

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

Form 10-Q

November 14, 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 SEPTEMBER 30, 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 November 14, 2018, the Registrant had 976,175,844 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”, “will” 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>September 30, 2018</b>	<b>December 31, 2017</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 21,205	\$ 29
Accounts receivable, net	2,020	-
Inventory	1,545	1,515
Prepaid expenses and other current assets	181,778	1,054
<b>Total current assets</b>	<b>206,548</b>	<b>2,598</b>
<b>Other assets</b>	<b>23,942</b>	<b>23,927</b>
<b>Total assets</b>	<b>\$ 230,490</b>	<b>\$ 26,525</b>

**LIABILITIES AND SHAREHOLDERS' DEFICIT**

<b>Current liabilities:</b>		
Accounts payable	\$ 335,366	\$ 343,810
Accrued expenses and other current liabilities	652,756	432,640
Convertible notes payable, net of discount of \$75,402 and \$28,541 at September 30, 2018 and December 31, 2017, respectively	41,598	27,459
Notes payable-related parties	451,027	429,201
Derivative liabilities	222,421	107,769
<b>Total current liabilities</b>	<b>1,703,168</b>	<b>1,340,879</b>

**Shareholders' Deficit:**

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Preferred stock, \$ 0.001 par value; 5,000,000 shares authorized	-	-
Common stock, \$ 0.001 par value; 990,000,000 shares authorized; 931,175,844 and 806,501,000 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively.	931,176	806,501
Additional paid-in capital	3,923,277	3,147,811
Accumulated deficit	(6,327,131)	(5,268,666)
<b>Total shareholders' deficit</b>	<b>(1,472,678)</b>	<b>(1,314,354)</b>
<b>Total liabilities and shareholders' deficit</b>	<b>\$ 230,490</b>	<b>\$ 26,525</b>

*See accompanying notes to condensed consolidated financial statements.*

## THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

## Condensed Consolidated Statements of Operations

(Unaudited)

	For the Three Months ended September 30, 2018	For the Three Months ended September 30, 2017	For the Nine Months ended September 30, 2018	For the Nine Months ended September 30, 2017
<b>Net Sales</b>	\$ 3,301	\$ 630	\$ 4,920	\$ 1,923
Cost of Sales	560	191	769	616
<b>Gross Profit</b>	2,741	439	4,151	1,307
<b>Operating expenses:</b>				
General and administrative	20,715	22,694	56,953	75,437
Salaries, wages, and related costs	110,114	95,536	309,763	279,838
Selling expenses	593	712	1,771	2,538
Consulting fees	51,346	22,950	80,717	29,650
Legal and professional fees	42,672	64,226	170,899	216,945
Research and development	33,896	2,038	73,760	24,114
<b>Total operating expenses</b>	259,336	208,156	693,863	628,522
<b>Loss from operations</b>	(256,595)	(207,717)	(689,712)	(627,215)
<b>Other income (expense):</b>				
Loss on derivative liability	(139,221)	(83,968)	(260,676)	(83,968)
Change in fair value of derivatives liabilities	299,448	35,285	52,352	35,285
Interest expense	(71,406)	(10,363)	(160,429)	(24,675)
<b>Total other income (expense)</b>	88,821	(59,046)	(368,753)	(73,358)

<b>Net loss</b>	\$	(167,774)	\$	(266,763)	\$	(1,058,465)	\$	(700,573)
<b>Net loss per share - basic and diluted</b>	\$	(0.00)	\$	(0.00)	\$	(0.00)	\$	(0.00)
<b>Weighted average shares outstanding - basic and diluted</b>		895,023,749		783,207,044		870,304,630		769,394,382

*See accompanying notes to condensed consolidated financial statements.*

**Therapeutic Solutions International, Inc.**  
**Condensed Consolidated Statements of Changes in Shareholders' Deficit**  
**September 30, 2018**  
**(Unaudited)**

