

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

Form 10-Q

July 05, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2017

.. 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

**(State or Other Jurisdiction of
Incorporation or Organization)**

45-1226465

(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)

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

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

Indicate by check mark 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	<input type="checkbox"/>	Non-Accelerated Filer	<input type="checkbox"/>
		(Do not check if a smaller reporting company)	
Accelerated Filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

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

As of July 5, 2017, the Registrant had 777,251,000 outstanding shares of Common Stock with a par value of \$0.001 per share.

IMPORTANT PREFATORY NOTE

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this report and the information incorporated by reference herein may contain forward-looking statements (as such term is defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended). These statements, which involve risks and uncertainties, reflect our current expectations, intentions, or strategies regarding our possible future results of operations, performance, and achievements. Forward-looking statements include, without limitation: statements regarding future products or product development; statements regarding future selling, general and administrative costs and research and development spending; statements regarding our product development strategy; and statements regarding future financial performance, results of operations, capital expenditures and sufficiency of capital resources to fund our operating requirements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and applicable rules of the Securities and Exchange Commission and common law.

These forward-looking statements may be identified in this report and the information incorporated by reference by words such as anticipate, believe, could, estimate, expect, intend, plan, predict, project, should, expressions, including references to assumptions and strategies. These statements reflect our current beliefs and are based on information currently available to us. Accordingly, these statements are subject to certain risks, uncertainties, and contingencies, which could cause our actual results, performance, or achievements to differ materially from those expressed in, or implied by, such statements.

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.

.

Other factors not specifically described above, including the other risks, uncertainties, and contingencies described under Description of Business , Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations in Items 1 and 7 of our Annual Report on Form 10-K for the year ended December 31, 2016.

When considering these forward-looking statements, you should keep in mind the cautionary statements in this report and the documents incorporated by reference. We have no obligation and do not undertake to update or revise any such forward-looking statements to reflect events or circumstances after the date of this report.

Actual results may vary materially from those in such forward-looking statements as a result of various factors. No assurance can be given that the risk factors described in this Quarterly Report on Form 10-Q are all of the factors that could cause actual results to vary materially from the forward-looking statements. References in this Quarterly Report on Form 10-Q to the Company, TSOI, we, our, and us refer to Therapeutic Solutions International, Inc.

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

INDEX

	<u>PAGE</u>
<u>PART I. Financial Information</u>	
Item 1. Financial Statements (Unaudited)	4
Condensed Consolidated Balance Sheets as of March 31, 2017 and December 31, 2016	4
Condensed Consolidated Statements of Operations for the three months ended March 31, 2017 and March 31, 2016	5
Condensed Consolidated Statement of Changes in Shareholders' Deficit for the Period from January 1, 2017 to March 31, 2017	6
Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2017 and March 31, 2016	7
Notes to Condensed Consolidated Financial Statements	8
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	11
Item 3. Quantitative and Qualitative Disclosures about Market Risk	18
Item 4. Controls and Procedures	18
<u>PART II. Other Information</u>	
Item 1. Legal Proceedings	19
Item 1A. Risk Factors	19
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	19
Item 3. Defaults upon Senior Securities	20
Item 4. Mine Safety Disclosures	20
Item 5. Other Information	20
Item 6. Exhibits	20
Signatures	20

PART I Financial Information

Item 1.

Financial Statements

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

	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,100	\$ 21,910
Inventory	35,471	36,435
Prepaid expenses and other current assets	3,231	14,304
Total current assets	44,802	72,649
Other non-current assets	38,490	32,226
Total assets	\$ 83,292	\$ 104,875
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 326,353	\$ 327,592
Accrued expenses and other current liabilities	195,718	135,164
Notes payable-related parties, current portion	225,003	221,451
Total current liabilities	747,074	684,207
Notes payable-related parties, less current portion	77,000	75,500
Shareholders' Deficit:		
Preferred stock, \$ 0.001 par value; 5,000,000 shares authorized	-	-
Common stock, \$ 0.001 par value; 990,000,000 shares authorized; 765,251,000 and 740,251,000 shares	765,251	740,251

issued and outstanding at March 31,
2017 and December 31, 2016,
respectively.

