

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.  
Form 10-Q  
May 21, 2018

**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 MARCH 31, 2018**

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

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

Commission File Number: **000-54554**

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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

**45-1226465**  
(I.R.S. Employer  
Identification No.)

**4093 Oceanside Boulevard, Suite B**

**Oceanside, California 92056**

(Address of principal executive offices, including zip code)

**(760) 295-7208**

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer  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 May 21, 2018, the Registrant had 800,165,450 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, 2017.

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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**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**Condensed Consolidated Balance Sheets**

**(Unaudited)**

	<b>March 31, 2018</b>	<b>December 31, 2017</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 7,446	\$ 29
Inventory	1,411	1,515
Prepaid expenses and other current assets	67,670	1,054
<b>Total current assets</b>	<b>76,527</b>	<b>2,598</b>
<b>Other assets</b>	<b>23,926</b>	<b>23,927</b>
<b>Total assets</b>	<b>\$ 100,453</b>	<b>\$ 26,525</b>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 346,730	\$ 343,810
Accrued expenses and other current liabilities	511,360	432,640
Convertible notes payable, net of discount of \$51,580 and \$28,541, at March 31, 2018 and December 31, 2017, respectively	32,420	27,459
Notes payable-related parties	436,958	429,201
Derivative liabilities	143,850	107,769
<b>Total current liabilities</b>	<b>1,471,318</b>	<b>1,340,879</b>
<b>Shareholders' Deficit:</b>		
Preferred stock, \$ 0.001 par value; 5,000,000 shares authorized	-	-
Common stock, \$ 0.001 par value; 990,000,000 shares authorized; 840,301,713 and 806,501,000 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively.	840,302	806,501
Additional paid-in capital	3,335,133	3,147,811
Accumulated deficit	(5,546,300)	(5,268,666)

<b>Total shareholders' deficit</b>	(1,370,865)	(1,314,354)
<b>Total liabilities and shareholders' deficit</b>	\$ 100,453	\$ 26,525

*See accompanying notes to condensed consolidated financial statements.*



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

	<b>For the Three Months Ended March 31, 2018</b>	<b>For the Three Months Ended March 31, 2017</b>
<b>Net Sales</b>	\$ 600	\$ 548
Cost of Goods Sold	105	198
<b>Gross Profit</b>	495	350
<b>Operating expenses:</b>		
General and administrative	13,966	17,487
Salaries, wages, and related costs	98,609	89,431
Selling expenses	572	784
Consulting fees	10,765	-
Legal and professional fees	69,834	51,490
Research and development	5,575	20,926
<b>Total operating expenses</b>	199,320	180,118
<b>Loss from operations</b>	(198,825)	(179,768)
<b>Other income (expense):</b>		
Loss on derivatives liability	(79,351)	-
Change in fair value of derivatives liabilities	44,827	-
Interest expense	(44,284)	(6,182)
<b>Total other income (expense)</b>	(78,808)	(6,182)
<b>Net loss</b>	\$ (277,634)	\$ (185,950)
<b>Net loss per share - basic and diluted</b>	\$ (0.00)	\$ (0.00)
<b>Weighted average shares outstanding - Basic and Diluted</b>	825,126,417	751,767,854

*See accompanying notes to condensed consolidated financial statements.*

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**Therapeutic Solutions International, Inc.**  
**Unaudited Condensed Consolidated Statements of Changes in Shareholders' Deficit**  
**March 31, 2018**

	<b>Common</b>	<b>Common</b>	<b>Additional</b>		
	<b>Stock</b>	<b>Stock</b>	<b>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, 2018</b>	<b>806,501,000</b>	<b>\$ 806,501</b>	<b>\$ 3,147,811</b>	<b>\$ (5,268,666)</b>	<b>\$1,314,354)</b>
Common stock issued for services	10,000,000	10,000	73,000	-	83,000
Common stock issued in payment of convertible note payable	8,800,713	8,801	69,322	-	78,123
Common stock issued	15,000,000	15,000	45,000	-	60,000
Net Loss	-	-	-	(277,634)	(277,634)
<b>Balance at March 31, 2018</b>	<b>840,301,713</b>	<b>\$ 840,302</b>	<b>\$ 3,335,133</b>	<b>\$ (5,546,300)</b>	<b>\$1,370,865)</b>