	<b>Common Stock</b>	<b>Common Stock</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</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	30,000,000	30,000	253,750	-	283,750
Common stock issued upon conversion of convertible note payable	33,674,844	33,675	333,716	-	367,391
Common stock issued	61,000,000	61,000	188,000	-	249,000
Net Loss	-	-	-	(1,058,465)	(1,058,465)
<b>Balance at September 30, 2018</b>	<b>931,175,844</b>	<b>\$ 931,176</b>	<b>\$ 3,923,277</b>	<b>(6,327,131)</b>	<b>\$ (1,472,678)</b>

*See accompanying notes to condensed consolidated financial statements*

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

	<b>For the Nine</b>	<b>For the Nine</b>
	<b>Months Ended</b>	<b>Months Ended</b>
	<b>September 30,</b>	<b>September 30,</b>
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (1,058,465)	\$ (700,573)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation to consultants	283,750	121,200
Accrued interest, notes payable	6,720	18,876
Loss on derivative liability	260,676	83,968
Change in fair value of derivative liabilities	(52,352)	(35,285)
Amortization of debt discount	126,139	9,092
Changes in operating assets and liabilities:		
Accounts receivable	(2,020)	-
Inventory	(30)	14,402
Prepaid expenses and other current assets	(180,724)	(26,068)
Other assets	-	8,300
Accounts payable	(8,444)	12,747
Accrued expenses and other current liabilities	243,925	186,479
<b>Net cash used in operating activities</b>	<b>(380,825)</b>	<b>(306,862)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock	249,000	141,000
Proceeds from issuance of convertible notes payable	155,000	50,000
Payments on notes payable - related parties	(1,984)	-
Net proceeds from investments by related parties	-	99,235

<b>Net cash provided by financing activities</b>		402,016	290,235
Net increase (decrease) in cash, cash equivalents, and restricted cash		21,191	(16,627)
Cash, cash equivalents, and restricted cash at beginning of period		10,185	32,066
Cash, cash equivalents, and restricted cash at end of period	\$	31,376 \$	15,439
<b>Supplemental Cash Flow Information:</b>			
Cash paid for interest	\$	3,761 \$	3,681
Cash paid for income taxes	\$	800 \$	-
<b>Non-cash investing and financing transactions</b>			
Original issuance discount on convertible notes payable	\$	18,000 \$	6,000
Debt discount recorded in connection with derivative liability	\$	155,000 \$	50,000
Common stock issued in payment of convertible note payable	\$	367,391 \$	-
<b>Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets:</b>			
Cash and cash equivalents	\$	21,205 \$	5,283
Restricted cash included in other assets		10,171	10,156
Total cash, cash equivalents, and restricted cash shown in the condensed consolidated statements of cash flows:	\$	31,376 \$	15,439

*See accompanying notes to condensed consolidated financial statements.*

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 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 focused 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 November 14, 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 has currently suspended its application in seeking regulatory approval for its device to treat sleep apnea. As of November 14, formal operations have not commenced.

Management does not expect existing cash as of September 30, 2018 to be sufficient to fund the Company's operations for at least twelve months from the issuance date of these September 30, 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 September 30, 2018, the Company has incurred losses totaling \$6.3 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 twelve months subsequent to the issuance 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 nine months ended September 30, 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**

**September 30, 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 and nine months ended September 30, 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.

#### Net loss per share

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 September 30, 2018, a total of 226,902,346 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 was 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 new standard in the first quarter of 2018 did not have a current or retrospective material effect on our consolidated financial statements.



**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 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 flows for the nine months ended September 30, 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, 2019 and is used as collateral for a Company credit card, pursuant to a security agreement dated June 20, 2011 and is not expected to be paid within the next twelve months.

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

At September 30, 2018 and December 31, 2017, the Company has unsecured interest bearing demand notes outstanding to certain officers and directors amounting to \$451,027 and \$429,201, respectively. Interest accrued on these notes during the nine months ended September 30, 2018 and 2017 was \$23,809 and \$12,541, respectively.