Additional paid-in capital	2,953,111	2,878,111
Accumulated deficit	(4,459,144)	(4,273,194)
Total shareholders' deficit	(740,782)	(654,832)
Total liabilities and shareholders' deficit	\$ 83,292	\$ 104,875

See accompanying notes to condensed consolidated financial statements.

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

	For the Three Months Ended March 31, 2017	For the Three Months Ended March 31, 2016
Net Sales	\$ 548	\$ 530
Cost of Goods Sold	198	140
Gross Profit	350	390
Operating expenses:		
Selling, general and administrative	18,271	13,110
Salaries, wages, and related costs	89,431	88,388
Consulting fees	-	108,400
Legal and professional fees	51,490	16,146
Research and development	20,926	-
Total operating expenses	180,118	226,044
Loss from operations	(179,768)	(225,654)
Other expense:		
Interest expense	(6,182)	(3,134)
Total other expense	(6,182)	(3,134)
Net loss	\$ (185,950)	\$ (228,788)
Net loss per share - basic and diluted	\$ (0.00)	\$ (0.00)
Weighted average shares outstanding		
basic and diluted	751,767,854	569,538,341

See accompanying notes to condensed consolidated financial statements.

Therapeutic Solutions International, Inc.
Condensed Consolidated Statements of Changes in Shareholders' Deficit
For the 3 month period ended March 31, 2017
(Unaudited)

	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)
Stock issued on January 17, 2017	12,500,000	12,500	37,500	-	50,000
Stock Issued on March 2, 2017	12,500,000	12,500	37,500	-	50,000
Net Loss	-	-	-	(185,950)	(185,950)
Balance at March 31, 2017	765,251,000	\$ 765,251	\$ 2,953,111	\$ (4,459,144)	\$ (740,782)

See accompanying notes to condensed consolidated financial statements

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For the Three Months Ended March 31, 2017	For the Three Months Ended March 31, 2016
Cash flows from operating activities		
Net loss	\$ (185,950)	\$ (228,788)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation to consultants	-	63,853
Accrued interest, notes payable - related parties	5,436	2,336
Changes in operating assets and liabilities:		
Inventory	965	140
Accounts receivable	-	1,896
Prepaid expenses and other current assets	11,072	134,170
Other non-current assets	(6,264)	(16,353)
Accounts payable	(1,239)	(410)
Accrued expenses and other current liabilities	60,554	1,574
Net cash used in operating activities	(115,426)	(41,582)
Cash flows from financing activities		
Proceeds from issuance of common stock	100,000	274,500
Repayments of notes payable related parties	(384)	(692)
Net cash provided by financing activities	99,616	273,808
Net (decrease) increase in cash	(15,810)	232,226
Cash at beginning of period	21,910	2,183
Cash at end of period	\$ 6,100	\$ 234,409
Supplemental Cash Flow Information:		
Cash paid for interest	\$ 745	\$ 797

See accompanying notes to condensed consolidated financial statements.

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2017

Note 1 Organization and Business Description

Therapeutic Solutions International, Inc. (TSOI 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 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.

TSOI 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 TSOI 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 . In addition we recently introduced a line of oncologist friendly nutraceuticals in liposome formula. These include CoQ10, Curcumin, Glutathione, and Vitamin-C in 16oz bottles.

TSOI has experienced recurring losses over the past years which have resulted in accumulated deficits of approximately \$4,459 thousand and a working capital deficit of approximately \$702.3 thousand at March 31, 2017. These conditions raise uncertainty about the Company s ability to continue as a going concern. The Company s ability to continue as a going concern is contingent upon its ability to secure additional financing, increase sales of its products and attain profitable operations. It is the intent of management to continue to raise additional capital.

However, there can be no assurance that the Company will be able to secure such additional funds or obtain such on terms satisfactory to the Company, if at all. The accompanying consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Note 2 Summary of Significant Accounting Policies

During the three months ended March 31, 2017, there have been no changes to the Company's significant accounting policies as described in the Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC on June 7, 2017.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 8 of the Securities and Exchange Commission (SEC) Regulation S-X, and should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2016, included in the Company's Annual Report on Form 10-K filed with the SEC on June 7, 2017. The accompanying unaudited condensed consolidated financial statements include the accounts of TSOI and its subsidiaries. All significant inter-company transactions and balances have been eliminated in consolidation. The unaudited condensed consolidated financial statements contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the balances and results for the interim period included herein. The results of operations for the three months ended March 31, 2017 and 2016 are not necessarily indicative of the results to be expected for the full year or any future interim periods. The accompanying condensed consolidated balance sheet at December 31, 2016 has been derived from the audited consolidated balance sheet at December 31, 2016, contained in the above referenced Form 10-K.

