THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.
Form 10-K
April 15, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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, 2018

OR

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

For the transition period from to

Commission File Number: **000-54554**

Therapeutic Solutions International, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**45-1226465**

(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

4093 Oceanside Boulevard, Suite B

Oceanside, California 92056

(Address of principal executive offices, including zip code)

(760) 295-7208

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: **None**

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

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

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

Yes [ ] No [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. [ ]

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	[X]	Smaller reporting company	[X]
		Emerging growth company	[ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $654,902 based on a closing price of $0.0022 as of June 30, 2018

As of April 15, 2019, 1,101,102,071 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.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of federal securities laws, 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 2019 and thereafter. These statements may appear in a number of places and can be identified by the use of forward-looking terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "future," "intend," or "certain" or the negative of these terms or other variations or comparable terminology, or by discussions of strategy.

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

Need for additional capital;

Limited operating history in our new business model;

Limited experience introducing new products;

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

Difficulty in managing our growth and expansion;

Dilutive effects of any raising of additional capital;

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

Material weaknesses reported in our internal control over financial reporting;

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

The potential for product liability claims against us;

Our dependence on third party manufacturers to manufacture our products;

Our common stock is currently classified as a penny stock;

Our stock price may experience future volatility;

The illiquidity of our common stock; and

Substantial sales of shares of our common stock.

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

ITEM 1 BUSINESS.

Corporate History

Therapeutic Solutions International, Inc. ("TSI" or the "Company") was organized August 6, 2007 under the name Friendly Auto Dealers, Inc., under the laws of the State of Nevada. In the first quarter of 2011 the Company changed its name from Friendly Auto Dealers, Inc. to Therapeutic Solutions International, Inc., and acquired Splint Decisions, Inc., a California corporation.

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

Activating one's immune system is now an accepted method to cure certain cancers, reduce recovery time from viral or bacterial infections and to prevent illness. Additionally, 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.

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. TSI filed a patent application for ProJuvenol® on 07-08-2015 titled: "Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions" and was granted that patent on June 20, 2017.

Emvolio, Inc., – was a wholly-owned subsidiary of TSI, incorporated in the State of Delaware on October 3, 2016, for the purpose of filing an Investigation New Drug ("IND") application with the FDA for our StemVacs immunotherapy vaccine. In May of 2018 President Donald J. Trump signed into the law, the Right To Try bill. Because of this change, Emvolio has decided to withdraw the IND for a Phase 1 trial in the USA because TSI had previously completed a 10 patient trial in Mexico. TSI has since generated Good Clinical Practice ("GCP") documentation for the previously treated 10 patients into a Phase I trial, which will be presented to the FDA by TSI as part of an Ex-US trial compliant with 21 CFR 312.120 Foreign clinical studies not conducted under an IND. Therefore we have dissolved Emvolio, Inc. as it is no longer needed.

SandBox Dental Labs, Inc. – is a wholly-owned subsidiary of TSI consisting of a future dental laboratory to manufacture and fill prescriptions from dentists who will use our proprietary Sleep Appliance to treat their patients with mild to moderate obstructive sleep apnea. The Company needs to seek regulatory approval for its device to treat sleep apnea. As of December 31, 2018 and April 1, 2019, formal operations have not commenced.

Management does not expect existing cash as of December 31, 2018 or as of March 31, 2019 to be sufficient to fund the Company's operations for at least twelve months from the issuance date of these December 31, 2018 financial statements. These financial statements have been prepared on a going concern basis which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. As of December 31, 2018, the Company has incurred losses totaling $7.1 million since inception, has not yet generated material revenue from operations, and will require additional funds to maintain its operations. These factors raise substantial doubt regarding the Company's ability to continue as a going concern within one year after the consolidated financial statements are issued. The Company's ability to continue as a going concern is dependent upon its ability to generate future profitable operations and obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they become due. The Company intends to finance operating costs over the next twelve months through its existing financial resources and we may also raise additional capital through equity offerings, debt financings, collaborations and/or licensing arrangements. If adequate funds are not available on acceptable terms, we may be required to delay, reduce the scope of, or curtail, our operations. The accompanying consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

CURRENT BUSINESS DESCRIPTION

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

Activating one's immune system is now an accepted method to treat certain cancers, reduce recovery time from viral or bacterial infections and to prevent illness. Additionally, 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.

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". On April 28, 2016 the Company announced the filing of a patent application covering the use of ProJuvenol© and its active ingredient pterostilbene for augmentation of stem cell activity.

SandBox Dental Labs, Inc. SandBox Dental Labs, Inc., is a wholly-owned subsidiary of TSI consisting of a dental laboratory to manufacture and fill prescriptions from dentists who will use our proprietary Sleep Appliance to treat their patients with mild to moderate obstructive sleep apnea.

Nutraceutical Division (TSOI)

ProJuvenol® is a patented and powerful synergistic blend of complex anti-aging ingredients in capsules.

NanoStilbene™ is an easily absorbed nanoemulsion of nanoparticle pterostilbene derived from the '047 patent.

DermalStilbene is a topical form of pterostilbene delivered via spray application onto skin, derived from the ‘047 patent.

IsoStilbene an injectable formulation of pterostilbene is available by prescription only, derived from the ‘047 patent.

NeuroStilbene™ is an intranasal form of pterostilbene delivered via spray application inside the nostril, derived from the ‘047 patent.

Nutraceutical Patents:

TSOI filed a patent in July 2015 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. That patent, U.S. No.: 9,682,047 was granted on 6-20-2017.

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, cardiovascular disease, and neurodegenerative diseases 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 and undergo accelerated neurological recovery after stroke as compared to patients with lower numbers of such stem cells.

On October 16, 2017 the Company filed a patent application titled "Synergistic Inhibition of Glioma Using Pterostilbene and Analogues Thereof" which was developed to utilize the ability of the immune system to augment the possibility of increasing overall survival of glioma patients after treatment with conventional therapies. Our data suggests that when pterostilbene is combined with brain cancer therapeutics such as Gefitinib, Sertraline, or Temozolomide, the prognosis is vastly improved.

On August 13, 2018 the company filed a patent application titled “Enhancement of Ozone Therapy using Pterostilbene” showing pterostilbene potently augments killing of breast cancer, prostate cancer, and ovarian cancer cells by ozone therapy. The data obtained is an extension of ongoing work at the Company seeking to identify means of enhancing the effects of pterostilbene administration for treatment of a variety of cancers, as well as enhancing the efficacy of

existing cancer therapies.