*See accompanying notes to condensed consolidated financial statements*

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

	<b>For the Three</b>	<b>For the Three</b>
	<b>Months Ended</b>	<b>Months Ended</b>
	<b>March 31, 2018</b>	<b>March 31, 2017</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (277,634)	\$ (185,950)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation to consultants	83,000	-
Accrued interest, notes payable	1,680	-
Accrued interest, notes payable - related parties	7,936	5,436
Loss on derivative liability	79,351	-
Change in fair value of derivative liabilities	(44,827)	-
Amortization of debt discount	32,961	-
Changes in operating assets and liabilities:		
Inventory	104	965
Prepaid expenses and other current assets	(66,616)	11,072
Other assets	1	(6,264)
Accounts payable	2,920	(1,239)
Accrued expenses and other current liabilities	78,720	60,554
<b>Net cash used in operating activities</b>	<b>(102,404)</b>	<b>(115,426)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock	60,000	100,000
Proceeds from convertible notes payable	50,000	-
Payments on notes payable - related parties	(179)	(384)
<b>Net cash provided by financing activities</b>	<b>109,821</b>	<b>99,616</b>
Net increase (decrease) in cash, cash equivalents, and restricted cash	7,417	(15,810)
Cash, cash equivalents, and restricted cash at beginning of period	10,185	32,066
Cash, cash equivalents, and restricted cash at end of period	\$ 17,602	\$ 16,256
<b>Supplemental Cash Flow Information:</b>		
Cash paid for interest	\$ 1,707	\$ 745
Cash paid for income taxes	\$ -	\$ -

**Non-cash investing and financing transactions**

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Original issuance discount on convertible notes payable	\$	6,000	\$	-
Debt discount recorded in connection with derivative liability	\$	50,000	\$	-
Common stock issued in payment of convertible note payable	\$	78,123	\$	-
Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets:				
Cash and cash equivalents	\$	7,446	\$	6,100
Restricted cash included in other assets		10,156		10,156
Total cash, cash equivalents, and restricted cash shown in the condensed consolidated statements of cash flows	\$	17,602	\$	16,256

*See accompanying notes to condensed consolidated financial statements.*

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2018**

**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 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 – 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” and was granted that patent on June 20, 2017.

**Emvolio, Inc.** (“EMVO”) – is a wholly-owned subsidiary of TSI, incorporated in the State of Delaware on October 03, 2016. EMVO intends to focus on developing 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. Mr. Dixon and Mr. Berg, and Dr. Ichim, of the Company, are also officers and officers and/or directors of EMVO. As of May 21, 2018, formal operations have not commenced.

**SandBox Dental Labs, Inc.** – is a wholly-owned subsidiary of TSI consisting of a dental laboratory to manufacture and fill prescriptions from dentists who will use our proprietary Sleep Appliance to treat their patients with mild to moderate obstructive sleep apnea. The Company is currently in the process of seeking regulatory approval for its device to treat sleep apnea. As of May 21, 2018, formal operations have not commenced.

Management does not expect existing cash as of March 31, 2018 to be sufficient to fund the Company's operations for at least twelve months from the issuance date of these March 31, 2018 financial statements. These financial statements have been prepared on a going concern basis which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. As of March 31, 2018, the Company has incurred losses totaling \$5.6 million since inception, has not yet generated material revenue from operations, and will require additional funds to maintain its operations. These factors raise substantial doubt regarding the Company's ability to continue as a going concern within one year after the consolidated financial statements are issued. The Company's ability to continue as a going concern is dependent upon its ability to generate future profitable operations and obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they become due. The Company intends to finance operating costs over the next twelve months through its existing financial resources and we may also raise additional capital through equity offerings, debt financings, collaborations and/or licensing arrangements. If adequate funds are not available on acceptable terms, we may be required to delay, reduce the scope of, or curtail, our operations. The accompanying consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts.

During the three months ended March 31, 2018, 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, 2017 filed with the SEC on April 17, 2018.

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2018**

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

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, 2017, included in the Company's Annual Report on Form 10-K filed with the SEC on April 17, 2018. The accompanying unaudited condensed consolidated financial statements include the accounts of TSOI and its subsidiaries. All significant inter-company transactions and balances have been eliminated in consolidation. The unaudited condensed consolidated financial statements contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the balances and results for the interim period included herein. The results of operations for the three months ended March 31, 2018 and 2017 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, 2017 has been derived from the audited consolidated balance sheet at December 31, 2017, contained in the above referenced Form 10-K.