**Note 5 – Convertible Notes Payable**

On January 3, 2018, February 27, 2018, May 1, 2018, June 5, 2018, July 2, 2018 and August 6, 2018, the Company entered into five \$28,000 convertible promissory notes and one \$33,000 convertible promissory note with a third party for which the proceeds were used for operations. The Company received net proceeds of \$155,000 and a \$18,000 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 October 15, 2018, November 20, 2018, February 15, 2019, January 2, 2019 and February 6, 2019 and \$33,000 plus accrued interest is due March 30, 2019. 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 prices 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 at September 30, 2018, a total of 226,902,346 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 six notes issued during the nine months ended September 30, 2018, the Company valued the conversion feature on the date of issuance resulting in initial liability of \$415,676. Since the fair value of the derivatives were in excess of the proceeds received of \$155,000, a full discount to convertible notes payable and a day one loss on derivative liabilities of \$260,676 was recorded during the nine months ended September 30, 2018. Upon issuance, the Company valued the conversion feature using the Black-Scholes option pricing model with the following assumptions: conversion prices ranging from \$0.003 to \$0.006, the closing stock price of the Company's common stock on the date of valuation ranging from \$0.0052 to \$0.0220, an expected dividend yield of 0%, expected volatility ranging from 214% to 304%, risk-free interest rates ranging from 1.81% to 2.33%, and an expected term ranging from 0.76 to 0.82 years.

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2018**

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

At December 31, 2017, the Company had existing derivative liabilities of \$107,769 related to two \$28,000 convertible notes. During the nine months ended September 30, 2018, four of the \$28,000 convertible notes were 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 nine months ended September 30, 2018, the Company recorded a gain of \$114,892 related to the change of fair value of the derivative liability and recorded \$333,716 to additional paid-in capital. The derivative liabilities were revalued using the Black-Scholes option pricing model with the following assumptions: conversion prices ranging from \$0.0033 to \$0.0046 the closing stock price of the Company's common stock on the date of valuation ranging from \$0.0052 to \$0.02720, an expected dividend yield of 0%, expected volatility ranging from 185% to 277%, risk-free interest rates ranging from 1.81% to 2.33%, and expected terms ranging from 0.07 to 0.27 years.

On September 30, 2018, the derivative liabilities on the remaining four convertible notes were revalued at \$222,421 resulting in a loss of \$196,239 for the three months ended September 30, 2018 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: exercise price of \$0.004, the closing stock price of the Company's common stock on the date of valuation of \$0.01, an expected dividend yield of 0%, expected volatility ranging from 256% to 272%, risk-free interest rate of 2.33%, and an expected term ranging from 0.38 to 0.66 years.

The Company amortizes the discounts over the term of the convertible promissory notes using the effective interest method. For the nine months ended September 30, 2018, the Company amortized \$126,139 to interest expense. As of September 30, 2018, discounts of \$75,402 remained which will be amortized

**Note 6 – Subsequent Events**

On October 3, 2018, we issued a nine month convertible note in the amount of \$33,000 with an annual interest rate of 12%.

On October 25, 2018, the officers and a director were granted a Restricted Stock Award (“RSA”) for 15,000,000 shares each of Company’s common stock in accordance with a Restricted Stock Award Agreement dated October 25, 2018.

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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, 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 and diseases.

**Nutraceutical Division** – TSI has been producing high quality nutraceuticals. Its flagship product, ProJuvenol®, is a proprietary mixture containing pterostilbene – one of the most potent antioxidants known. TSOI was granted U.S. Patent No.: 9,682,047 for ProJuvenol® on 06-20-2017.

**Emvolio, Inc.** (“EMVO”) – is a wholly-owned subsidiary of TSI focused 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 November 14, 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 has currently suspended its application in seeking regulatory approval for its device to treat sleep apnea. As of November 14, 2018, formal operations have not commenced.