On September 17, 2018 the company filed a patent application titled “Pterostilbene and Compositions Thereof for Prevention and Treatment of Chronic Traumatic Encephalopathy” with new data demonstrating the ability of its NeuroStilbene intranasal formulation of pterostilbene to successfully prevent the development of brain injury in an animal model of Chronic Traumatic Encephalopathy aka CTE.

On September 25, 2018 the company filed a patent application titled “Pterostilbene and Formulations Thereof for Treatment of Pathological Immune Activation” covering novel clinical data using its NanoStilbene™ formulation to reduce inflammatory cytokine production in cancer patients.

The Star Ingredient is Pterostilbene

Pterostilbene, (trans-3,5-dimethoxy-4-hydroxystilbene) is a stilbene compound that is structurally similar to other popular stilbenes such as resveratrol or piceatannol; it is named after its first discovered source (the pterocarpus genus) but is also a component of blueberries and grape products. It is a phytoalexin (compound produced by plants as a defense against parasites and insects) similar to resveratrol albeit more potent.

Pterostilbene has been found to be significantly more stable in vivo than resveratrol, its half-life in vivo is approximately 104 minutes versus resveratrol, for 13 minutes. Further, studies indicate that the body better absorbs pterostilbene than resveratrol, and pterostilbene is more biologically active than resveratrol, and is more efficacious than resveratrol in inhibiting certain biological activities including pro-inflammatory enzymes (providing anti-inflammatory benefits), and cell membranes producing lipid peroxidation (providing anti-oxidant support).

Each of the benefits below are specifically a growing concern within our targeted demographics, the availability of a natural product to the existing medical protocols provides a logical and affordable alternative, without many of the adverse side effects of traditional medicines.

Reduced insulin sensitivity

Reduction in VLDL and LDL (bad) cholesterol levels

Increasing HDL (good) cholesterol levels

Positive vascular smooth muscle cells

Anti-inflammatory benefits

Anti-oxidant benefits

Cognitive function improvement

Skin protection from Ultra Violet light exposure

ProJuvenol® which contains 200mg of >99% pure Pterostilbene in each daily dose is 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.

ProJuvenol® was inspired by natures design and formulated to assist nature’s rejuvenation of the body's cells helping to slow and actually reverse the aging processes and decline in vitality. U.S. Patent No.: 9,682,047

ProJuvenol® includes:

Pterostilbene, (trans-3,5-dimethoxy-4-hydroxystilbene) is a stilbene compound that is structurally similar to other popular stilbenes such as resveratrol or piceatannol; it is named after its first discovered source (the pterocarpus genus) but is also a component of blueberries and grape products. It is a phytoalexin (compound produced by plants as a defense against parasites and insects) similar to resveratrol albeit more potent.

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. It may also assist in preventing aging or liver spots, improving red blood cell function, and extending life span.

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.

NanoStilbene is prepared by low-energy emulsification which allows for better solubility, stability, and the release performance of pterostilbene nanoparticles. The pterostilbene placed in a nanoemulsion droplet is free from air, light, and hard environment; therefore, as a delivery system, nanoemulsion can not only improve the bioavailability of pterostilbene but also protect it from oxidation and hydrolysis, while it possesses an ability of sustained release at the same time.

The recommended dose is 1.5 milliliters yielding 300 milligrams per dose. In addition to the benefits of the nanoparticle pterostilbene we chose to use medium chain triglycerides (MCT), derived from coconut oil, as one of our oil mediums in preparing the nanoemulsion.

MCTs are not stored as fat, but rather convert quickly into Adenosine triphosphate (ATP), which provides energy for the body and brain at the cellular level.

MCT's are also shown to increase metabolic thermo-genesis, improve stamina, endurance, athletic performance, and energy levels, as well as exhibiting potent anti-microbial properties – providing immune system benefits and helping in balancing candida in the gut.

NanoStilbene is available in 60ml bottles at a concentration of 200mg per ml with a recommended daily dose of 1.5ml which is equal to 300mg.

Nanotechnology

Therapeutic uses of nanotechnology typically involve the delivery of small-molecule drugs, peptides, proteins, and nucleic acids. Nanoparticles have advanced pharmacological effects compared with the therapeutic entities they contain. Active intracellular delivery and improved pharmacokinetics and pharmacodynamics of drug nanoparticles depend on various factors, including their size and surface properties.

Nanoparticle therapeutics is an emerging treatment modality in cancer and other inflammatory disorders. The National Cancer Institute has recognized nanotechnology as an emerging field with the potential to revolutionize modern medicine for detection, treatment, and prevention of cancer.

On May 15, 2018 TSI announced Institutional Review Board (IRB) clearance to initiate a pilot pharmacokinetic trial of "NanoStilbene." Then on July 02, 2018 the Company announced receiving pilot clinical data providing proof of concept that NanoStilbene more effectively increases blood levels of the molecule as compared to conventional formulations. The clinical trial involved the administration of NanoStilbene in comparison to powder in capsule form pterostilbene with healthy volunteers, whom underwent a series of blood draws to determine the concentration of the compound.

NanoStilbene Administration Results in Superior Pharmacokinetic Profile

Compared to Pterostilbene Administration

Blood was collected in EDTA tubes and plasma collected subsequent to centrifugation at 700g for 10 minutes. Collection time points were prior to administration of test compound, as well as at times 2hr, 4hr, 6hr, 8hr, 10hr, and 12 hrs. Test compounds were 10 ml of NanoStilbene (provided by Therapeutic Solutions International) and 6 capsules of 50 mg pterostilbene (VitaMonk). A wash out period of 3 days was allowed between two test compound administration.

Results

The results were that at peak concentration NanoStilbene (Square) had a 55% increase in serum levels over the traditional powder (Triangle) form of pterostilbene. The data also shows the half-life to be double to that of the powder form.

The data in Granted U.S. Patent No.: 9,682,047 strongly suggest that pterostilbene administration may be an inexpensive and safe method of augmenting efficacy of numerous immunotherapeutic drugs. Although cancer immunotherapy has revolutionized the prognosis of many patients, the majority of patients still possess poor or suboptimal responses to this approach.

Clinical Trial of NanoStilbene for Immune Derepression in Advanced Cancer

Patients

Twelve advanced cancer patients were recruited for the study. All patients signed informed consent and were told of the investigational nature of the clinical trial. To be eligible patients must have at least 6 months life expectancy, ECOG over 2, metastatic advanced solid tumor, be ambulatory, and not suffer organ failure. Characteristics of the patients is described in Table 1.

NanoStilbene

NanoStilbene, was administered at a concentration of 10 ml orally per day (300mg) for a total of three weeks. Administration was performed by the patients at home and patients were instructed to note the time of dose intake as well as any side effects associated with ingestion. Patients were also instructed to ingest NanoStilbene on a full stomach.

