

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.  
Form 10-Q  
April 17, 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 SEPTEMBER 30, 2016**

**. 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  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 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"/> X .

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

As of April 17, 2017, the Registrant had 765,251,000 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 and Form 10-K/A for the year ended December 31, 2015.

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.**

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## PART I Financial Information

Item 1.

Financial Statements

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**  
**Unaudited Condensed Consolidated Balance Sheets**

	<b>September 30,</b>	<b>December 31,</b>
	<b>2016</b>	<b>2015</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 45,233	\$ 2,183
Accounts Receivable, net	-	2,184
Inventories	38,351	29,675
Prepaid expenses and other current assets	13,287	213,446
<b>Total current assets</b>	<b>96,871</b>	<b>247,488</b>
<b>Other assets</b>	<b>28,844</b>	<b>12,476</b>
<b>Total assets</b>	<b>\$ 125,715</b>	<b>\$ 259,964</b>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 321,691	\$ 277,342
Accrued expenses and other current liabilities	91,430	17,986
Notes payable-related parties	198,669	193,664
<b>Total current liabilities</b>	<b>611,790</b>	<b>488,992</b>
<b>Shareholders' Deficit:</b>		

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Preferred stock, \$ 0.001 par value; 5,000,000 shares authorized	-	-
Common stock, \$ 0.001 par value; 699,999,999 shares authorized; 695,251,000 and 541,000,000 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively.	695,251	541,000
Additional paid-in capital	2,720,611	2,440,709
Accumulated deficit	(3,901,937)	(3,210,737)
<b>Total shareholders' deficit</b>	<b>(486,075)</b>	<b>(229,028)</b>
<b>Total liabilities and shareholders' deficit</b>	<b>\$ 125,714</b>	<b>\$ 259,964</b>

*See accompanying notes to condensed consolidated financial statements.*

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

	<b>For the Three Months ended September 30, 2016</b>	<b>For the Three Months ended September 30, 2015</b>	<b>For the Nine Months ended September 30, 2016</b>	<b>For the Nine Months ended September 30, 2015</b>
<b>Net Sales</b>	\$ 1,321	\$ 325	\$ 2,586	\$ 745
Cost of Goods Sold	394	166	750	264
<b>Gross Profit</b>	927	159	1,836	481
<b>Operating expenses:</b>				
General and administrative	26,065	25,727	101,786	56,991
Salaries, wages, and related expenses	89,911	71,323	267,638	193,489
Selling expenses	1,197	429	957	911
Consulting fees	2,000	55,467	148,750	83,800
Legal and professional fees	61,136	25,708	158,298	30,046
Research and development	-	-	5,990	-
<b>Total operating expenses</b>	180,309	178,654	683,419	365,237
<b>Loss from operations</b>	(179,382)	(178,495)	(681,583)	(364,756)
<b>Other income (expense):</b>				
Interest expense	(3,366)	(1,301)	(9,617)	(4,140)
<b>Total other income (expense)</b>	(3,366)	(1,301)	(9,617)	(4,140)
<b>Net loss from continuing operations</b>	(182,748)	(179,796)	(691,200)	(368,896)
Net loss from discontinued operations	-	-	-	(8,722)

<b>Net loss</b>	\$	(182,748)	\$	(179,796)	\$	(691,200)	\$	(377,618)
<b>Net loss per share - basic and diluted</b>	\$	(0.00)	\$	(0.00)	\$	(0.00)	\$	(0.00)
<b>Weighted average shares outstanding basic and diluted</b>		684,275,390		467,869,565		644,158,474		440,619,048

*See accompanying notes to condensed consolidated financial statements.*

**Therapeutic Solutions International, Inc.**  
**Unaudited** Condensed Consolidated Statement of Changes in Shareholders' Deficit  
**For the Nine Months Ended September 30, 2016**