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2017

Use of Estimates

Estimates were made relating to valuation allowances, impairment of assets, share-based compensation expense and accruals. Actual results could differ materially from those estimates.

Comprehensive Loss

Comprehensive loss for the periods reported was comprised solely of the Company's net loss.

Net Loss Per Share

Basic net loss per share is calculated based on the weighted-average number of common shares outstanding. Diluted net loss per share is calculated using the weighted-average number of common shares outstanding plus common stock equivalents. Common stock equivalents are excluded from the calculation of diluted net loss per share when their effect is anti-dilutive. As of March 31, 2017 and 2016, outstanding common stock equivalents were not material.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new standard requires lessees to recognize most leases on their balance sheets as lease liabilities with corresponding right-of-use assets and eliminates certain real estate-specific provisions. ASU 2016-02 will be effective for the Company in the first quarter of 2019 and will be adopted on a modified retrospective transition basis for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). The new standard is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 will be effective for the Company in the first quarter of 2018 and allows for full retrospective or a modified retrospective adoption approach. The adoption of this standard is not expected to have a material impact on the Company's financial position or results of operations.

Note 3 Restricted Cash

Other non-current assets include a \$10,000 certificate of deposit with an annual interest rate of 0.6%. This certificate matures on June 17, 2018, and is used as collateral for a Company credit card, pursuant to a security agreement dated June 20, 2011.

Note 4 Notes Payable-Related Party

At March 31, 2017 and December 31, 2016, the Company has unsecured interest bearing demand notes outstanding to certain officers and directors amounting to \$302,003 and \$296,951, respectively. Interest accrued on these notes during the three months ended March 31, 2017 and 2016 was \$5,436 and \$2,336, respectively. At March 31, 2017 and December 31, 2016, \$77,000 and \$75,500, respectively, was classified as long-term.

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2017

Note 5 Subsequent Events

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 May 8, 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.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis contains forward-looking statements within the meaning of the federal securities laws. The safe harbor provided in section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934 ("statutory safe harbors") shall apply to forward-looking information provided pursuant to the statements made in this filing by the Company. We urge you to carefully review our description and examples of forward-looking statements included in the section entitled "Cautionary Note Regarding Forward-Looking Statements" at the beginning of this report. Forward-looking statements speak only as of the date of this report and we undertake no obligation to publicly update any forward-looking statements to reflect new information, events or circumstances after the date of this report. Actual events or results may differ materially from such statements. In evaluating such statements, we urge you to specifically consider various factors identified in this report, any of which could cause actual results to differ materially from those indicated by such forward-looking statements. The following discussion and analysis should be read in conjunction with the accompanying financial statements and related notes, as well as the Financial Statements and related notes in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and the risk factors discussed therein.

General

Our principal executive office is located at 4093 Oceanside Blvd., Suite B, Oceanside, California 92056, our telephone number is (760) 295-7208 and our website is www.therapeuticsolutionsint.com. The reference to our website does not constitute incorporation by reference of the information contained on our website.

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

DESCRIPTION OF BUSINESS

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.

TSOI 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 TSOI 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. In addition we recently launched 4 new products in Liposomal formulation. They are CoQ10, Curcumin, Glutathione, and Vitamin-C in 16oz bottles.

OmniBiome, Inc., (OMNI) - is a majority-owned subsidiary of TSOI, incorporated in the State of Delaware on October 20, 2015, where the intellectual property surrounding probiotics is housed. OMNI is focused on therapeutic / RX approaches to either utilize or intervene with systemic effects of the vaginal, lactal-duct and oral microbiomes for improving maternal healthcare and resulting birth outcomes. The Officers and Directors of the Company are also Officers and Directors of OMNI. As of March 31, 2017 and June xx, 2017, TSOI owns approximately 73.75% of the outstanding share of OMNI. As of March 31, 2017 and July 5, 2017, formal operations have not commenced.