Results

The study assessed whether the administration of NanoStilbene, a nanoformulation of pterostilbene, is effective at reducing inflammatory markers and augmenting immune function in 12 advanced cancer patients.

It has previously been known that pterostilbene possesses direct anticancer activity in the majority of cancers including melanoma[1], glioma[2], ovarian cancer[3], prostate cancer[4], pancreatic cancer[5], breast cancer[6], liver cancer[7], colorectal cancer[8], and various liquid tumors (leukemias)[9].

Chronic inflammation, as measured by CRP, TNF-alpha and IL-6 levels in the blood, has been reported to be immune suppressive in cancer patients and we sought to reduce them through orally administered NanoStilbene. On average we saw CRP reduced by 27%, Interleukin 6 (IL-6) by 26% and TNF-alpha also by 26%. This dramatic reduction showed clinically relevant levels of downregulation of inflammatory cytokines as a result of the NanoStilbene administration.

The suppression of interferon gamma (IFN-g) is a hallmark of cancer immune evasion. Given that this cancer immune evasion is typically associated with inflammatory mediators such as TNF-alpha, we assessed the impact of NanoStilbene administration on the production of interferon gamma. We observed an average increase by 12% among the patients treated. The augmentation of interferon gamma production was due to the reduction of pro-inflammatory cytokines CRP, TNF-a, and IL-6.

The augmentation of natural killer cell (NK) activity is one of the most sensitive indicators of anticancer immunity seen clinically. Previous studies have shown that efficacy of antibody, as well as chemotherapy-induced cancer cell death, is dependent on NK activity. Unfortunately, cancer patients have suppressed NK activity, usually as a result of oxidative stress, therefore, it was postulated that NanoStilbene may reverse cancer associated NK depression. We observed on average an increase in NK activity of 37%, validating that 300mg of NanoStilbene daily was sufficient to cause these results.

These results suggest that NanoStilbene may be a useful adjuvant to immunotherapy of cancer rescuing T cell and NK cell activities. Augmentation of NK cell function may stimulate efficacy of approved therapies that depend on an active NK compartment such as Herceptin, Rituximab, and Cetuximab.

**The data provided here is partial and does not contain all materials submitted for publication and is preliminary until peer review is complete. These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.*

Dental

SandBox Dental Labs, Inc. – is a wholly-owned subsidiary of TSI consisting of a future dental laboratory to manufacture and fill prescriptions from dentists who will use our proprietary Sleep Appliance to treat their patients with mild to moderate obstructive sleep apnea. The Company needs to seek regulatory approval for its device to treat sleep apnea. As of December 31, 2018 and April 1, 2019, formal operations have not commenced.

Immune-Oncology – Right To Try

In May of 2018 President Donald J. Trump signed into the law, the Right To Try bill. In 2015/2016 TSI began and completed a 10 patient clinical trial of advanced cancer patients in Mexico at the Pan Am Cancer Treatment Center located in Tijuan Mexico using our dendritic cell vaccine code named StemVacs. TSI has since generated GCP

documentation for the previously treated 10 patients into a Phase I trial, which will be presented to the FDA by TSI as part of an Ex-US trial compliant with 21 CFR 312.120 Foreign clinical studies not conducted under an IND. This is a required step to conform to the new Right To Try law.

StemVacs is an immunotherapy platform that consists of 5 components. The overarching approach to the StemVacs Immunotherapy Platform is as follows:

1. Treat innate immune suppression: Administration of oral apigenin/NanoStilbene (Cancer DeTox Product) to decrease immune suppressive toxic molecules made by tumor and tumor microenvironment.

2. Treat adaptive immune suppression: Administration of MemoryMune to activate dormant memory cells recognizing the tumor. Administration of LymphoBoost to repair deficient IL-12 production.

3. Stimulation of immune response to cancer stem cells (StemVacs).

4. Consolidation and maintenance of immunity: Cycles of StemVacs, supported by innaMune and LymphoBoost

StemVacs: StemVacs is a subcutaneously administered vaccine comprised of immune stimulatory peptides resembling cancer stem cell specific proteins.

Cancer Metabolic DeTox: This is an orally administered agent that is derived from various herbs termed apigenin. The unique property of apigenin is that it inhibits a cancer associated metabolic pathway that degrades the amino acid tryptophan. Specifically, apigenin inhibits the enzyme indolamine 2,3 deoxygenase (IDO), which is responsible for breaking down tryptophan in the vicinity of the tumor and generating by-products such as kynurenine. It is known that immune activation is dependent on tryptophan being present in the tumor environment. The depletion of tryptophan and generation of kynurenine by tumor cells and tumor associated cells is a major cause of immune suppression in cancer. By administering Cancer Metabolic DeTox, the innate arm of the immune system has a chance to regenerate. This positions the patient for better outcome after administration of specific immune stimulating vaccines.

MemoryMune: This is a product derived from a two-step culture process of donor blood cells. The product MemoryMune reawakens dormant immune memory cells. It is known that many cancer patients possess memory T cells that enter the tumor, however, once inside the tumor these cells are inactivated. MemoryMune contains a unique combination of growth factors specific for immune system cells called “cytokines”.

LymphoBoost: LymphoBoost is a proprietary formulation of Misoprostol, a drug approved for another indication, which we have shown to be capable of stimulating lymphocytes, particularly NK cells and T cells, both critical in maintaining anti-tumor immunity.

innaMune: This is a biological product derived from tissue culture of blood cells derived from healthy donors. It is a combination of cytokines that maintain activity of innate immune system cells, as well as having ability to shift M2 macrophages to M1.

Chronic Traumatic Encephalopathy (CTE), and Traumatic Brain Injury (TBI) – Right To Try

On December 10, 2018 Therapeutic Solutions International, Inc., announced the signing of an agreement between TSOI and Jadi Cell LLC for licensing of the Jadi Cell universal donor adult stem cell, as covered in US Patent No.: 9,803,176 B2 for use in Chronic Traumatic Encephalopathy (CTE), and Traumatic Brain Injury (TBI).

The Jadi Cell product, which belongs to the mesenchymal stem cell (MSC) family of cells, is a unique adult stem cell, which produces higher levels of therapeutic factors compared to other stem cells. The cells have demonstrated safety in animal models and pilot human trials. The Jadi Cell product is generated from umbilical cords, which are a source of medical waste and available in large quantities at inexpensive prices.

Chronic Traumatic Encephalopathy (CTE) is caused by repetitive concussive/sub-concussive hits to the head sustained over a period of years and is often found in football players. The condition is characterized by memory loss, impulsive/erratic behavior, impaired judgment, aggression, depression, and dementia. In many patients with CTE, it is anatomically characterized by brain atrophy, reduced mass of frontal and temporal cortices, and medial temporal lobe.