	<b>Common Stock</b>	<b>Common Stock</b>	<b>Additional Paid-in</b>	<b>Accumulated</b>	
	<b>Shares</b>	<b>Amount</b>	<b>Capital</b>	<b>Deficit</b>	<b>Total</b>
<b>Balance at January 1, 2016</b>	<b>541,000,000</b>	<b>\$ 541,000</b>	<b>\$ 2,440,709</b>	<b>\$ (3,210,737)</b>	<b>\$ (229,028)</b>
Stock issued for services on January 4, 2016	2,500,000	2,500	3,750	-	6,250
Stock issued for services on January 22, 2016	2,500,000	2,500	6,250	-	8,750
Stock issued for services on February 1, 2016	2,500,000	2,500	5,000	-	7,500
Stock issued on February 5, 2016	8,000,000	8,000	12,000	-	20,000
Stock issued for a license agreement on February 22, 2016	5,451,000	5,451	10,902	-	16,353
Stock issued on February 26, 2016	1,000,000	1,000	1,500	-	2,500
Stock issued for services on March 7, 2016	10,000,000	10,000	15,000	-	25,000
Stock issued on March 21, 2016	100,000,000	100,000	150,000	-	250,000
Stock issued on March 24, 2016	800,000	800	1,200	-	2,000
Stock issued on May 2, 2016	1,000,000	1,000	1,500	-	2,500
Stock issued for services on May 2, 2016	1,000,000	1,000	4,300	-	5,300
Stock issued on May 26, 2016	2,000,000	2,000	3,000	-	5,000
Stock issued for services on May 26, 2016	2,500,000	2,500	14,000	-	16,500
Stock issued for services on May 31, 2016	2,500,000	2,500	14,000	-	16,500
	<b>12,500,000</b>	<b>12,500</b>	<b>37,500</b>	<b>-</b>	<b>50,000</b>

Stock issued on September 16, 2016					
Net Loss	-	-	-	(691,200)	(691,200)
<b>Balance at September 30, 2016</b>	<b>695,251,000</b>	<b>\$ 695,251</b>	<b>\$ 2,720,611</b>	<b>\$ (3,901,937)</b>	<b>\$ (486,075)</b>

*See accompanying notes to condensed consolidated financial statements*

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**  
**Unaudited Condensed Consolidated Statement of Cash Flows**

	<b>For the Nine</b>	<b>For the Nine</b>
	<b>Months</b>	<b>Months</b>
	<b>Ended</b>	<b>Ended</b>
	<b>September</b>	<b>September</b>
	<b>30,</b>	<b>30,</b>
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (691,200)	\$ (377,618)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation to consultants	85,800	126,300
Shares issued for license agreement	16,353	-
Accrued interest, notes payable-related parties	6,149	802
Changes in operating assets and liabilities:		
Inventory	(8,676)	(28,572)
Accounts receivable	2,184	-
Prepaid expenses and other current assets	200,159	132,148
Other assets	(16,368)	(15)
Accounts payable	44,349	(1,065)
Accrued expenses and other current liabilities	73,444	3,387
Cash used in operating activities-continuing operations	(287,806)	(144,633)
Cash provided (used) in operating activities-discontinued operations	-	46,845
<b>Net cash used in operating activities</b>	<b>(287,806)</b>	<b>(97,788)</b>
<b>Cash flows from investing activities</b>		
<b>Net cash used in investing activities</b>	<b>-</b>	<b>-</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock	332,000	105,000
Proceeds from notes payable-related parties	1,000	-
Repayments of notes payable-related parties	(2,144)	(1,612)
<b>Net cash provided by financing activities</b>	<b>330,856</b>	<b>103,388</b>
Net increase in cash	43,050	5,600
Cash at beginning of period	2,183	2,894

Cash at end of period	\$	45,233	\$	8,494
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**Supplemental Cash Flow Information:**

Cash paid for interest	\$	1,578	\$	2,478
Cash paid for income taxes	\$	800	\$	800

*See accompanying notes to condensed consolidated financial statements.*



**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2016**

**Note 1 Organization and Business Description**

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

**OmniBiome, Inc.,** ( Omni ) - is a majority-owned subsidiary of TSI, incorporated in the State of Delaware on October 20, 2015. As of September 30, 2016 and April 17, 2017, TSI owns approximately 73.75% of the outstanding shares of OmniBiome. Omni intends to focus on the use of probiotics to prevent pre-term labor and on using probiotics to reverse periodontal disease. Mr. Dixon and Mr. Berg, of the Company, are also officers and Directors of Omni. As of April 17, 2017 operations have not commenced.