Emvolio, Inc., (EMVO) is a wholly-owned subsidiary of TSOI, incorporated in the State of Delaware on October 3, 2016, where the intellectual property surrounding immune-oncology is housed. EMVO intends to develop products that can be used together to attack cancer at different levels, as well as to be used alone or in combination with existing therapies. The Officers and Directors of the Company are also the Officers and Directors of EMVO. As of March 31, 2017 and July 5, 2017, formal operations have not commenced.

SandBox Dental Labs, Inc., is a wholly-owned subsidiary of TSOI 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. The Officers and Directors of the Company are also the Officers and Directors of SandBox. As of March 31, 2017 and July 5, 2017, formal operations have not commenced.

Nutraceutical Division (TSOI)

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

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

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

Patents:

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

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

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

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

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.

TSOI markets currently several other nutraceuticals, they include T-Rx[®], a testosterone booster, and Vital[®] Female an estrogen enhancer, Liposomal CoQ10, Curcumin, and Vitamin-C, all powerful antioxidants.

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

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

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

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

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

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

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

On June 22, 2016 the Company announced the addition of four new consumer products to our nutraceutical division.

The four new products are all be in Liposome formulas. Many orally consumed nutrients are absorbed from 4% to 19%! Those same nutrients in a Liposomal Delivery System are absorbed at a much higher level in the bloodstream. Liposomes have layers that can encapsulate an ingredient and serve to protect the ingredient from the environment as well as act as a slow release mechanism. A liposome is a microscopic, fluid-filled pouch whose walls are made of layers of phospholipids identical in makeup to the phospholipids that make up cell membranes.

Liposomes represent a versatile and advanced nanodelivery system for a wide range of biologically active compounds. Liposomes have been used to improve the therapeutic index of new or established ingredients by modifying their absorption, reducing metabolism, and prolonging biological half-life.

Liposomes can be used to deliver substances to the blood stream and even target cells much more efficiently than normal. The liposomes offer a unique delivery system for nutrients because these microscopic spheres are so tiny that absorption becomes almost perfect.

The four new high absorption formulas are Liposomal Vitamin-C, CoQ10, Curcumin, and Glutathione, sold in 16oz bottles.

FUTURE BUSINESS DESCRIPTION

Dental

SandBox Dental Labs, Inc.

SandBox Dental Labs, Inc., is a wholly-owned subsidiary of TSOI 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. The Officers and Directors of the Company are also Officers and Directors of EMVO. As of March 31, 2017 and July 5, 2017, formal operations have not commenced.

Fetal-Maternal Health

OmniBiome, Inc.

OmniBiome, Inc. (OMNI), a majority-owned subsidiary of TSOI, is focused on therapeutic / Rx approaches to either utilize or intervene with the systemic effects of the vaginal, lactal-duct and oral microbiomes for improving maternal healthcare and resulting birth outcomes. The Officers and Directors of the Company are also officers and Directors of OMNI. As of March 31, 2017 and July 5, 2017, TSOI owns approximately 73.75% of the outstanding shares of OMNI. As of March 31, 2017 and July 5, 2017 operations have not commenced.

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

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

MicroBiome Targets

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

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

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

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

Licensed Patents

Omni is the licensee of the following patents:

Patent titled "Prevention of Pregnancy Complications by Probiotic Administration."

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

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

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

Immune-Oncology

Emvolio, Inc.

Emvolio, Inc., (EMVO) is a wholly-owned subsidiary of TSOI where the intellectual property surrounding immune-oncology is housed. The Company intends to develop products that can be used together to attack cancer at different levels, as well as to be used alone or in combination with existing therapies. The Officers and Directors of the Company are also Officers and Directors of EMVO. As of March 31, 2017 and July 5, 2017, formal operations have not commenced.

On April 10, 2017, TSOI licensed to EMVO a patent titled "Targeting the Tumor Microenvironment through Nutraceutical Based Immunoadjuvants" known clinically as "StemVacs".