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

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

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

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

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

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

### **Nutraceutical Patents:**

TSOI filed a patent in July 2015 covering the use of its ProJuvenol® product, as well as various pterostilbene compositions, for use in augmenting efficacy of existing immuno-oncology drugs that are currently on the market. The patent is based on the ability of pterostilbene, one of the major ingredients of ProJuvenol®, to reduce oxidative stress produced by cancer cells, which in turn protects the immune system from cancer mediated immune suppression. That patent, U.S. No.: 9,682,047 was granted on 6-20-2017.

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

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

such stem cells.

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

On August 13, 2018 the Company filed a patent application titled "Enhancement of Ozone Therapy using Pterostilbene" showing pterostilbene potently augments killing of breast cancer, prostate cancer, and ovarian cancer cells by ozone therapy.

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

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

## **Pterostilbene**

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

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



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

Reduced insulin sensitivity

Reduction in VLDL and LDL (bad) cholesterol levels

Increasing HDL (good) cholesterol levels

Positive vascular smooth muscle cells

Anti-inflammatory benefits

Anti-oxidant benefits

Cognitive function improvement

Skin protection from Ultra Violet light exposure

**ProJuvenol®** which contains 200mg of >99% pure Pterostilbene in each daily dose is powerful synergistic blend of complex anti-aging ingredients inspired by nature to help promote cellular rejuvenation and healthy functionality for everyday living. Based upon pterostilbene, one of nature's unique and intelligent antioxidants/anti-inflammatories. ProJuvenol® includes a scientifically valid blend of interactive ingredients with anti-aging and cellular protective properties to help support optimal health and provide the benefits of mental alertness and physical well-being.

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

**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** is available in 150ml & 300ml bottles at a concentration of 30mg per ml with a recommended daily dose of 5ml – 10ml which is equal to 150-300mg.

### *Nanotechnology*

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

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

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

### **NanoStilbene Administration Results in Superior Pharmacokinetic Profile**

#### **Compared to Pterostilbene Administration**

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

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

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

**DermalStilbene** is delivered via spray application onto skin. This product contains DMSO (Dimethyl Sulfoxide) as a carrier and caution should be used not to spray product near eyes. Each 60ml bottle contains 300 applications of spray.

When using this product, you may notice some of the following; as spray lands on your skin you may feel heat sensation, and as the mist settles on your skin you may notice tingling or itching, this is all normal and will usually subside within 5 -10 minutes of use, although it can last longer. DermalStilbene is manufactured and sold under US Patent No.: 9,682,047

As previously stated, pterostilbene has been demonstrated in numerous publications to possess therapeutic effects in animal models of numerous inflammatory-associated conditions including cancer, diabetes, and heart failure, but it has also been shown to “protect hairless mice against UVB radiation-induced skin damage and carcinogenesis”, and “was able to reduce biofilm formation and kill the MRSA in immune cells by virtue of its strong antibacterial activity and facile delivery across biomembranes<sup>2</sup>”.

Pterostilbene is a more potent form of resveratrol, which both activate similar molecular pathways including SIRT-1. This protein called a “sirtuin” is known to possess anti-aging effects based on laboratory studies. While clinical studies have not been performed yet, it is not outside of the realm of possibility that pterostilbene based products may possess a beneficial effect on aging cells.

**IsoStilbene** an injectable formulation of pterostilbene under granted ‘047 Patent for Augmentation of Immunotherapy and Targeting of Cancer Stem Cells.

Peer reviewed publications have demonstrated efficacy of the pterostilbene molecule at stimulating immunity to cancer, as well as targeting cancer stem cells. Unfortunately, classical formulations of pterostilbene do not appear to deliver effective amounts of pterostilbene to cancer cells.

For this reason, Therapeutic Solutions International has developed several alternative dosing formulations including the previously discussed NanoStilbene, and now, IsoStilbene.