TSI has experienced recurring losses over the past years which have resulted in accumulated deficits of approximately \$3,902 thousand and a working capital deficit of approximately \$515 thousand at September 30, 2016. 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 nine months ended September 30, 2016, 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, 2015 filed with the SEC on October 31, 2016 and Form 10-K/A filed on January 25, 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, 2015, included in the Company's Annual Report on Form 10-K/A filed with the SEC on January 25, 2017. The accompanying unaudited condensed consolidated financial statements include the accounts of TSI and its subsidiary. 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 and nine months ended September 30, 2016 and 2015 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, 2015 has been derived from the audited consolidated balance sheet at December 31, 2015, contained in the above referenced Form 10-K/A.



### 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 September 30, 2016 and 2015, there were no common stock equivalents outstanding.

### 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 August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The new standard requires management to assess, at each annual and interim reporting period, an entity's ability to continue as a going

concern within one year after the date that the financial statements are issued and to provide related footnote disclosures. ASU 2014-15 will be effective for the Company for the year ending December 31, 2016. The adoption of this standard is not expected to have a material impact on the Company's financial position or results of operations.

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

### **Note 4 Notes Payable-Related Party**

At September 30, 2016 and December 31, 2015, the Company has unsecured interest bearing demand notes outstanding to certain officers and directors amounting to \$198,669 and \$193,664, respectively. Interest accrued on these notes during the nine months ended September 30, 2016 and 2015 was \$6,149 and \$802, respectively.

**Note 5 Subsequent Events**

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.

On November 29, 2016, we issued an eighteen month 8% Convertible Note to a Related Party for \$75,000.

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 by 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 by a related party.

## **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/A for the fiscal year ended December 31, 2015 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](http://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](http://www.sec.gov), which contains reports, proxy and information statements, and other information regarding issuers which file electronically with the SEC. The periodic and current reports that we file with the SEC can also be obtained from us free of charge by directing a request to Therapeutic Solutions International, Inc., 4093 Oceanside Blvd, Suite B, Oceanside, California 92056, Attn: Corporate Secretary.

### **DESCRIPTION OF BUSINESS**

## 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. The following outlines our relationships and divisions to focus on each of these programs:

**Nutraceutical Division** TSI has been producing high quality nutraceuticals. Its flagship product, ProJuvenol<sup>®</sup>, is a proprietary mixture containing pterostilbene – one of the most potent antioxidants known. TSOI filed a patent application for ProJuvenol<sup>®</sup> on 07-08-2015 titled: Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions . On April 28, 2016 the Company announced the filing of a patent application covering the use of ProJuvenol<sup>®</sup> 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 TSI, incorporated in the State of Delaware on October 20, 2015, where the intellectual property surrounding probiotics is housed.

Future programs will focus on the use of probiotics to prevent pre-term labor and on using probiotics to reverse periodontal disease.



### **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<sup>®</sup>, may be useful as a nutraceutical adjuvant to conventional cancer immunotherapies.

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

In addition, on April 28, 2016 the Company filed a patent application covering the use of ProJuvenol<sup>®</sup> and its active ingredient pterostilbene for augmentation of stem cell activity. Diseases such as diabetes, 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<sup>®</sup>, a testosterone booster, and Vital<sup>®</sup> 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**

### **Fetal-Maternal Health**

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

OmniBiome, Inc. ( OMNI ), a majority-owned subsidiary of TSI, is focused on therapeutic / Rx approaches to either utilize or intervene with the systemic effects of the vaginal, lactal-duct and oral microbiomes for improving maternal healthcare and resulting birth outcomes. The Officers and Directors of the Company are also officers and Directors of OMNI. As of September 30, 2016 and April 17, 2017, TSI owns approximately 73.75% of the outstanding shares of OMNI. As of April 17, 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.

## GOVERNMENT REGULATION

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

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product claims and advertising;

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product labels;

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product ingredients; and

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how we pack/Age, distribute, import, export, sell and store our products.

