

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

Form 10-Q

November 16, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 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**

**45-1226465**

(State or Other Jurisdiction of (I.R.S. Employer Identification No.)

Incorporation or Organization)

**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  Accelerated Filer   
Non-Accelerated Filer  (Do not check if a smaller reporting company) Smaller reporting company

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 November 15, 2017, the Registrant had 806,501,000 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” and similar 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.**

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## PART I Financial Information

## Item 1. Financial Statements

## THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

## Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2017	December 31, 2016
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 5,283	\$ 21,910
Inventory	22,033	36,435
Prepaid expenses and other current assets	40,372	14,304
<b>Total current assets</b>	<b>67,688</b>	<b>72,649</b>
<b>Other non-current assets</b>	<b>23,927</b>	<b>32,226</b>
<b>Total assets</b>	<b>\$ 91,615</b>	<b>\$ 104,875</b>

**LIABILITIES AND SHAREHOLDERS' DEFICIT**

<b>Current liabilities:</b>		
Accounts payable	\$ 340,339	\$ 327,592
Accrued expenses and other current liabilities	321,643	135,164
Convertible notes payable, net of discount of \$46,908	9,092	-
Notes payable-related parties, current portion	415,063	221,451
Derivative liability	98,683	-
<b>Total current liabilities</b>	<b>1,184,820</b>	<b>684,207</b>
<b>Notes payable-related parties, less current portion</b>	<b>-</b>	<b>75,500</b>

**Shareholders' Deficit:**

Preferred stock, \$ 0.001 par value; 5,000,000 shares authorized	-	-
Common stock, \$ 0.001 par value; 990,000,000 shares authorized; 791,501,000 and 740,251,000 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively.	791,501	740,251
Additional paid-in capital	3,089,061	2,878,111
Accumulated deficit	(4,973,767)	(4,273,194)
<b>Total shareholders' deficit</b>	<b>(1,093,205)</b>	<b>(654,832)</b>
<b>Total liabilities and shareholders' deficit</b>	<b>\$ 91,615</b>	<b>\$ 104,875</b>

*See accompanying notes to condensed consolidated financial statements.*



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

	<b>For the Three Months ended September 30, 2017</b>	<b>For the Three Months ended September 30, 2016</b>	<b>For the Nine Months ended September 30, 2017</b>	<b>For the Nine Months ended September 30, 2016</b>
<b>Net Sales</b>	\$ 630	\$ 1,321	\$ 1,923	\$ 2,586
Cost of Goods Sold	191	394	616	750
<b>Gross Profit</b>	439	927	1,307	1,836
<b>Operating expenses:</b>				
General and administrative	22,694	26,065	75,437	101,786
Salaries, wages, and related expenses	95,536	89,911	279,838	267,638
Selling expenses	712	1,197	2,538	957
Consulting fees	22,950	2,000	29,650	148,750
Legal and professional fees	64,226	61,136	216,945	158,298
Research and development	2,038	-	24,114	5,990
<b>Total operating expenses</b>	208,156	180,309	628,522	683,419
<b>Loss from operations</b>	(207,717) \$	(179,382) \$	(627,215) \$	(681,583)
<b>Other income (expense):</b>				
Interest expense	(10,363)	(3,366)	(24,675)	(9,617)
Loss on derivative liability	(83,968)	-	(83,968)	-
Change in fair value of derivative liability	35,285	-	35,285	-
<b>Total other income (expense)</b>	(59,046)	(3,366)	(73,358)	(9,617)
<b>Net loss</b>	\$ (266,763) \$	(182,748) \$	(700,573) \$	(691,200)

<b>Net loss per share - basic and diluted</b>	\$	(0.00)	\$	(0.00)	\$	(0.00)	\$	(0.00)
<b>Weighted average shares outstanding –</b>								
<b>basic and diluted</b>		783,207,044		684,275,390		769,394,382		644,158,474

