.

The aggregate fees billed to us by our principal accountants, PLS CPA, A Professional Corporation, for auditing and accounting services for 2013 was $40,000 (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 2014 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 2013 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

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: June 15, 2016

/s/ Timothy G. Dixon
Timothy G. Dixon
Chief Executive Officer, President and Director (Principal Executive Officer)
Date: June 15, 2016

/s/ Gerry B. Berg
Gerry B. Berg
Vice President, Chief Financial Officer and Director (Principal Financial and Accounting Officer)
Date: June 15, 2016

/s/ Thomas E. Ichim
Thomas E. Ichim
Director
Date: June 15, 2016

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, 2014 and 2013 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, 2014 and 2013, 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.

June 15, 2016

San Diego, CA 92111