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.

Basic loss per share is computed by dividing net income available to common stockholders by the weighted average number of common shares outstanding during the period of computation. Diluted loss per share is computed similar to



basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if potential common shares had been issued, if such additional common shares were dilutive. Since we had net losses for all the periods presented, basic and diluted loss per share are the same, and additional potential common shares have been excluded as their effect would be antidilutive.

As of March 31, 2018, a total of 214,869,052 potential common shares, consisting of shares underlying outstanding convertible notes payable were excluded as their inclusion would be antidilutive.

#### Intangible Assets

Intangible assets consisted primarily of intellectual properties such as proprietary nutraceutical formulations. Intellectual assets are capitalized in accordance with ASC Topic 350 “Intangibles – Goodwill and Other.”

#### 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. Management believes that this new standard does not have a current or retrospective material effect on our consolidated financial statements.

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2018**

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

On November 17, 2016, the FASB issued ASU 2016-18, “Restricted Cash,” which requires that the statement of cash flows explain the change during a reporting period in the total of cash, cash equivalents, and the amounts generally described as restricted cash and restricted cash equivalents. This standard states that transfers between cash, cash equivalents, and restricted cash are not part of the entity’s operating, investing, and financing activities. Therefore, restricted cash should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. On January 1, 2018, the Company adopted the standard and retrospectively applied the guidance of the standard to the prior period presented, which resulted in an increase of \$10,156 in cash, cash equivalents, and restricted cash at the beginning of the first period presented on its consolidated statements of cash flow for the three months ended March 31, 2017.

**Note 3 – Restricted Cash**

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

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

At March 31, 2018 and December 31, 2017, the Company has unsecured interest bearing demand notes outstanding to certain officers and directors amounting to \$436,958 and \$429,201, respectively. Interest accrued on these notes during the three months ended March 31, 2018 and 2017 was \$7,936 and \$5,436, respectively.

**Note 5 – Convertible Notes Payable**

On September 7, 2017, January 3, 2018 and February 17, 2018, the Company entered into three \$28,000 convertible promissory notes with a third party for which the proceeds were used for operations. The Company received net proceeds of \$75,000 and a \$9,000 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 June 15, 2018, October 15, 2018 and November 20, 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 of 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 214,869,052 common shares in connection with the promissory notes.

#### *Derivative Liabilities*

The Company's 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.

For the two \$25,000 notes issued during the three months ended March 31, 2018, the Company valued the conversion feature on the date of issuance resulting in initial liability of \$129,351. 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 \$79,351 was recorded during the three months ended March 31, 2018. The Company valued the conversion feature using the Black-Scholes option pricing model with the following assumptions: conversion price of \$0.003, the closing stock price of the Company's common stock on the date of valuation of \$0.0075, an expected dividend yield of 0%, expected volatility ranging from 296% to 304%, risk-free interest rates ranging from 1.81% to 2.08%, and an expected term of 0.77 years.

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2018**

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

At December 31, 2017, the Company had existing derivative liabilities of \$107,769 related to two \$25,000 convertible notes. During the three months ended March 31, 2018, one of the \$25,000 convertible notes was converted into shares of common stock. At each conversion date, the Company recalculated the value of the derivative liability associated with the convertible note recording a gain (loss) in connection with the change in fair market value. In addition, the pro-rata portion of the derivative liability as compared to the portion of the convertible note converted was reclassified to additional paid-in capital. During the three months ended March 31, 2018, the Company recorded a gain of \$3,983 related to the change of fair value of the derivative liability and recorded \$48,443 to additional paid-in capital. The derivative liabilities were revalued using the Black-Scholes option pricing model with the following assumptions: conversion price of \$0.0033, the closing stock price of the Company's common stock on the date of valuation ranging from \$0.0065 to \$0.0090, an expected dividend yield of 0%, expected volatility of 267%, risk-free interest rate of 1.31%, and an expected term of 0.25 years.

On March 31, 2018, the derivative liabilities on remaining three \$25,000 convertible notes were revalued at \$143,850, resulting in a gain of \$40,844 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 \$0.003, the closing stock price of the Company's common stock on the date of valuation of \$0.007, an expected dividend yield of 0%, expected volatility of 214%, risk-free interest rate of 1.31%, and an expected term ranging from 0.21 to 0.67 years.