*See accompanying notes to condensed consolidated financial statements.*

**Therapeutic Solutions International, Inc.**

**Condensed Consolidated Statement of Changes in Shareholders' Deficit**

**For the nine month period ended September 30, 2017**

**(Unaudited)**

	<b>Common Stock Shares</b>	<b>Common Stock Amount</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
<b>Balance at January 1, 2017</b>	<b>740,251,000</b>	<b>\$ 740,251</b>	<b>\$ 2,878,111</b>	<b>\$ (4,273,194)</b>	<b>\$ (654,832)</b>
Stock issued	35,250,000	35,250	105,750	-	141,000
Stock issued for services	16,000,000	16,000	105,200	-	121,200
Net Loss	-	-	-	(700,573)	(700,573)
<b>Balance at September 30, 2017</b>	<b>791,501,000</b>	<b>\$ 791,501</b>	<b>\$ 3,089,061</b>	<b>\$ (4,973,767)</b>	<b>\$ (1,093,205)</b>

*See accompanying notes to condensed consolidated financial statements*

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

	<b>For the Nine Months Ended September 30, 2017</b>	<b>For the Nine Months Ended September 30, 2016</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (700,573)	\$ (691,200)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation to consultants	121,200	85,800
Shares issued for license agreement	-	16,353
Loss on derivative liability	83,968	-
Change in fair value of derivative liability	(35,285)	-
Amortization of debt discount	9,092	-
Accrued interest, notes payable - related parties	18,876	6,149
Changes in operating assets and liabilities:		
Inventory	14,402	(8,676)
Accounts receivable	-	2,184
Prepaid expenses and other current assets	(26,068)	200,159
Other assets	8,300	(16,368)
Accounts payable	12,747	44,349
Accrued expenses and other current liabilities	186,479	73,444
<b>Net cash used in operating activities</b>	<b>(306,862)</b>	<b>(287,806)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock	141,000	332,000
Proceeds from notes payable	50,000	-
Net proceeds from notes payable - related parties	99,235	(1,144)
<b>Net cash provided by financing activities</b>	<b>290,235</b>	<b>330,856</b>
<b>Net (decrease) increase in cash</b>	<b>(16,627)</b>	<b>43,050</b>
Cash at beginning of period	21,910	2,183
Cash at end of period	\$ 5,283	\$ 45,233

**Supplemental Cash Flow Information:**

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Cash paid for interest	\$	3,681	\$	1,578
Cash paid for income taxes	\$	-	\$	800
Non-cash investing and financing transactions				
Original issuance discount on convertible notes payable	\$	6,000	\$	-
Debt discount recorded in connection with derivative liability	\$	50,000	\$	-

*See accompanying notes to condensed consolidated financial statements.*

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 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 very high quality nutraceuticals. Its flagship product, ProJuvenol<sup>®</sup>, is a patented proprietary mixture containing pterostilbene – one of the most potent antioxidants known. On June 20th, 2017, TSOI was granted U.S. Patent No.: 9,682,047 for ProJuvenol<sup>®</sup> 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.

**Going Concern**

As of September 30, 2017, the Company has incurred losses over the past years which have resulted in accumulated deficits of \$4,973,767, has not yet generated material revenue from operations, and will require additional funds to

maintain its operations. Management does not expect existing cash resources as of September 30, 2017 to be sufficient to fund the Company's operations for at least twelve months from the issuance date of these interim financial statements. These financial statements have been prepared on a going concern basis which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. These factors raise substantial doubt regarding the Company's ability to continue as a going concern within one year after the consolidated financial statements are issued. The Company's ability to continue as a going concern is dependent upon its ability to generate future profitable operations and obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they become due. The Company intends to finance operating costs over the next twelve months through its existing financial resources and by raising additional capital through equity offerings, debt financings, collaborations and/or licensing arrangements. If adequate funds are not available on acceptable terms, the Company may be required to delay, reduce the scope of, or curtail, its operations. The accompanying consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern

## **Note 2 – Summary of Significant Accounting Policies**

During the nine months ended September 30, 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 nine months ended September 30, 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**

**September 30, 2017**

**Note 2 – Summary of Significant Accounting Policies (continued)**

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 potential common shares outstanding. Potential common shares outstanding are excluded from the calculation of diluted net loss per share when their effect is anti-dilutive. As of September 30, 2017, outstanding potential common shares outstanding included shares underlying convertible debt and amounted to 133,989,887 shares.