Traumatic brain injury (TBI) is an insult to the brain, not of a degenerative or congenital nature, but caused by external physical force that may produce a diminished or altered state of consciousness, which results in an impairment of cognitive abilities or physical functioning.

CTE represents a significant unmet medical need which we believe is amenable to stem cell intervention. We are eager to accelerate treatments and potential cures for debilitating conditions such as CTE and traumatic brain injury and plan to leverage New regulatory pathways such as the recently approved “Right to Try” Law to deliver these medicines as soon as possible to patients which currently have no other options.

The Jadi Cell product because of its advanced stage of development in contrast to other stem cell types, which require years, if not decades of development before entry into American patients, will allow us we believe to be treating patients within 12 months. Currently means of isolating, producing, scaling up, and delivery of the cells has all been worked out by Jadi Cell and Collaborators.

GOVERNMENT REGULATION

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

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

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

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

- the identification of dietary or nutritional supplements and their nutrition and ingredient labeling;
- requirements related to the wording used for claims about nutrients, health claims, and statements of nutritional support;
- labeling requirements for dietary or nutritional supplements for which "high potency" and "antioxidant" claims are made;
- notification procedures for statements on dietary and nutritional supplements; and

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

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

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

EMPLOYEES

As of December 31, 2018, we had three full-time employees, all non-union. We believe that our relations with our employees are good.

COMPETITION

The bio-technology, bio-pharma, and nutraceutical industries are subject to rapid technological change. Competition from domestic and foreign companies, large pharmaceutical companies and other interested businesses is intense and expected to increase. A number of companies with significantly greater resources are pursuing the development of pharmaceuticals, biologics, and nutraceuticals in our targeted areas.

ITEM 1A RISK FACTORS

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

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

Internal Control

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

Our management concluded that as of December 31, 2018 our internal control over financial reporting was not effective, and that material weaknesses existed in the following areas as of December 31, 2018:

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

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

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

Based on our current plan, we believe we will need additional capital to support our operations.

Based on our current business plan, we believe that our cash and cash equivalents at December 31, 2018 will not be sufficient to meet our anticipated cash requirements during the twelve-month period subsequent to the issuance of the financial statements included in this Annual Report on Form 10-K. Our current commercialization of products and clinical trial strategy will undergo continual prioritization and in the future we may adjust our commercialization efforts to preserve our existing cash. We need to raise additional capital to fund our operations. We may raise additional capital through equity offerings, debt financings, collaborations and/or licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or curtail, our operations. To the extent that we raise additional funds by issuing equity securities, our shareholders will experience dilution, and debt financing or other preferred equity instruments, if available, may involve restrictive covenants.

There is substantial doubt about our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2018 with respect to this uncertainty. This going concern uncertainty, and any future going concern uncertainty, could materially limit our ability to raise additional capital. We have incurred significant losses since our inception, and it is possible we will never achieve future profitability. The Company is currently developing its new NanoStilbene product for commercialization. In addition, we are currently seeking regulatory clearance for our subsidiary SandBox's product to treat obstructive sleep apnea in the United States. As a result, we continue to incur significant general and administrative expenses related to our operations. As a result, we have incurred substantial net losses to date. Our net losses for the years ended December 31, 2018 and 2017 were $1.9 million and $0.99 million, respectively. As of December 31, 2018, we had an accumulated deficit of $7.135 million. Meaningful revenues will likely not be available until, and unless, the Company can successfully launch our current TSI product line and our SandBox subsidiary's product is cleared by the FDA and successfully commercialized. The perception that we may not be able to continue as a going concern may cause potential partners or investors to choose not to deal with us due to concerns about our ability to meet our contractual and financial obligations.

SandBox Dental Labs, Inc.

We are subject to FDA regulations which have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. Before we can market or sell our proprietary Sleep Appliance named Morpheus™ in the U.S., we must obtain clearance under Section 510(k) from the FDA.

Emvolio, Inc.

Emvolio, Inc., – was a wholly-owned subsidiary of TSI, incorporated in the State of Delaware on October 3, 2016, for the purpose of filing an Investigation New Drug application with the FDA for our StemVacs immunotherapy vaccine. In May of 2018 President Donald J. Trump signed into the law, the Right To Try bill. Because of this change, Emvolio has decided to withdraw the IND for a Phase 1 trial in the USA because TSI had previously completed a 10 patient trial in Mexico. TSI has since generated GCP documentation for the previously treated 10 patients into a Phase I trial, which will be presented to the FDA by TSI as part of an Ex-US trial compliant with 21 CFR 312.120 Foreign clinical studies not conducted under an IND. Therefore we have dissolved Emvolio, Inc. as it is no longer needed.

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

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

retain additional personnel across several departments in the Company;

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

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

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

establish, maintain, expand and manage multiple relationships with various vendors, strategic partners, licensees and other third parties, including suppliers of the products we sell on our website and elsewhere, warehousing distributors, shipping companies and others;

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

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

expand our IT infrastructure to respond to increasing customer traffic to our website, demand for content from site users and to manage growing e-commerce transactions;

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

control our expenses;

provide competitive employee salaries and benefit packages; and,

avoid lawsuits and other adverse claims.

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

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

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

We face significant competition for our products.

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

- traditional and well established companies with recognized and well patronized brands in the nutritional supplements and health products industry segment;
- entrenched nutritional supplements and health products companies with well known customer on-line services and portals and other high-traffic web sites that provide sales access to healthcare and nutritional supplements and related products; and
- companies that focus on providing on-line and/or off-line healthcare related content, including some that promote competitor brands.

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

Government regulation could adversely affect our business.

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

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

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

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

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

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

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

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

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

Risks Associated With Our Restricted Securities

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

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

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

As a Smaller Reporting Company, we are not required to furnish information under this Item 1B.

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.

From time to time, claims are made against us in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties and unfavorable outcomes could occur, such as monetary damages, fines, penalties or injunctions prohibiting us from selling one or more products or engaging in other activities. The occurrence of an unfavorable outcome in any specific period could have a material adverse effect on our results of operations for that period or future periods.

However, as of the date of this report, management believes the outcome of currently identified potential claims and lawsuits will not have a material adverse effect on our financial condition or results of operations.

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 171 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, 2017 through December 31, 2018.

Quarter Ended	High	Low
December 31, 2018	$0.017	$0.003
September 30, 2018	$0.032	$0.008
June 30, 2018	$0.025	$0.004
March 31, 2018	$0.009	$0.005
December 31, 2017	$0.009	$0.004
September 30, 2017	$0.02	$0.005
June 30, 2017	$0.018	$0.004
March 31, 2017	$0.013	$0.002

Dividends

We did not declare or pay dividends during 2017 to 2018.