On April 12, 2017, EMVO filed an Investigational New Drug (IND) application for use of its StemVacs cancer immunotherapeutic licensed to EMVO by TSOI, in patients with solid tumors. The trial seeks to establish safety and immune response of the cancer, targeting a new personalized dendritic cell vaccine.

On May 01, 2017, TSOI licensed to EMVO a patent titled "Targeting the Tumor Microenvironment through Nutraceutical Based Immunoadjuvants" known clinically as "Cancer Metabolic Detox".

On May 17, 2017, TSOI licensed to EMVO a patent titled "Activated Leukocyte Extract for Repair of Innate Immunity in Cancer Patients" known clinically as "innaMune".

On June 01, 2017, TSOI licensed to EMVO a patent titled "Augmentation of Anti-Tumor Immunity by Mifepristone and Analogues Thereof" known clinically as "LymphoBoost".

On June 12, 2017, TSOI licensed to EMVO a patent titled "Methods of Re-Activating Dormant Memory Cells with Anticancer Activity" known clinically as "MemoryMune".

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.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting

principles. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

There have been no material changes to the critical accounting policies as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the SEC on June 7, 2017.

Recent Accounting Pronouncements

Recent accounting pronouncements are disclosed in Note 2 to the accompanying unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations

You should read the following discussion of our financial condition and results of operations together with the unaudited financial statements and the notes to the unaudited financial statements included in this quarterly report. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results may differ materially from those anticipated in these forward-looking statements.

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.

Nutraceutical Division TSOI 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. In addition we recently introduced a line of oncologist friendly nutraceuticals in liposome formula. These include CoQ10, Curcumin, Glutathione, and Vitamin-C in 16oz bottles.

For the three months ended March 31, 2017 and 2016

We had a net loss of approximately \$186.0 thousand for the three months ended March 31, 2017 compared to a net loss of approximately \$228.8 thousand for the three months ended March 31, 2016.

Net sales slightly increased \$18, from \$530 to \$548, for the three months ended March 31, 2016 and March 31, 2017, respectively.

Cost of goods sold increased \$58, from \$140 to \$198, for the three months ended March 31, 2016 and March 31, 2017, respectively.

Total operating expenses for the three month ended March 31, 2017 and 2016 were \$180,118 and \$226,044, a decrease of \$45,926. This was mainly due to a combination of decreased consulting fees and increased general and administrative costs and legal expenses.

Selling, general and administrative expenses increased \$5,161, from \$13,110 to \$18,271 for the three months ended March 31, 2016 and 2017, respectively. This increase was mainly due to increases in overall operating expenses.

Salaries, wages and related expenses increased \$1,043, from \$88,388 to \$89,431 for the three months ended March 31, 2016 and 2017, respectively. This increase was mainly due to an increase in salary related expenses.

Consulting fees decreased \$108,400 from \$108,400 to \$0 for the three months ended March 31, 2016 and 2017, respectively, due to no consulting services for three months ended March 31, 2017.

Legal and professional fees increased \$35,344, from \$16,146 to \$51,490 for the three months ended March 31, 2016 and 2017, respectively, due to an increase in independent public accounting fees and legal expense.

Research and Development costs increased \$20,926, from \$0 to \$20,926, for the three months ended March 31, 2016 and 2017, respectively. This increase was mainly due to research and development expenses related to the Company's new products in 2017.

Net interest expense increased \$3,048 from \$3,134 to \$6,182 for the three months ended March 31, 2016 and 2017, 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 \$4.5 million and a negative working capital of approximately \$702.3 thousand at March 31, 2017. 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.

As of March 31, 2017, our cash and cash equivalents were \$6,100 compared to \$21,910 at March 31, 2016. Our current cash reserves are not adequate to fund our operations for the 12 month period subsequent to the issuance of our financial statement contained in Item 1. Cash used in operating activities for the three months ended March 31, 2017 was \$115.4 thousand, compared to \$41.6 thousand for the same period in 2016. The increase was primarily due to decreased prepaid expenses, and increased accrued expenses and other current liabilities. For the three months ended March 31, 2017 net cash provided in financing activities was \$99.6 thousand, compared to \$273.8 thousand for the same period in 2016. The decrease was mainly due a decrease in the issuance of common stock. At March 31, 2017, we had negative working capital of \$702.3 thousand, compared to negative working capital of \$612.0 thousand at December 31, 2016. This increase was mainly due to an overall increase in current liabilities. The Company plans to continue to reduce costs and seek additional funding for operations.