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 Parties**

At September 30, 2017 and December 31, 2016, the Company has unsecured interest bearing demand notes outstanding to certain officers and directors amounting to \$415,063 and \$296,951, respectively. Interest accrued on these notes during the nine months ended September 30, 2017 and 2016 was \$18,876 and \$6,149, respectively.

### **Note 5 – Convertible Notes Payable**

On July 24, 2017 and September 7, 2017, the Company entered into two \$28,000 convertible promissory notes with a third party for which the proceeds were used for operations. The Company received net proceeds of \$50,000 and thus a \$6,000 original issuance discount was recorded. The convertible promissory notes incur interest at 12% per annum for which \$28,000 plus accrued interest are due on April 30, 2018 and June 15, 2018. The convertible promissory notes are convertible to shares of the Company's common stock 180 days after issuance. The conversion price per share is equal to 55% of the average of the three (3) lowest trading price of the Company's common stock during the fifteen (15) trading days immediately preceding the applicable conversion date. The Company has the option to prepay the convertible notes in the first 180 days from closing subject to prepayment penalties ranging from 120 to 145% of principal balance plus interest, depending upon the date of prepayment. The convertible promissory notes include various default provisions for which the default interest rate increases to 22% per annum with the outstanding principal and accrued interest increasing by 150%. The Company was required to reserve a total of 133,898,887 common shares in connection with the promissory notes.

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2017**

**Note 5 – Convertible Notes Payable (continued)**

These convertible promissory notes are convertible into a variable number of shares of common stock for which there is not a floor to the number of common stock we might be required to issue. Based on the requirements of ASC 815 Derivatives and Hedging, the conversion feature represented an embedded derivative that is required to be bifurcated and accounted for as a separate derivative liability. The derivative liability is originally recorded at its estimated fair value and is required to be revalued at each conversion event and reporting period. Changes in the derivative liability fair value are reported in operating results each reporting period.

On July 24, 2017 and September 7, 2017, the convertible note issuance dates, the Company valued the conversion feature resulting in initial liability of \$133,968. Since the fair value of the derivatives were in excess of the proceeds received of \$50,000, a full discount to convertible notes payable and a day one loss on derivative liabilities of \$83,968 was recorded. The Company valued the conversion feature using the Black-Scholes option pricing model with the following assumptions: conversion prices ranging from of \$0.003 to \$0.004, the closing stock price of the Company's common stock on the date of valuation ranging from \$0.008 to \$0.009, an expected dividend yield of 0%, expected volatility ranging from 299% to 319%, risk-free interest rates ranging from 1.21% to 1.23%, and an expected term of 0.77 years. On September 30, 2017, the derivative liabilities were revalued at \$98,683 resulting in a gain of \$35,285 related to the change in fair value of the derivative liabilities. The derivative liabilities were revalued using the Black-Scholes option pricing model with the following assumptions: conversion price of \$0.004, the closing stock price of the Company's common stock on the date of valuation of \$0.008, an expected dividend yield of 0%, expected volatility ranging from 330% to 341%, risk-free interest rate of 1.31%, and an expected term ranging from 0.58 to 0.71 years.

The Company amortizes the discounts over the term of the convertible promissory notes using the interest method. During the three and nine months ended September 30, 2017, the Company amortized \$9,092 to interest expense. As of September 30, 2017, discounts of \$46,908 remained for which will be amortized through June 30, 2018.

**Note 6 – Subsequent Events**

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

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

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## 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](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.

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 very high quality nutraceuticals. Its flagship product, ProJuvenol<sup>®</sup>, is a patented proprietary mixture containing pterostilbene – one of the most potent antioxidants known. On June 20th, 2017, TSOI was granted U.S. Patent No.: 9,682,047 for ProJuvenol<sup>®</sup> titled “Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions”. 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 September 30, 2017 and November 15, 2017, TSOI owns approximately 73.75% of the outstanding share of OMNI. As of September 30, 2017 and November 15, 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 September 30, 2017 and November 15, 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 exclusively licensed 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 September 26, 2017, limited operations have begun.