Issuances of Unregistered Securities

On January 17, 2017, we issued 12,500,000 shares of common stock, valued at $0.004 per share, for an investment in the Company’s Private Placement to a related party.

On March 2, 2017, we issued 12,500,000 shares of common stock, valued at $0.004 per share, for an investment in the Company's Private Placement to a related party.

On April 3, 2017, we issued 1,000,000 shares of common stock, valued at $0.0067 per share for consulting services.

On April 20, 2017, we issued a six month convertible note in the amount of $100,000 with an annual interest rate of 10% to a related party.

On April 28, 2017, we issued 10,000,000 shares of common stock, valued at $0.008 per share, for legal services and 1,000,000 shares of common stock, valued at $0.004 per share, for an investment in the Company's Private Placement.

On July 6, 2017, we issued 2,000,000 shares of common stock, valued at $0.0083 per share for consulting services.

On July 24, 2017, we issued a six month convertible note in the amount of $28,000 with an annual interest rate of 10%.

On August 21, 2017, we issued 6,250,000 shares of common stock, valued at $0.004 per share, for an investment in the Company's Private Placement and 1,000,000 shares of common stock, valued at $0.0053 per share, for consulting services.

On August 28, 2017, we issued 2,000,000 shares of common stock, valued at $0.0063 per share, for consulting services.

On September 7, 2017, we issued a six month convertible note in the amount of $28,000 with an annual interest rate of 10%.

On September 20, 2017, we issued 3,000,000 shares of common stock, valued at $0.004 per share, for an investment in the Company's Private Placement to a related party.

On October 2, 2017, we issued 2,500,000 shares of common stock, valued at $0.0095 per share for consulting services.

On October 20, 2017, we issued 12,500,000 shares of common stock, valued at $0.004 per share, for an investment in the Company's Private Placement to a related party.

On January 26, 2018, we issued 2,424,242 shares of common stock for the partial conversion of $8,000 for convertible note dated July 24, 2017.

On February 1, 2018, we issued 6,376,471 shares of common stock for the conversion of the balance of $20,000 for convertible note dated July 24, 2017.

On February 1, 2018, we issued 5,000,000 shares of common stock, valued at $0.009 per share, for consulting services.

On February 1, 2018, we issued 2,500,000 shares of common stock, valued at $0.009 per share, for consulting services.

On February 20, 2018, we issued 15,000,000 shares of common stock, valued at $0.004 per share, for an investment in the Company’s Private Placement to a related party.

On February 20, 2018, we issued 2,500,000 shares of common stock, valued at $0.0062 per share, for consulting services.

On April 14, 2018, we issued 2,500,000 shares of common stock, valued at $0.004 per share, for an investment in the Company’s Private Placement to a related party.

On April 14, 2018, we issued 5,000,000 shares of common stock, valued at $0.0057 per share, for consulting services.

On April 27, 2018, we issued 3,225,806 shares of common stock for the partial conversion of $8,000 for convertible note dated September 7, 2017.

On May 1, 2018, we issued 4,137,931 shares of common stock for the partial conversion of $12,000 for convertible note dated September 7, 2017.

On May 2, 2018, we issued 25,000,000 shares of common stock, valued at $0.004 per share, for an investment in the Company's Private Placement to a related party.

On May 21, 2018, we issued 2,742,857 shares of common stock for the partial conversion of $6,000 for convertible note dated September 7, 2017.

On June 15, 2018, we issued 8,500,000 shares of common stock, valued at $0.004 per share, for an investment in the Company's Private Placement.

On July 3, 2018, we issued 5,000,000 shares of common stock, valued at $0.004 per share, for an investment in the Company's Private Placement.

On July 9, 2018, we issued 4,166,667 shares of common stock for the partial conversion of $15,000 for convertible note dated January 3, 2018.

On July 12, 2018, we issued 4,077,778 shares of common stock for the partial conversion of $13,000 for convertible note dated January 3, 2018.

On July 19, 2018, we issued 2,500,000 shares of common stock, valued at $0.015 per share, to a Scientific Advisory Board member for consulting services.

On August 7, 2018, we issued 11,000,000 shares of common stock at $0.011 per share, for consulting services.

On September 5, 2018, we issued 3,260,870 shares of common stock for the partial conversion of $15,000 for convertible note dated February 27, 2018.

On September 10, 2018, we issued 3,262,222 shares of common stock for the partial conversion of $13,000 for convertible note dated February 27, 2018.

On September 19, 2018, we issued 5,000,000 shares of common stock, valued at $0.005 per share, for an investment in the Company's Private Placement.

On September 19, 2018, we issued 1,500,000 shares of common stock, valued at $0.01 per share, to a Scientific Advisory Board member for consulting services.

On October 25, 2018, we issued 15,000,000 shares of common stock, valued at .0071 each to two officers and one director of the Company under a Restricted Stock Award.

On November 15, 2018, we issued 2,500,000 shares of common stock, valued at $0.008 per share, to a Scientific Advisory Board member for consulting services.

On November 23, 2018, we issued 3,805,899 shares of common stock for the partial conversion of $12,000 for convertible note dated May 1, 2018.

On November 26, 2018, we issued 4,347,826 shares of common stock for the partial conversion of $10,000 for convertible note dated May 1, 2018.

On November 28, 2018, we issued 3,657,143 shares of common stock for the partial conversion of $6,000 for convertible note dated May 1, 2018.

On December 7, 2018, we issued 8,823,529 shares of common stock for the partial conversion of $15,000 for convertible note dated June 5, 2018.

On December 14, 2018, we issued 5,882,353 shares of common stock for the partial conversion of $10,000 for convertible note dated June 5, 2018.

On December 17, 2018, we issued 5,870,588 shares of common stock for the partial conversion of $8,000 for convertible note dated June 5, 2018.

On January 3, 2019, we issued 15,000,000 shares of common stock, valued at .0071 each to two officers and one director of the Company under a Restricted Stock Award.

On January 3, 2019, we issued 10,000,000 shares of common stock, valued at $0.005 per share, to a Scientific Advisory Board member for consulting services.

On January 7, 2019, we issued 7,500,000 shares of common stock for the partial conversion of $12,000 for convertible note dated July 2, 2018.

On January 9, 2019, we issued 6,250,000 shares of common stock for the partial conversion of $10,000 for convertible note dated July 2, 2018.

On January 9, 2019, we issued 4,800,000 shares of common stock for the partial conversion of $7,680 for convertible note dated July 2, 2018.