There is no guarantee we will receive the required financing to complete our business strategies, and it is uncertain whether future financing will be available to us on acceptable terms. If financing is not available on satisfactory terms, we may be unable to continue, develop or expand our operations. Our independent registered public accounting firm has stated in their opinion on our 2016 annual financial statements dated June 7, 2017, that there is substantial doubt about our ability to continue as a going concern.

Off Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As a Smaller Reporting Company as defined by Rule 12b-2 of the Exchange Act and in Item 10(f)(1) of Regulation S-K, we are electing scaled disclosure reporting obligations and therefore are not required to provide this information requested by this item.

Item 4. Controls and Procedures

A. Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, or Exchange Act, our principal executive officer and principal financial officer evaluated our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of March 31, 2017. Based on this evaluation, these officers concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q, these disclosure controls and procedures were not operating effectively to ensure that the information required to be disclosed by the Company in reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and include controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

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

B. Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended March 31, 2017 that materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

Our management, including the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of March 31, 2017. In making our assessment, we used the framework and criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013). Based on that assessment, our management has identified certain material weaknesses in our internal control over financial reporting.

Our management concluded that as of March 31, 2017 our internal control over financial reporting was not effective, and that material weaknesses existed in the following areas as of March 31, 2017:

(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 insufficient accounting staff.

PART II - OTHER INFORMATION

Item 1. 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 1A. Risk Factors

No material changes to risk factors have occurred as previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the SEC on June 7, 2017.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

.

On January 4, 2016, we issued 2,500,000 shares of common stock, valued at \$0.0025 per share, for consulting services.

On January 22, 2016, we issued 2,500,000 shares of common stock, valued at \$0.0035 per share, for consulting services to a Director of the Company.

On February 1, 2016, we issued 2,500,000 shares of common stock, valued at \$0.003 per share, for consulting services.

Edgar Filing: THERAPEUTIC SOLUTIONS INTERNATIONAL, INC. - Form 10-Q

On February 5, 2016, we issued 8,000,000 shares of common stock, valued at \$0.0025 per share, for an investment in the Company's Private Placement.

On February 22, 2016, we issued 5,451,000 shares of common stock, valued at \$0.003 per share, in regard to a License Agreement (Form 8-K filed on February 25, 2016).

On February 26, 2016, we issued 1,000,000 shares of common stock, valued at \$0.0025 per share, for an investment in the Company's Private Placement from a Director of the Company.

On March 7, 2016, we issued 10,000,000 shares of common stock, valued at \$0.0025 per share, for consulting services.

On March 21, 2016, we issued 100,000,000 shares of common stock, valued at \$0.0025 per share, for an investment in the Company's Private Placement to a Related Party.

On March 21, 2016, we issued 800,000 shares of common stock, valued at \$0.0025 per share, for an investment in the Company's Private Placement.

On May 2, 2016, we issued 1,000,000 shares of common stock, valued at \$0.0025 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 May 26, 2016, we issued 2,500,000 shares of common stock, valued at \$0.0066 per share, for consulting services.

On May 26, 2016, we issued 2,000,000 shares of common stock, valued at \$0.0025 per share, for an investment in the Company's Private Placement.

On May 31, 2016, we issued 2,500,000 shares of common stock, valued at \$0.0066 per share, for legal services.

On September 16, 2016, 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 October 18, 2016, we issued 40,000,000 shares valued at \$0.0045 to the officers and directors of the Company for services, and 5,000,000 shares valued at \$0.0045 for consulting services to a related party.

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 May 8, 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.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

No disclosure required.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT

NUMBER DESCRIPTION

- | | |
|------|---|
| 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 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.

Date: July 5, 2017

By: */s/ Timothy G. Dixon*
Timothy G. Dixon
President and Chief Executive Officer

(Principal Executive Officer)

Date: July 5, 2017

By: */s/ Gerry B. Berg*
Gerry B. Berg

Chief Financial Officer

(Principal Financial Officer)