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

**ProJuvenol®** is a patented 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. On June 20th, 2017, TSOI was granted U.S. Patent No.: 9,682,047 for ProJuvenol® titled "Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions".

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. In the Granted U.S. Patent No.: 9,682,047 for ProJuvenol<sup>®</sup> for example, contains a claim covering the combination of pterostilbene, the active ingredient in ProJuvenol<sup>®</sup>, together with an FDA-approved immunotherapeutic drug named Proleukin<sup>®</sup> (aldesleukin), which is a recombinant form of the cytokine interleukin-2 (IL-2) for treatment of cancer.

Proleukin<sup>®</sup> is one of the first immunotherapeutic drugs approved by the FDA, being indicated for treatment of metastatic melanoma and metastatic renal cell carcinoma<sup>1</sup>. Scientists working with Therapeutic Solutions International performed animal studies showing that administration of pterostilbene increased efficacy of Proleukin<sup>®</sup> in melanoma models. In the studies performed to obtain FDA approval for Proleukin<sup>®</sup> responses were seen in 16% of patients<sup>2</sup>. Based on animal data, it is hoped that the response rate of Proleukin<sup>®</sup> can be increased by administration of products containing pterostilbene, such as ProJuvenol<sup>®</sup>.

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.

Then on October 16, 2017, TSOI announced the filing of an additional patent on the use of pterostilbene. The invention pertains to utilization of pterostilbene for augmenting immunogenicity of cancer cells treated with various therapies and is titled as "Synergistic Inhibition of Glioma Using Pterostilbene and Analogues Thereof"

This third pterostilbene patent represents several years of research and literature review and was developed to utilize the ability of the immune system to augment the possibility of increasing overall survival of glioma patients after treatment with conventional therapies. Our data suggests that when pterostilbene is combined with brain cancer therapeutics such as Gefitinib, Sertraline, or Temozolomide, the prognosis is vastly improved.

What is particularly interesting is that pterostilbene appears to make cancer cells more visible to the immune system subsequent to their being attacked by conventional drug approaches, specifically, we observed that this increase of immunogenicity that pterostilbene causes in chemotherapy treated cancer cells allows for enhanced immunity to cancer cells that have escaped chemotherapy, thus theoretically enhancing patient prognosis.

TSOI markets currently several other nutraceuticals, they include 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. U.S. Patent No.: 9,682,047.

**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 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 nano-delivery 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 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., (SandBox) is a wholly-owned subsidiary of TSOI consisting of a dental laboratory to manufacture and fill prescriptions from dentists who will use our exclusively licensed 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 SandBox. As of September 30, 2017, limited operations have begun.

On June 26, 2017, SandBox Dental Labs, Inc., filed a 510(k) application with the U.S. Food and Drug Administration (FDA) for market clearance of their custom oral appliance to treat mild to moderate obstructive sleep apnea (OSA).

The SandBox Dental Sleep Appliance, named Morpheus (CE Marked in the European Union as Sleepwell by S4S UK Ltd., our supplier, and MDSA in Australia, by inventor), has been tested by its original inventor (known clinically as MDSA) in a randomized controlled cross over trial against CPAP and a placebo, and it is also one of the most technologically advanced and patient friendly MAS's (mandibular advancement splint) on the market. The full clinical trial information is not contained in this document, but the headline success rate of Morpheus (MDSA) was 80.3% in fully apneic patients.

The appliance combines a high clinical success rate with key features that make it more comfortable and flexible for the patient.

Unlike some MAS devices, our appliance is fully patient adjustable negating the need for further clinical visits for simple titration. Should the patient need to modify the degree of mandibular advancement they can simply adjust with the key provided.

Our appliance is also uniquely designed with internal splint fixing, allowing the lips to be closed around the device preventing the dry lips and excess salivation associated with some splints. High levels of patient comfort meant that during clinical trials over 98% of patients found the device acceptable.

Our appliance is a laboratory-manufactured device molded specifically to patient impressions. As a soft, slim-line two-piece device it allows full lateral movement while retaining high levels of patient comfort and custom made accuracy. By allowing a degree of movement during the night the device remains in the mouth unlike some devices

that may dislocate. In addition the lateral movement provides a solution to some patients who experience TMJ stress with a fixed block device.