On February 8, 2019, we issued 8,333,333 shares of common stock for the partial conversion of $10,000 for convertible note dated August 6, 2018.

On February 12, 2019, we issued 8,155,556 shares of common stock for the partial conversion of $14,680 for convertible note dated August 6, 2018.

ITEM 6 SELECTED FINANCIAL DATA.

Not required for a “smaller reporting company”.

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis should be read in conjunction with the consolidated Financial Statements and Notes thereto appearing elsewhere in this Annual Report.

Overview

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

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

Critical accounting policies can be found in Note 2 and related party disclosures in Note 9 can be found in the Consolidated Notes to the Financal Statements elsewhere in this Annual Report.

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. TSI filed a patent application for ProJuvenol® on 07-08-2015 titled: "Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions".

Results of Operations

We had a net loss of approximately $1.9 million in 2018 compared to a net loss of approximately $0.99 million in 2017.

Net sales increased $614 from $2,851 to $3,485, for the years ended December 31, 2017 and 2018, respectively. This increase was mainly due to any increase in sales of the Company's nutraceutical line of products.

Cost of goods sold increased $1,334, from $823 to $2,157, for the years ended December 31, 2017 and 2018, respectively. This increase was mainly due an inventory write down in 2018 to higher net sales of the Company's new nutraceutical line of products in 2018 vs 2017

Operating expenses for the years ended December 31, 2018 and December 31, 2017 were approximately $1.201 million and $0.886 million, respectively, an increase of $0.315 million. This increase was mainly due a combination of increased general and administrative expenses, increased salaries, wages and related costs, an increase in consulting fees, a decrease in legal and accounting fees, and an increase in Research and development.

General and administrative expenses increased approximately $298 thousand, from $107 thousand to $405 thousand, for the years ended December 31, 2017 and 2018, respectively. This increase was mainly due to an increase in Restricted Stock Awards granted to two officers and one director during the year.

Salaries, wages and related expenses increased approximately $12 thousand, from $403 thousand to $415 thousand, for the years ended December 31, 2017 and 2018, respectively. This increase was mainly due to an increase in officers' salaries.

Selling expenses decreased approximately $0.8 thousand, from $3.3 thousand to $2.5 thousand, for the years ended December 31, 2017 and 2018, respectively. This decrease was mainly due to decreased selling and marketing expenses related to the Company's nutraceutical line of products.

Consulting fees increased approximately $43 thousand from $70 thousand to $113 thousand for the years ended December 31, 2017 and 2018, respectively, due to an increase in overall consulting services during 2018.

Legal and professional fees decreased approximately $88 thousand, from $278 thousand to $190 thousand for the years ended December 31, 2017 and 2018, respectively, due to a decrease in overall accounting, patent and general counsel services.

Research and Development costs increased approximately $50 thousand, from $25 thousand to $75 thousand, for the years ended December 31, 2017 and 2018, respectively. This increase was mainly due to research and development expenses related to the Company's nutraceutical line of products.

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Loss on derivatives liability increased approximately $304 thousand, from $84 thousand to $388 thousand, for the years ended December 31, 2017 and 2018, respectively. This increase was mainly due to derivative liability increases from certain convertible notes in 2018 compared to 2017.

Change in fair derivatives liabilities increased approximately $11 thousand from $26 to $37 thousand for the years ended December 31, 2017 and 2018, respectively. This increase was due to a derivative liability expense from certain convertible notes in 2018 compared to 2017.

Net interest expense increased approximately $189 thousand from $53 thousand to $242 thousand for the years ended December 31, 2017 and 2018, respectively. This increase was mainly due to increased debt balances.

Liquidity and Capital Resources

We have experienced recurring losses over the past years which have resulted in accumulated deficits of approximately $7.1 million and a working capital deficit of approximately $1.8 million at December 31, 2018. These conditions raise significant doubt about the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is contingent upon its ability to secure additional financing, increase sales of its products and attain profitable operations. It is the intent of management to continue to raise additional capital. However, there can be no assurance that the Company will be able to secure such additional funds or obtain such on terms satisfactory to the Company, if at all.

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.

Off-Balance Sheet Arrangements.

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

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not required for a “smaller reporting company”.

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.

On January 3, 2019, the Board of Directors engaged Fruci & Associates II, PLLC (“Fruci”), as the Company's independent registered public accounting firm for the year ending December 31, 2018. The Company filed a Form 8-K on January 7, 2019 in regard to this change.

ITEM 9A CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

At the end of the period covered by this Annual Report on Form 10-K for the fiscal year ended December 31, 2018, an evaluation was carried out under the supervision of and with the participation of our management, including the Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), of the effectiveness of the design and operations of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act). Based on that evaluation the CEO and the CFO have concluded that as of the end of the period covered by this Annual Report, our disclosure controls and procedures were not effective.

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Internal Control Over Financial Reporting

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

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

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

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

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

Our management, including the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making our assessment, we used the framework and criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") (2013) in Internal Control-Integrated Framework. Based on that assessment, our management has identified certain material weaknesses in our internal control over financial reporting.

Our management concluded that as of December 31, 2018 our internal control over financial reporting was not effective, and that material weaknesses existed in the following areas as of December 31, 2018:

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

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

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

Changes in Internal Control Over Financial Reporting

No substantial changes in our internal control over financial reporting occurred during 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except that we have increased our use of external accounting services, adopted policies to improve timely reviews by management and coordination with accounting consultants, and engaged corporate and securities legal counsel with better capabilities than our previous provider's.

ITEM 9B OTHER INFORMATION.

None

PART III

ITEM 10 DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The Company's executive officers and directors and their respective ages as of December 31, 2018 are as follows:

Directors:

Name of Director	Age
Timothy G. Dixon	60
Gerry B. Berg	72
Dr. Thomas E. Ichim	42

Executive Officers:

Name of Officer	Age	Office
Timothy G. Dixon	60	President & CEO
Gerry B. Berg	72	Vice President & CFO
Hong Ma	49	Chief Science Officer

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

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 SandBox Dental Labs, Inc. Mr. Dixon also served as President and Chairman of Emvolio, Inc. and 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 Director and Chief Financial Officer of SandBox Dental Labs, Inc. Mr. Berg also served as Director and Chief Financial Officer of Emvolio, 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 also served as Chief Executive Officer of Emvolio, Inc. Dr. Ichim is a seasoned biotechnology entrepreneur with a track record of scientific excellence. He has founded/co-founded several companies including Batu Biologics, Inc., Medvax Pharma Corp, ToleroTech, Inc, bioRASI, and OncoMune LLC. To date he has published 99 peer-reviewed articles and is co-editor of the textbooks "RNA Interference: From Bench to Clinical Translation" and "Immuno-Oncology Text Book."