**NeuroStilbene** s delivered via spray application inside the nostril. Each 30ml bottle contains 300 applications of spray.

Intranasal delivery with the intention to deliver high concentrations of substances into the brain across what is called the “blood-brain barrier.” This structure is a “security system” that keeps blood cells separate from the fluid surrounding the brain. This barrier does provide oxygen and nutrients to be transported by the blood cells but prevents harmful substances like bacteria or poisons from getting to the brain. While compounds such as pterostilbene, and alpha lipoic acid, can bypass the BBB, it is anticipated that higher concentrations can be delivered through the intranasal route.

## **FUTURE BUSINESS DESCRIPTION**

**Emvolio, Inc.** (“EMVO”) – is a wholly-owned subsidiary of TSI focused 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 November 14, 2018, formal operations have not commenced.

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On May 1, 2018 the Company licensed StemVacs to Pan Am Cancer Center in Tijuana, Mexico and on June 6, 2018 the Company further licensed Pan Am four additional immunotherapy products developed by the Company. These four patent-pending technologies are Cancer Metabolic Detox, MemoryMune, LymphoBoost, and innaMune.

We hope to develop new products that can be used together to attack cancer as different levels, as well as be used alone or in combination with existing therapies. The overarching approach to cancer is as follows:

The overarching approach to cancer on the StemVacs Platform is as follows:

Treat innate immune suppression: Administration of oral NanoStilbene to decrease immune suppressive toxic molecules made by tumor and tumor microenvironment.

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

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

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

**StemVacs:** StemVacs is a subcutaneously administered vaccine comprised of immune stimulatory peptides resembling cancer stem cell specific proteins. **StemVacs** is now available as a treatment option at the Pan American Cancer Treatment Center in Tijuana, Mexico for stages 1-4 breast and prostate cancers.

**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.

### **Clinical Programs, Vaccines and Adjuvants**

#### **NanoStilbene Clinical Study in Cancer**

**1)** 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. This has been completed as of this writing.

**2)** A small pilot study is in the planning stages 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. This has been completed as of this writing.

**3)** Publication by Dr. Kesari, Dr. Ichim and other members of our team. This is currently underway.

#### **NanoStilbene Clinical Study in Heart Disease**

1) A small pilot study is in the planning stages to be performed under the direction of Dr. Nassir Azimi in San Diego CA. by conducting a study using NanoStilbene in a group of heart attack patients.

2) Publication by Dr. Azimi, Dr. Guzman, and other members of our team.

### **StemVacs Immunotherapy Platform for Prostate Cancer**

**StemVacs** is a platform for antigen-nonspecific immune modulatory treatment that can be utilized as a monotherapy or as a combination with antigen-specific modalities such as peptide or protein-based vaccines.

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

**StemVacs** is now available as a treatment option at the Pan American Cancer Treatment Center in Tijuana, Mexico for stages 1-4 breast and prostate cancers.

### **Immunotherapy as an Alternative to Watchful Waiting**

Early Stage Prostate Cancer: Because prostate cancer often grows very slowly, some men (especially those who are older or have other serious health problems) might never need treatment for their prostate cancer. Instead, their doctors usually recommend approaches known as watchful waiting. If you have elevated PSA but slow-growing prostate cancer, does it make sense to play “Russian Roulette” with your health? Currently, the only medical intervention that is available to patients with early-stage prostate cancer who do not want to “wait” is taking *finasteride*, which although has been shown to decrease the overall incidence, the patients that developed aggressive cancer had higher aggression when taking finasteride as compared to controls.

Immunotherapy Instead of Waiting: One promising treatment that we are developing and offering at the Pan Am Cancer Treatment Center, for patients who are “watchfully waiting” is the application of an immunotherapy that expects to specifically train the immune system to attack cancer.