Key Benefits:

Full lateral movement

Full patient adjustability

High Patient Comfort

Clinically proven and effective

Internal fixings improve comfort

### **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 September 30, 2017 and August 11, 2017, TSOI owns approximately 73.75% of the outstanding shares of OMNI. As of September 30, 2017 and November 15, 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.

## **In-House Patents**

On March 29, 2017 OmniBiome announced the filing of a new patent titled "Modulation of Oral Microbiome for Treatment of Periodontitis."

This product will be marketed as a probiotic paste to be used in oral appliances similar to bleaching trays.

## **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 September 30, 2017 and November 15, 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 #17448 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”.

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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 very high quality nutraceuticals. Its flagship product, ProJuvenero®, is a patented proprietary mixture containing pterostilbene – one of the most potent antioxidants known. On June 20th, 2017, TSOI was granted U.S. Patent No.: 9,682,047 for ProJuvenero® titled “Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions”. In addition we recently launched 4 new products in Liposomal formulation. They are CoQ10, Curcumin, Glutathione, and Vitamin-C in 16oz bottles.

### For the three months and nine months ended September 30, 2017 and 2016

We had a net loss of \$266,763 for the three months ended September 30, 2017, compared to a net loss of \$182,748 for the three months ended September 30, 2016, an increase of \$84,015. This increase was mainly due to increases in Salaries, wages and related expenses, consulting fees and legal and professional fees. We had a net loss of \$700,573 for the nine months ended September 30, 2017, compared to a net loss of \$691,200 for the nine months ended September 30, 2016, an increase of \$9,373. This increase was mainly due to increases in legal and professional fees and decreases in general and administration expenses and consulting fees. .

Net sales decreased \$691, from \$1,321 to \$630, for the three months ended September 30, 2016 and September 30, 2017, respectively. Net sales slightly decreased \$663, from \$2,586 to \$1,923, for the nine months ended September 30, 2016 and September 30, 2017, respectively.

Cost of goods sold decreased \$203, from \$394 to \$191, for the three months ended September 30, 2016 and September 30, 2017, respectively. Cost of goods sold decreased \$134, from \$750 to \$616, for the nine months ended September 30, 2016 and September 30, 2017, respectively.

Operating expenses for the three month periods ended September 30, 2017 and 2016 were \$208,156 and \$180,309, an increase of \$27,847. This increase was mainly due to increases in salaries, wages and related expenses, consulting fees and legal and professional fees. Operating expenses for the nine month periods ended September 30, 2017 and 2016 were \$628,522 and \$683,419, a decrease of \$54,897. This decrease was mainly due to decreases in General and Administration expenses and consulting fees along with increases in legal and professional fees.

General and administrative expenses decreased \$3,371, from \$26,065 to \$22,694, for the three months ended September 30, 2016 and 2017, respectively. General and administrative expenses decreased \$26,349, from \$101,786 to \$75,437, for the nine months ended September 30, 2016 and 2017, respectively. These decreases were mainly due decreased bad debt expense in the comparable quarters in 2017 vs 2016.

Salaries, wages and related expenses increased \$5,625, from \$89,911 to \$95,536 for the three months ended September 30, 2016 and 2017, respectively. Salaries, wages and related expenses increased \$12,200, from \$267,638 to \$279,838 for the nine months ended September 30, 2016 and 2017, respectively. These increases are mainly due to an increase in wage related expenses.

Selling expenses decreased \$485, from \$1,197 to \$712, for the three months ended September 30, 2016 and 2017, respectively. This was mainly due a decrease in selling and marketing expenses related to the Company's products during the period. Selling expenses increased \$1,581, from \$957 to \$2,538, for the nine months ended September 30, 2016 and 2017, respectively. This increase was mainly due to selling and marketing expenses related to the Company's products.

Consulting fees increased \$20,950 from \$2,000 to \$22,950 for the three months ended September 30, 2016 and 2017, respectively, due to an increase in overall consulting services. Consulting fees decreased \$119,100 from \$148,750 to \$29,650 for the nine months ended September 30, 2016 and 2017, respectively, due to a decrease in overall consulting services.