The Company amortizes the discounts over the term of the convertible promissory notes using the interest method. For the three months ended March 31, 2018, the Company amortized \$32,961 to interest expense. As of March 31, 2018, discounts of \$51,980 remained for which will be amortized through November 30, 2018.

**Note 6 – Subsequent Events**

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

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

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

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

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

## 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, 2017 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.

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” and was granted that patent on June 20, 2017.

Emvolio, Inc. (“EMVO”) – is a wholly-owned subsidiary of TSI, incorporated in the State of Delaware on October 03, 2016. EMVO intends to focus on developing 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. Mr. Dixon and Mr. Berg, and Dr. Ichim, of the Company, are also officers and officers and/or directors of EMVO. As of May 21, 2018, formal operations have not commenced.

SandBox Dental Labs, Inc. – is a wholly-owned subsidiary of TSI consisting of a dental laboratory to manufacture and fill prescriptions from dentists who will use our proprietary Sleep Appliance to treat their patients with mild to moderate obstructive sleep apnea. The Company is currently in the process of seeking regulatory approval for its device to treat sleep apnea. As of May 21, 2018, formal operations have not commenced.

Nutraceutical Division (TSOI)

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

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

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

Patents:

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

from cancer mediated immune suppression.

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



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

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

utilized as part of an integrative approach to building up the immune response of cancer patients.

In addition, on April 28, 2016 the Company filed a patent application covering the use of pterostilbene for augmentation of stem cell activity. Diseases such as diabetes, cardiovascular disease, and neurodegenerative diseases are characterized by deficient stem cell activity. The patent covers the stimulation of stem cells that already exist in the patient's body, as well as stem cells that are administered therapeutically.

Studies have shown that patients who have higher levels of endogenous stem cell activity have reduced cardiovascular disease risk and undergo accelerated neurological recovery after stroke as compared to patients with lower numbers of such stem cells.

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

The Company continues their research into the use of pterostilbene the active ingredient in ProJuvenol. To that end we have been able to produce a nanoemulsion of pterostilbene we are tentatively naming “**NanoStilbene**”.

**Pterostilbene**, being extracted from many plants, has significant biological activities in preventing cancer, diabetes, and cardiovascular diseases so as to have great potential applications in pharmaceutical fields.

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

A typical dose would be 5-10 milliliters yielding between 150 – 300 milligrams per dose. In addition to the benefits of the nanoparticle pterostilbene we chose to use medium chain triglycerides (MCT), derived from coconut oil, as one of our oil mediums in preparing the nanoemulsion. MCTs are not stored as fat, but rather convert quickly into Adenosine triphosphate (ATP), which provides energy for the body and brain at the cellular level.

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

**NanoStilbene** will soon be available in 150ml & 300ml bottles at a concentration of 30mg per ml with a recommended daily dose of 150mg.

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

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

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

- Reduced insulin sensitivity
- Reduction in VLDL and LDL (bad) cholesterol levels
- Increasing HDL (good) cholesterol levels
- Positive vascular smooth muscle cells
- Anti-inflammatory benefits
- Anti-oxidant benefits
- Cognitive function improvement
- Skin protection from Ultra Violet light exposure

### ***NanoTechnology***

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

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

To perfect and scale up this product we need to accomplish several important steps.

Pharmacokinetics of blood serum concentration across a prescribed period of time.

This involves the study of the bodily absorption, distribution, metabolism, and excretion of drugs and the characteristic interactions of a drug and the body in terms of its absorption, distribution, metabolism, and excretion.

Small pilot study to be performed under the direction of Dr. Santosh Kesari at John Wayne Cancer Institute in Santa Monica CA. by conducting a clinical trial assessing the effects of pterostilbene in modulating immune response and inflammatory parameters in a group of advanced solid tumor cancer patients.

Translate our PIC process to our GMP manufacturer.

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

We are optimistic that if the proposed trial demonstrates positive results, this will serve as a foundation for initiating combination clinical trials aimed at turning non-responders to responders using pterostilbene.

**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.

**NanoStilbene** is an easily absorbed nanoemulsion of nanoparticle pterostilbene in the range of 75-100nm at a concentration of 30 milligrams per milliliter. The pterostilbene placed in a nanoemulsion droplet is free from air, light, and hard environment; therefore, as a delivery system, nanoemulsion can not only improve the bioavailability of pterostilbene but also protect it from oxidation and hydrolysis, while it possesses an ability of sustained release at the same time.