The FDA, in particular, regulates the formulation, manufacturing, pack/Aging, 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, pack/Aging, 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/A for the year ended December 31, 2015, which was filed with the SEC on January 25, 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.

### **For the three and nine months ended September 30, 2016 and 2015**

Operating expenses for the three month periods ended September 30, 2016 and 2015 were \$180,309 and \$178,654, an increase of \$1,655. Operating expenses for the nine month periods ended September 30, 2016 and 2015 were \$683,419 and \$365,237, an increase of \$318,182. This was mainly due to increased salaries, wages, and related costs, increased consulting fees and increased legal expenses.

General and administrative expenses increased \$338, from \$25,727 to \$26,065, for the three months ended September 30, 2015 and 2016, respectively. General and administrative expenses stayed relatively stable for these periods. General and administrative expenses increased \$44,795, from \$56,991 to \$101,786, for the nine months ended September 30, 2015 and 2016, respectively. This increase was mainly due to an increase in bad debt expense.

Salaries, wages and related expenses increased \$18,588, from \$71,323 to \$89,911 for the three months ended September 30, 2015 and 2016, respectively. Salaries, wages and related expenses increased \$74,149, from \$193,489 to \$267,638 for the nine months ended September 30, 2015 and 2016, respectively. This increase was mainly due to an increase in officers' salaries.

Selling expenses increased \$768, from \$429 to \$1,197, for the three months ended September 30, 2015 and 2016, respectively. Selling expenses increased \$46, from \$911 to \$957, for the nine months ended September 30, 2015 and 2016, respectively. This increase was mainly due to selling and marketing expenses related to the Company's new products in 2016.

Consulting fees decreased \$53,467 from \$55,467 to \$2,000 for the three months ended September 30, 2015 and 2016, respectively, due to a decrease in overall consulting services for the periods. Consulting fees increased \$64,950 from \$83,800 to \$148,750 for the nine months ended September 30, 2015 and 2016, respectively, due to an increase in overall consulting services for the periods.

Legal and professional fees increased \$35,428, from \$25,708 to \$61,136 for the three months ended September 30, 2015 and 2016, respectively, due to an increase in overall patent and general counsel services. Legal and professional fees increased \$128,252, from \$30,046 to \$158,298 for the nine months ended September 30, 2015 and 2016, respectively, due to an increase in overall patent and general counsel services.

Research and Development costs were \$0 and \$0 for the three months ended September 30, 2015 and 2016, respectively. Research and Development costs increased \$5,990, from \$0 to \$5,990, for the nine months ended September 30, 2015 and 2016, respectively. This increase was mainly due to research and development expenses related to the Company's new products in 2016.

Net interest expense increased \$2,065 from \$1,301 to \$3,366 for the three months ended September 30, 2015 and 2016, respectively. Net interest expense increased \$5,477 from \$4,140 to \$9,617 for the nine months ended September 30, 2015 and 2016, respectively. These increases were mainly due to increased debt balances.

### **Liquidity and Capital Resources**

Net cash used in operating activities totaled \$287,806 for the nine months ended September 30, 2016. As of September 30, 2016, we had cash of \$45,233. During the nine months ended September 30, 2016 the Company raised \$332,000 through the sale of common stock in private transactions. Subsequent to September 30, 2016, the Company raised \$100,000 through the sale of common stock in private transactions.

We believe we will need additional outside financing to execute our business plan in 2017 and beyond. 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 former independent registered public accounting firm has stated in their opinion on our 2015 annual financial statements dated October 31, 2016, 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 September 30, 2016. 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 September 30, 2016 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 September 30, 2016. 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 September 30, 2016 our internal control over financial reporting was not effective, and that material weaknesses existed in the following areas as of September 30, 2016:

(1)

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

(2)

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

(3)

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

(4)

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

## **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/A for the year ended December 31, 2015, which was filed with the SEC on January 25, 2017.

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

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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.

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.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

DESCRIPTION

EXHIBIT  
NUMBER

- 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: April 17, 2017

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

Date: April 17, 2017

By: */s/ Gerry B. Berg*  
Gerry B. Berg  
  
Chief Financial Officer  
(Principal Financial Officer)