Immunotherapy has been approved by the FDA for treatment of late-stage prostate cancer in the form of the cellular drug Provenge. This drug is comprised of a type of immune system cell, termed “dendritic cell” that is generated from the blood of patients.



It has the capacity to activate other immune cells in the body to attack proteins found on prostate-derived cells. Since prostate cancer cells possess prostate proteins, the immune system of patients treated with Provenge begins attacking prostate cancer cells not only in the prostate but all throughout the body. One of the main reasons why Provenge is not utilized in the United States for early-stage prostate cancer is its high costs.

This is very unfortunate because in the early stages of prostate cancer the immune system of the patient is still relatively intact, thus offering a much higher chance of success.

With the advantage of 10 years of experience in cellular processing and manufacturing, as well as a partnership with Key Opinion Leaders in the area of dendritic cell therapy, the Pan Am Cancer Treatment Center offers a novel way of dealing with early-stage prostate cancer.

Instead of “watchful waiting” or taking drugs that potentially increase the possibility of developing aggressive tumors, we offer a prostate cancer immunotherapeutic based on the same scientific principles as Provenge except for increased efficacy and lower price.

**Rationale for Immunotherapy:** The immune system is an ever-vigilant defense against bacterial, viral and parasitic infections, as well as against cancer<sup>7</sup>. Early studies demonstrated that some cancer patients whose immune systems are activated as a result of bacterial infections undergo remissions. Importantly, patients who have a chronically low level of immune activity are characterized by staggeringly high incidence of cancer.

Further support for an active role of the immune system in protecting the body against cancer comes from recent clinical trials in which a class of immune system stimulatory drugs termed “checkpoint inhibitors” have achieved previously unheard-of results in cancers resistant to treatment such as advanced prostate cancer.

It is well recognized that various types of cancers possess an incrementally higher level of ability to suppress the immune system the more advanced the cancer is. For example, in prostate cancer patients, those possessing a higher Gleason score suffer from an increased suppression of immune function.

Accordingly, augmentation of anticancer responses by introducing immunotherapy earlier in the pathogenesis of cancer progression increases the probability of success.

**Conclusion:**

At present, the only options available for patients with early-stage prostate cancer is waiting or taking drugs that potentially could increase aggressiveness.

**StemVacs Immunotherapy Platform for Breast Cancer**

**StemVacs** is a platform for antigen-nonspecific immune modulatory treatment that can be utilized as a monotherapy or as a combination with antigen-specific modalities such as peptide or protein-based vaccines.

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

**StemVacs** is now available as a treatment option at the Pan American Cancer Treatment Center in Tijuana, Mexico for stages 1-4 breast and prostate cancers.

***BRS-001: Cancer Stem Cell Targeted Immunotherapy***

**BRS-001** is a patent-pending cellular immunotherapy developed by scientists at Therapeutic Solutions International, Inc., a San Diego Biotechnology Company, which is available at the Pan Am Cancer Treatment Center in Tijuana Mexico to treat stages 1-4 in breast cancer.

**BRS-001** activates the immune system to seek and destroy cancer stem cells, based on their expression of a protein named Brother of the Regulator of Imprinted Sites (BORIS). BRS-001 is generated using white blood cells of the patient, which are grown outside of the body to create dendritic cells. The patient's own dendritic cells are treated in vitro with peptides derived from BORIS, and subsequently are injected back into the patient in order to program the immune response to kill cells that express the protein BORIS, which are cancer stem cells.

### **Without Killing of Cancer Stem Cells, it is Impossible to Cure Cancer**

All tumor cells are the offspring of a single, aberrant cell, but they are not all alike. Only a few retain the capacity of the original cell to create an entire tumor. Such cancer stem cells can migrate to other tissues and become fatal metastases. To fully cure a patient's cancer, it is crucial to find and eliminate all of these cells because any that escape can regenerate the tumor and trigger its spread through the body.