## Dental

### SandBox Dental Labs, Inc.

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

The SandBox Dental Sleep Appliance, named Morpheus™, has been tested 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 splints) on the market.

The Company has submitted to FDA a new 510(k) application on June 20, 2017. On June 27, 2017, the Company was notified that our Submission for premarket notification was received and has been given Submission Number: K171918. Currently K171918 is in a clinical hold until we are able to conduct cytotoxicity and biocompatibility testing of the plastic and acrylic materials used in the construction of the appliance.

The full clinical trial information is not contained in this document, but the headline success rate of Morpheus was 80.3% in fully apneic patients. The potential exists for the device to be even more successful in non-apneic snorers (Barnes et al. (2004). Efficacy of Positive Airway Pressure and Oral Appliance in Mild to Moderate Obstructive Sleep Apnoea.).

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.

### Education, Training & Marketing

Our goal is to make every effort to educate our physicians and dentists so that evidenced based decision making leads to a patient centric system. Oral appliance therapy will only increase in its value in sleep medicine, if the education of our physicians and patients as well as dentists leads to increased awareness, a patient centric decision becomes more likely.

The Company intends to provide Continuing Education and Training as part of our overall marketing. We are staffed and prepared to offer the high quality courses that are indeed evidenced based and taught with our Dental Advisor and key opinion leader, Dr. Barry Glassman, other carefully chosen and trained dental instructors, and an appropriate physician team as well.

There is no field in medicine that has experienced growth and the dynamic changes more than sleep medicine. Those changes are seen as “traumatic” by traditionalists who do not recognize the problems of the existing model of sleep medicine and how that model actually prevents effective diagnosis and treatment. In an attempt to maintain “status quo” sleep medicine tends to react defensively.

There are many instances of resolution of severe Obstructive Sleep Apnea (OSA) with oral appliance therapy, and at the same time, one can point to instances of failure of oral appliance therapy to treat mild OSA. Clearly the number of outliers using AHI alone is significant. In addition, recent work of Cistuli, Sullivan, Anandam and others make it clear that oral appliance therapy can be as effective as CPAP in prevention of severe cardiovascular accidents in patients with severe OSA. There is no question, then, that Oral Appliance Therapy (OAT) has a real role in treatment, and that programs that do not have OAT as an alternative may not an effective treatment for patients.

## **Market Competition**

According to a new research study from Global Market Insights, Inc., the Sleep Apnea Devices Market size is poised to exceed USD 8.7 billion by 2023.

The **'Morpheus'** is an "in-patent" 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. TSOI has exclusivity in the USA until patent expires in 2033.

The **'Thornton Adjustable Positioner'**, or **TAP**, is an "out-of-patent" mandibular (lower jaw) advancement device specifically engineered for keeping your airway open during sleep. Currently the #1 prescribed appliance in the USA.

The **'SomnoDent'** oral appliance is a premium, custom-fitted dental sleep appliance developed for the treatment of snoring and obstructive sleep apnea. Currently the #2 prescribed appliance in the USA with sales of 5000 new appliances monthly.

### **Operational Workflow and Support**

The Company has plans to eventually build-out our own physical dental lab but for a period of time we will engage contract manufacturing to produce our appliances until sufficient capital is available to construct our own laboratory.

### **Contract Manufacturing with S4S Dental UK**

The Company has exclusivity in the USA in a licensing agreement with S4S Dental Laboratory of Sheffield England (s4sdental.com). TSOI has had a relationship with S4S Dental for many years and they are more than capable of meeting our needs as we grow our market.

S4S Dental markets the Morpheus in the UK as the "Sleepwell" and so there is no difference between the two appliances and their expertise in manufacturing is to our benefit as we grow our own US Market.

### **Workflow:**



- SandBox will receive dental impressions and prescription from dentist.
- SandBox lab techs will produce dental models from impressions that will be scanned 3-Dimensionally and transmitted to manufacturer.
- Appliance will then be fabricated to the specifications of prescribing dentist.
- Finished appliance will be returned to SandBox and subsequently delivered to prescribing dentist.
- All of this will be accomplished within the general two-week turnaround time of most labs.

### **Technical and Clinical Support:**

- Tier 1 technical support will be provided through support line and electronic communications.
- Tier 2 clinical support (doctor to doctor) will be provided by Dr. Glassman for a period of time with the addition of future assistants as we grow.