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

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

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

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

Information with Respect to Our Board of Directors

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

Audit Committee Related Function

We do not have a separately designated standing audit committee in place. Our full Board of Directors currently serves in that capacity. This is due to the small number of members of our Board of Directors, the small number of

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

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

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

Compensation Committee Related Function

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

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

Nominating Committee Related Function

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

SCIENTIFIC ADVISORY BOARD

The following are members of the Company's Scientific Advisory Board as of December 31, 2018:

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

Dr. Kesari 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.

He 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. Franceso Marincola is currently Chief Science Officer at Refuge Biotechnologies, Menlo Park, California. Most recently, he served as a distinguished research fellow and strategist for immune oncology discovery at AbbVie, Inc Previously, he was the Inaugural Chief Research Officer of Sidra Medical and Research Centre in Doha, Qatar. He was previously a tenured Senior Investigator at the U.S. National Institutes of Health. He is past-President of the Society for the Immunotherapy of Cancer and Editor-in-Chief of the Journal of Translational Medicine.

Dr. Marincola received his MD summa cum laude from the University of Milan and did his surgery training at Stanford University, California. His scientific work deepened the understanding of the mechanisms leading to rejection of tumors or transplanted organs by the immune system and development of autoimmunity. With over 500 peer-reviewed scientific papers, Dr. Marincola is considered one of the world's leading experts in cancer immunotherapy.

Dr. Pablo Guzman, is a cardiologist in Fort Lauderdale, Florida where he is on staff at Holy Cross Hospital. He received his medical degree from University of Puerto Rico School of Medicine and his Cardiology Fellowship at The Johns Hopkins Hospital where he then spent the first part of his career continuing his basic science and clinical research along with his clinical duties. His CV includes over 25 papers published in peer reviewed journals and more

than 15 abstracts.

He is a Fellow of the American College of Cardiology and practiced for more than 30 years. Dr. Guzman is well experienced in basic and clinical research, having participated in many clinical trials. He is also the acting Chief Medical Officer of Variant Pharmaceuticals, a Specialty Pharma company developing treatments for kidney diseases.

Dr. Juergen Winkler is presently practicing at Quantum Functional Medicine in Carlsbad, CA, which he founded in July of 2012. In 2005 he was the co-founder of Genesis Health Systems (Integrative Cancer and Medical Treatment Center) located in Oceanside, CA. He has been a featured speaker for: the NSCC Women's Health Seminar, Annual IPT/IPTLD Integrative Cancer Care Conference (Multiple years), Health Freedom Expo 2011 & 2012, the Japanese Society of Oxidative Medicine in Osaka Japan, ACOSPM 2010 & 2011 conferences, NSCC Health and Wellness Series 2013, and various other events. He is the physician author of Chapter 5 in the Defeat Cancer book and has been a featured physician in the Townsend Letter.

Dr. Nassir Azimi is a cardiologist in La Mesa, California and attended Dartmouth Medical School and completed his residency at the University of Colorado. He finished his four year fellowship in Cardiovascular and Peripheral Interventions at Yale University in New Haven. Dr. Azimi has been in private practice for over 13 years establishing a thriving clinical practice for cardiac patients as well as treating patients for peripheral vascular disease. He is active in Interventional Cardiology and Peripheral Interventions. Dr. Azimi is the director of La Mesa Cardiac Center's Nuclear Cardiology Laboratory. He is also an investigator in multiple clinical research studies for various cardiac and peripheral diseases.

He has been recognized as San Diego's Top Interventional Cardiologists by San Diego Magazine 2013,2014,2016, 2017 and also by Castle Connoly for 2013, 2014, 2015,2016, 2017, and 2018. He is a former chief of biomedical ethics (6 years), former chief of Medicine and former chief of Endovascular Medicine as well as Vice Chief of Cardiology at SGH. He is on the board of directors of the California ACC where he serves as chair of the public relations committee. He is on Editorial Review Board for multiple medical journals. He is a national speaker on various topics in cardiology and internal medicine.

Dr. James Veltmeyer, is a board certified family physician in La Mesa, California. A graduate of UC San Diego and the Ross University School of Medicine, he completed his residency through the UC San Francisco system where he became Chief of Family Medicine Residency, overseeing 36 doctors.

Dr. Veltmeyer, a member of the San Diego Critical Care Medical Group, has been elected for four years (2012, 2014, 2016, and 2017) by his colleagues in the San Diego County Medical Society as a "Physician of Exceptional Excellence," the most prestigious honor awarded to a "Top Doctor" in San Diego County. He is among a select group of San Diego physicians who was chosen four of the last fifteen years and he consistently ranks in the top 1% to 2% for patient satisfaction. He is currently the Chief of the Department of Family Medicine at Sharp Grossmont Hospital where he provides senior leadership to over 200 doctors.

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. 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, 2018, 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, 2018 and 2017 for services rendered to us in all capacities, to each person who served as an executive officer of the Company.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Nonequity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Timothy G. Dixon	2018	174,000 (1)	-	106,500	-	-	-	280,500
President and CEO	2017	165,000 (2)	-	-	-	-	-	165,000
Gerry B. Berg	2018	174,000 (3)	-	106,500	-	-	-	280,500
Vice President, Chief Financial Officer	2017	165,000 (4)	-	-	-	-	-	165,000

(1) $136,000 was accrued and unpaid as of December 31, 2018

(2) $130,500 was accrued and unpaid as of December 31, 2017

(3) $136,000 was accrued and unpaid as of December 31, 2018

(4) $130,500 was accrued and unpaid as of December 31, 2017

Outstanding Equity Awards

None

Employment Agreements

We do not have any employment agreements as of December 31, 2018.

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 December 31, 2018, 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 December 31, 2018, a total of 1,011,063,182 shares of our common stock were outstanding.

Name of Beneficial Owners	Amount and Nature of Beneficial Ownership	Percent of Shares Outstanding
Timothy G. Dixon (1)	136,475,671	13.50%
Gerry B. Berg (2)	122,750,000	12.14%
Thomas E. Ichim (3)	33,500,000	3.31%
Robert F. Graham	102,500,000	10.14%
John Peck, Jr.	217,500,000	21.51%
All directors and executive officers as a group (3 persons) (1)(2)(3)	398,337,510	39.40%

(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 officers of the Company. As of December 31, 2018 we disclose that we had no independent directors.

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 fees billed to us by Fruci & Associates II, PLLC , for auditing and accounting services for December 31, 2018 was $37,000.