Legal and professional fees increased \$3,090, from \$61,136 to \$64,226 for the three months ended September 30, 2016 and 2017, respectively, due to an increase in independent public accounting fees and legal expense. Legal and professional fees increased \$58,647, from \$158,298 to \$216,945, for the nine months ended September 30, 2016 and 2017, respectively, due to an increase in independent public accounting fees and legal expense.

Research and Development costs increased \$2,038, from \$0 to \$2,038, for the three months ended September 30, 2016 and 2017, respectively. This increase was mainly due to increased research and development expenses for the comparable three month periods. Research and Development costs increased \$18,124, from \$5,990 to \$24,114, for the nine months ended September 30, 2016 and 2017, respectively. This increase was mainly due to research and development expenses incurred in the first three months of 2017.

Net interest expense increased \$6,997 from \$3,366 to \$10,363 for the three months ended September 30, 2016 and 2017, respectively. This increase was mainly due to increased debt balances. Net interest expense increased \$15,058 from \$9,617 to \$24,675 for the nine months ended September 30, 2016 and 2017, respectively. This increase was mainly due to increased debt balances.

Loss on derivative liabilities increased \$83,968, from \$0 to \$83,968, for the three and nine months ended September 30, 2016 and 2017, respectively. This increase was due to a loss incurred on derivative liabilities during the three months ended September 30, 2017.

Change in fair value of derivative liability was \$35,285 for the three and nine months ended September 30, 2017 versus \$0 for the three and nine months ended September 30, 2016. This change was due to a change in derivative liability during the three months ended September 30, 2017.

## **Liquidity and Capital Resources**

As of September 30, 2017, the Company has incurred losses over the past years which have resulted in accumulated deficits of \$4,973,767, has not yet generated material revenue from operations, and will require additional funds to maintain its operations. Management does not expect existing cash resources as of September 30, 2017 to be sufficient to fund the Company's operations for at least twelve months from the issuance date of these interim financial statements. These financial statements have been prepared on a going concern basis which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. These factors raise substantial doubt regarding the Company's ability to continue as a going concern within one year after the consolidated financial statements are issued. The Company's ability to continue as a going concern is dependent upon its ability to generate future profitable operations and obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they become due. The Company intends to finance operating costs over the next twelve months through its existing financial resources and by raising additional capital through equity offerings, debt financings, collaborations and/or licensing arrangements. If adequate funds are not available on acceptable terms, the Company may be required to delay, reduce the scope of, or curtail, its operations. The

accompanying consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern

As of September 30, 2017, our cash and cash equivalents were \$5,283 compared to \$21,910 at December 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 nine months ended September 30, 2017 was \$306,862, compared to \$287,806 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 nine months ended September 30, 2017 net cash provided in financing activities was \$290,235, compared to \$330,856 for the same period in 2016. The decrease was mainly due a decrease in the issuance of common stock. At September 30, 2017, we had negative working capital of \$1,117,132, compared to negative working capital of \$611,558 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 September 30, 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 September 30, 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 September 30, 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 September 30, 2017 our internal control over financial reporting was not effective, and that material weaknesses existed in the following areas as of September 30, 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.

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.

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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.

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

On July 24, 2017, we issued a six month convertible note in the amount of \$28,000 with an annual interest rate of 12%.

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

On August 21, 2017, we issued 1,000,000 shares of common stock, valued at \$0.0053 per share, for consulting services.

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

On September 7, 2017, we issued a six month convertible note in the amount of \$28,000 with an annual interest rate of 12%.

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

**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
<u>31.1</u>	Rule 13a14(a)/Section 302 Certification of Principal Executive Officer
<u>31.2</u>	Rule 13a14(a)/Section 302 Certification of Principal Financial Officer
<u>32.1</u>	Certification pursuant to 18 U.S.C. Section 1350/Rule 13a14(b)

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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: November 16, 2017 By: */s/ Timothy G. Dixon*  
Timothy G. Dixon  
President and Chief Executive Officer  
  
(Principal Executive Officer)

Date: November 16, 2017 By: */s/ Gerry B. Berg*  
Gerry B. Berg  
  
Chief Financial Officer  
  
(Principal Financial Officer)

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