The Officers and Directors of the Company are also officers and Directors of SandBox. As of May 21, 2018, formal operations have not commenced. Expenses to date have been funded by TSI.

### **Immune-Oncology**

#### **Emvolio, Inc.**

Emvolio, Inc., (EMVO) is a wholly-owned subsidiary of TSI 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 May 21, 2018, TSI has licensed certain patents to Emvolio, but formal commercial operations have not commenced. Expenses to date have been funded by TSI.

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

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

On May 17, 2017, TSI 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, TSI licensed to EMVO a patent titled “Augmentation of Anti-Tumor Immunity by Mifepristone and Analogues Thereof” known clinically as “**LymphoBoost**”.

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

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

On April 12, 2017, the Company announced the submission of an Investigational New Drug Application with the US FDA for use of its StemVacs cancer immunotherapeutic in patients with solid tumors. The trial seeks to establish safety and immune response of the cancer, targeting a new personalized dendritic cell vaccine.

This is a single center, open label, non-randomized phase I trial to test the safety and potential efficacy of StemVacs in advanced cancer patients. We plan to treat a total of 15 patients that are ineligible for current treatments or have failed standard therapy using a total of 2 intravenously administered ascending doses of irradiated StemVacs. Doses will be 10, 25, and 50 million cells per injection. Injections will be performed on days 0 and 14 and responses will be evaluated at 1, 3, 6 and 12 months based on RECIST criteria (Response Evaluation Criteria In Solid Tumors (RECIST) is a set of published rules that define when tumors in cancer patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment.).

Additionally immune response changes will be assessed at baseline, 3, 6 and 12 months. The study will last 1 year. As of May 21, 2018, enrollment has not commenced.

Thomas Ichim, Ph.D., will be the person responsible for monitoring the conduct and progress of the clinical investigation as well as responsibility to review and evaluate information relevant to the safety of StemVacs.

Santosh Kesari, M.D., Ph.D., will be the Principal Investigator and the trial will be conducted at the John Wayne Cancer Institute with the cellular product being generated, tested, and filled by the John Wayne Cancer Institute Cell Processing Facility with cells previously generated from autologous patients.

The Primary Objective is safety and feasibility of StemVacs administration at 12 months as assessed by lack of adverse medical events. The Secondary Objective is efficacy as judged by tumor response, time to progression, and immunological monitoring.

Patients will be divided into 3 groups of 5 and administered: a) Group 1: 10 million cells; b) Group 2; 25 million and c) Group 3; 50 million cells of StemVacs intravenously administered. Each injection will be in a volume of 20 ml. StemVacs administration will be performed on days 0 and 14. Between dose escalation there will be a minimum 1 month break to assess adverse events by the data safety monitoring board.

Stimulation of immunity by Dendritic Cells (DC) has been demonstrated to function via antigen specific and non-specific manner. The current study will test the hypothesis that administration of peripheral blood DC matured by Transfer Factor (TF) will possess a favorable toxicity criteria and induce immune modulation in patients with advanced solid tumors.

Given the known suppression of DC activity by tumor cells, one hypothesis of the clinical trial will be that exogenously generated and matured DC will allow for an antigen non-specific immune modulation in the T cell and Natural Killer (NK) cell compartment. The findings of this study will support the use of StemVacs as an antigen-nonspecific immune modulatory treatment that will be utilized as a monotherapy or as combination with antigen specific modalities such as peptide or protein based vaccines.

In addition to StemVacs, the following four products will also be licensed exclusively to EMVO by TSOI who owns the intellectual property.

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

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

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

maintaining anti-tumor immunity.

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

The overarching approach to cancer at EMVO is as follows:

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

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

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

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

## 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, 2017, which was filed with the SEC on April 17, 2018.

### **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** – 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”.

### For the three months ended March 31, 2018 and 2017

Prepaid expenses and other current assets increased \$66,616, from \$1,054 to \$67,670 as of March 31, 2017 and 2018, respectively. This increase was mainly due to an increase in consulting agreements and scientific board member agreements that were entered into during the three months ended March 31, 2018. These agreements are capitalized over the number of months of their respective agreements.

We had a net loss of \$277,634 for the three months ended March 31, 2018, compared to a net loss of \$185,950 for the three months ended March 31, 2017, an increase of \$91,684. This increase was mainly due to increases in salaries, wages and related expenses, consulting fees and legal and professional fees.



Net sales increased \$52, from \$548 to \$600, for the three months ended March 31, 2017 and March 31, 2018, respectively.