### **BORIS is Essential for Cancer "To be Cancer"**

The BORIS protein functions to disable a tumor suppressor termed "CTCF". The role of CTCF is to ensure that parts of DNA that should not be activated, indeed are not activated. For example, one of the roles of CTCF is to block expression of genes that cause cancer. In cancer stem cells, BORIS blocks the function of CTCF, thus allowing for propagation of cancer. It has been shown that if BORIS is blocked in cancer stem cells, the cancer stem cells no longer form tumors.

### **BRS-001 is Selective Immunotherapy**

Dendritic cells are the most potent immune stimulatory cell of the body. Currently, dendritic cell therapy is approved in the USA in the form of the drug Provenge. BRS-001 consists of dendritic cells that are treated with parts of the BORIS protein in order to stimulate killer T cell responses against any cell that expresses BORIS. Using dendritic cells to stimulate immunity offers the advantage of inducing immunological memory against the tumor. Published studies by us in collaboration with the NIH showed immunity to BORIS results in tumor killing.

### **Preclinical Proof**

The BRS-001 construct is capable of stimulating immune responses that cross over to wild-type tumors without having the potential of causing cancer. This ability to induce tumor immunity was validated across a broad variety of tissue types making the BRS-001 approach broadly applicable for numerous cancers. This was described in peer-reviewed papers by Company scientists demonstrating that immunization with BRS-001 not only inhibits growth of aggressive breast cancer 4T1 cells in BALB/c mice, but also that mice immunized with BRS-001 contain high numbers of CD8+ T cells that have spontaneous cytolytic activity against breast, leukemia, and glioma cells in vitro.

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Company scientists have determined that vaccination with BRS-001 in the context of various immune stimulatory technologies induces a CD8 cytotoxic T cell response that recognizes tumors independent of tissue origin.

**Conclusion:**

This type of immune response is usually associated with remission of the tumor. Based on this mechanism of action, Therapeutic Solutions International, Inc. has decided to develop a dendritic cell BORIS-peptide pulsed candidate as the most promising method of stimulating immune responses to BORIS in cancer patients.

**Additional StemVacs Platform Immunotherapeutics**

**NanoStilbene: Patented Augmenter of Cancer Immunotherapy**

**NanoStilbene**, a nanoparticle formulation of pterostilbene, is covered for use in cancer immunotherapy under the Company's issued U.S. Patent No.: 9,682,047 and is included as part of the Prostate and Breast Cancer Protocol with StemVacs.

**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.

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.

**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.

#### **Patent Title: Targeting the Tumor Microenvironment through Nutraceutical Based Immunoadjuvants**

Disclosed are compositions useful for the treatment of cancer which modulate tumor associated immunosuppression, thus acting as immunoadjuvants. In one embodiment a composition containing apigenin, is provided, said composition useful for inhibition of tumor associated immune suppression mediated through the molecule indolamine 2,3 deoxygenase (IDO). In another embodiment, liposomal apigenin is administered as a means of decreasing IDO expression.

**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.

**Patent Title: Activated Leukocyte Extract for Repair of Innate Immunity in Cancer Patients**

Disclosed are compositions, methods of use, and pharmaceutical preparations useful for modulation of immune responses. In one embodiment a composition is extracted polyvalently activated peripheral blood mononuclear cells through dialysis. Said immune modulator is useful for treatment of cancer and alleviation of cancer associated immune depression. In one embodiment, said immunomodulator acts as a costimulatory of T cell activation by modulation of cytokine production. In one embodiment said immune modulator is concentrated for miRNA species capable of activating innate immune cells.

**LymphoBoost:** LymphoBoost is a proprietary formulation of Mifepristone, 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.

**Augmentation of Anti-Tumor Immunity by Mifepristone and Analogues Thereof**

The present invention relates to compositions of matter and methods useful for improving a treatment outcome and/or an alteration of immunity in a condition that benefits from immune stimulation. In particular, one embodiment of the invention teaches administration of sufficient doses of mifepristone or a derivative, alone, or in combination with an immunotherapeutic such as, but not limited to, an antibody, a vaccine, a cytokine, or a medicament whose therapeutic activity is associated with immune modulation.