The aggregate fees billed to us by Squar Milner LLP, for auditing and accounting services through September 30, 2018 was $44,280 (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 2018 and 2017 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 15EXHIBITS 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 DESCRIPTION

NUMBER	
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
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: April 15, 2019

/s/ Timothy G. Dixon
Timothy G. Dixon
Chief Executive Officer, President and Director (Principal Executive Officer)
Date: April 15, 2019

/s/ Gerry B. Berg
Gerry B. Berg
Vice President, Chief Financial Officer and Director (Principal Financial and Accounting Officer)
Date: April 15, 2019

/s/ Thomas E. Ichim
Thomas E. Ichim
Director
Date: April 15, 2019

F-1

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Therapeutic Solutions International, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Therapeutic Solutions International, Inc. and its subsidiaries (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations, changes in shareholders' deficit, and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has a history of significant recurring losses from operations through December 31, 2017, and does not have sufficient working capital to fund its planned operations during the twelve-month period subsequent to the issuance of these financial statements. This raises substantial doubt about the Company’s ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material

misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Squar Milner LLP

SQUAR MILNER LLP

We have served as the Company’s auditor since 2016.

San Diego, California

April 17, 2018

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,397	$ 29
Inventory	-	1,515
Prepaid expenses and other current assets	113,521	1,054
Total current assets	135,918	2,598
Other assets	71,013	23,927
Total assets	$ 206,931	$ 26,525
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 320,812	$ 343,810
Accounts payable-related parties	7,981	-
Accrued expenses and other current liabilities	717,723	432,640
Convertible notes payable, net of discount of $105,556 and $28,541, at December 31, 2018 and 2017, respectively	45,784	27,459
Notes payable-related parties	458,487	429,201
Derivative liabilities	466,612	107,769
Total current liabilities	2,017,399	1,340,879
Commitments and contingencies	-	-
Shareholders' Deficit:		
Preferred stock, $ 0.001 par value; 5,000,000 shares authorized	-	-
Common stock, $ 0.001 par value; 2,500,000,000 and 990,000,000 shares authorized at December 31, 2018 and 2017, respectively; 1,011,063,182 and 806,501,000 shares issued and outstanding at December 31, 2018 and 2017, respectively.	1,011,063	806,501
Additional paid-in capital	4,314,047	3,147,811
Accumulated deficit	(7,135,578)	(5,268,666)

Total shareholders' deficit	(1,810,468)	(1,314,354)
Total liabilities and shareholders' deficit	$ 206,931	$ 26,525

See accompanying notes to consolidated financial statements.

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.
Consolidated Statements of Operations

	For the Year Ended December 31, 2018	For the Year Ended December 31, 2017
Net Sales	$ 3,484	$ 2,851
Cost of Goods Sold	2,157	823
Gross Profit	1,327	2,028
Operating expenses:		
General and administrative	405,871	107,380
Salaries, wages, and related costs	415,072	402,758
Selling expenses	2,493	3,310
Consulting fees	112,877	69,672
Legal and professional fees	189,853	278,069
Research and development	74,970	25,106
Total operating expenses	1,201,136	886,295
Loss from operations	(1,199,809)	(884,267)
Other income (expense):		
Loss on derivatives liability	(388,121)	(83,968)
Change in fair value of derivative liability	(37,230)	26,199
Interest expense	(241,752)	(53,436)
Total other income (expense)	(667,103)	(111,205)
Net loss	$ (1,866,912)	$ (995,472)
Net loss per share - basic and diluted	$ (0.00)	$ (0.00)
Weighted average shares outstanding –		
Basic and Diluted	896,851,647	778,150,315

See accompanying notes to consolidated financial statements.

Therapeutic Solutions International, Inc.
Consolidated Statements of Changes in Shareholders' Deficit
For the Years Ended December 31, 2018 and 2017

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2017	**740,251,000**	**$ 740,251**	**$ 2,878,111**	**$ (4,273,194)**	**$ (654,832)**
Common stock issued for services	18,500,000	18,500	126,450	-	144,950
Common stock issued	47,750,000	47,750	143,250	-	191,000
Net Loss	-	-	-	(995,472)	(995,472)
Balance at December 31, 2017	**806,501,000**	**$ 806,501**	**$ 3,147,811**	**$ (5,268,666)**	**$1,314,354)**
Common stock issued for services	77,500,000	77,500	545,750	-	623,250
Common stock issued upon conversion of convertible note payable	66,062,182	66,062	432,486	-	498,548
Common stock sold	61,000,000	61,000	188,000	-	249,000
Net Loss	-	-	-	(1,866,912)	(1,866,912)
Balance at December 31, 2018	**1,011,063,182**	**$ 1,011,063**	**$ 4,314,047**	**$ (7,135,578)**	**$1,810,468)**

See accompanying notes to consolidated financial statements

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.
Consolidated Statements of Cash Flows

	For the Year Ended December 31, 2018	For the Year Ended December 31, 2017
Cash flows from operating activities		
Net loss	$ (1,866,912)	$ (995,472)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation to consultants	303,750	144,950
Stock based compensation to related parties	319,500	-
Accrued interest, notes payable	10,380	28,414
Accounts payable, related parties	7,981	-
Loss on derivative liability	388,121	83,968
Change in fair value of derivative liabilities	37,230	(26,199)
Amortization of debt discount	194,985	27,459
Changes in operating assets and liabilities:		
Inventory	1,515	34,920
Prepaid expenses and other current assets	(112,467)	13,250
Other assets	(47,086)	8,299
Accounts payable	(22,998)	16,218
Accrued expenses and other current liabilities	316,829	297,476
Net cash used by operating activities	(469,172)	(366,717)
Cash flows from financing activities		
Proceeds from issuance of common stock	249,000	191,000
Proceeds from convertible notes payable	245,000	50,000
Proceeds from notes payable - related parties	-	105,721
Payments on notes payable - related parties	(2,460)	(1,885)
Net cash provided by financing activities	491,540	344,836
Net increase (decrease) increase in cash, cash equivalents and restricted cash	22,368	(21,881)
Cash, cash equivalents and restricted cash at beginning of period	10,202	32,083
Cash, cash equivalents and restricted cash at end of period	$ 32,570	$ 10,202

Supplemental Cash Flow Information:				
Cash paid for interest	$	4,608	$	3,565
Cash paid for income taxes	$	1,600	$	-
Non-cash investing and financing transactions				
Original issuance discount on convertible notes payable	$	27,000	$	6,000
Debt discount recorded in connection with derivative liability	$	245,000	$	50,000
Common stock issued in payment of convertible note payable	$	498,548	$	-
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:				
Cash and cash equivalents	$	22,397	$	29
Restricted cash included in other assets		10,173		10,156
Total cash, cash equivalents, and restricted cash shown in the consolidated statements of cash flows:	$	32,570	$	10,185