Cost of goods sold decreased \$93, from \$198 to \$105, for the three months ended March 31, 2017 and March 31, 2018, respectively.

Operating expenses for the three month periods ended March 31, 2018 and 2017 were \$199,320 and \$180,118, an increase of \$19,202. This increase was mainly due to increases in salaries, wages and related expenses, consulting fees and legal and professional fees.

General and administrative expenses decreased \$3,521, from \$17,487 to \$13,966, for the three months ended March 31, 2017 and 2018, respectively. This decrease was mainly due decreased continuing education expense in the comparable quarters in 2018 vs 2017.

Salaries, wages and related expenses increased \$9,178, from \$89,431 to \$98,609 for the three months ended March 31, 2017 and 2018, respectively. This increase was mainly due to an increase in wage related expenses.

Selling expenses decreased \$212, from \$784 to \$572, for the three months ended March 31, 2017 and 2018, respectively. This was mainly due a decrease in selling and marketing expenses related to the Company's products during the period.

Consulting fees increased \$10,765 from \$0 to \$10,765 for the three months ended March 31, 2017 and 2018, respectively, due to an increase in overall consulting services.

Legal and professional fees increased \$18,344, from \$51,490 to \$69,834 for the three months ended March 31, 2017 and March 31, 2018, respectively, due to an increase in independent public accounting fees and legal expense.

Research and Development costs decreased \$15,351, from \$20,926 to \$5,575, for the three months ended March 31, 2017 and 2018, respectively. This increase was mainly due to increased research and development expenses for the comparable three month periods.

Loss on derivatives liability increased \$79,351, from \$0 to \$79,351 for the three months ended March 31, 2017 and March 31, 2018, respectively. This increase was due to a derivative liability loss from certain convertible notes at

March 31, 2018 compared to March 31, 2017.

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Change in fair value of derivative liabilities increased \$44,827 from \$0 to \$44,827 for the three months ended March 31, 2017 and March 31, 2018, respectively. This increase was due to a derivative liability revaluation change from certain convertible notes at March 31, 2018 compared to March 31, 2017.

Net interest expense increased \$38,102 from \$6,182 to \$44,284 for the three months ended March 31, 2017 and March 31, 2018, respectively. This increase was mainly due to increased debt balances.

### **Liquidity and Capital Resources**

We have experienced recurring losses over the past years which have resulted in accumulated deficits of approximately \$5.6 million and a working capital deficit of approximately \$1.4 million at March 31, 2018. These conditions raise significant doubt about the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is contingent upon its ability to secure additional financing, increase sales of its products and attain profitable operations. It is the intent of management to continue to raise additional capital. However, there can be no assurance that the Company will be able to secure such additional funds or obtain such on terms satisfactory to the Company, if at all.

There is no guarantee we will receive the required financing to complete our business strategies, and it is uncertain whether future financing will be available to us on acceptable terms. If financing is not available on satisfactory terms, we may be unable to continue, develop or expand our operations.

### **Off Balance Sheet Arrangements**

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

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

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

### **Item 4. Controls and Procedures**

*A. Disclosure Controls and Procedures*

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, or Exchange Act, our principal executive officer and principal financial officer evaluated our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of March 31, 2018. Based on this evaluation, these officers concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q, these disclosure controls and procedures were not operating effectively to ensure that the information required to be disclosed by the Company in reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and include controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

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

*B. Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended March 31, 2018 that materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

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

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

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

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

(3) we have ineffective controls over the period end financial disclosure and reporting process caused by 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, 2017, which was filed with the SEC on April 17, 2018.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

### **Item 3. Defaults Upon Senior Securities**

None.

### **Item 4. Mine Safety Disclosures**

No disclosure required.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

EXHIBIT

NUMBER DESCRIPTION

31.1 Rule 13a14(a)/Section 302 Certification of Principal Executive Officer

31.2 Rule 13a14(a)/Section 302 Certification of Principal Financial Officer

32.1 Certification pursuant to 18 U.S.C. Section 1350/Rule 13a14(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: May 21, 2018 By: */s/ Timothy G. Dixon*  
Timothy G. Dixon  
President and Chief Executive Officer  
  
(Principal Executive Officer)

Date: May 21, 2018 By: */s/ Gerry B. Berg*  
Gerry B. Berg  
  
Chief Financial Officer  
  
(Principal Financial Officer)

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