**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”.

**Patent Title: Methods of Re-Activating Dormant Memory Cells with Anticancer Activity**

Disclosed are methods, protocols and compositions of matter useful for stimulation of anticancer immune responses. In one embodiment of the invention culture of buffy coat cells is performed in an environment resembling non-physiological conditions. Buffy coat derived products are subsequently harvested, concentrated, and added to a culture of monocytes and lymphocytes. Conditioned media from said second culture is subsequently utilized as an injectable solution for stimulation of anticancer immunity.

**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, ProJuvenerol<sup>®</sup>, is a proprietary mixture containing pterostilbene – one of the most potent antioxidants known. TSOI was granted U.S. Patent No.: 9,682,047 for ProJuvenerol<sup>®</sup> on 06-20-2017.

**For the three and nine months ended September 30, 2018 and 2017**

Prepaid expenses and other current assets increased \$180,724, from \$1,054 to \$181,778 as of September 30, 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 nine months ended September 30, 2018. These agreements are capitalized over the number of months of their respective agreements.

We had a net loss of \$167,774 for the three months ended September 30, 2018, compared to a net loss of \$266,763 for the three months ended September 30, 2017, a decrease of \$98,989. This decrease was mainly due to increases in consulting fees, loss on derivative liability, interest expense, a decrease in legal and professional fees and changes in fair value of derivatives liabilities. We had a net loss of \$1,058,465 for the nine months ended September 30, 2018, compared to a net loss of \$700,573 for the nine months ended September 30, 2017, an increase of \$357,892. This increase was mainly due to increases in salaries, wages and related costs, consulting fees, research and development, loss on derivative liability, interest expense, a decrease in legal and professional fees, and changes in fair value of derivatives liabilities.

Net sales increased \$2,671, from \$630 to \$3,301, for the three months ended September 30, 2017 and September 30, 2018, respectively. Net sales increased \$2,997, from \$1,923 to \$4,920, for the nine months ended September 30, 2017 and September 30, 2018, respectively.

Cost of goods sold increased \$369, from \$191 to \$560, for the three months ended September 30, 2017 and September 30, 2018, respectively. Cost of goods sold increased \$153, from \$616 to \$769, for the nine months ended September 30, 2017 and September 30, 2018, respectively. These increases were mainly increases in net sales for products in 2018 and 2017.

Operating expenses for the three month periods ended September 30, 2018 and 2017 were \$259,336 and \$208,156, an increase of \$51,180. This increase was mainly due to an increase in salaries, wages, and related costs, consulting fees, research and development, and a decrease in legal and professional fees. Operating expenses for the nine month periods ended September 30, 2018 and 2017 were \$693,863 and \$628,522, an increase of \$65,342. This increase was mainly due to increases in salaries, wages and related costs, consulting fees, research and development, coupled with a decrease in legal and professional fees.

General and administrative expenses decreased \$1,979, from \$22,694 to \$20,715, for the three months ended September 30, 2017 and 2018, respectively. This decrease was mainly due to decreased continuing education expense in the comparable quarters in 2018 compared to 2017. General and administrative expenses decreased \$18,484, from \$75,437 to \$56,953, for the nine months ended September 30, 2017 and 2018, respectively. This decrease was mainly due decreased bad debt expense in the comparable quarters in 2018 compared to 2017.

Salaries, wages and related costs increased \$14,578, from \$95,536 to \$110,114 for the three months ended September 30, 2017 and 2018, respectively. This increase was mainly due to an increase in wage related expenses. Salaries, wages and related costs increased \$29,925, from \$279,838 to \$309,763 for the nine months ended September 30, 2017 and 2018, respectively. This increase was mainly due to an increase in wage related expenses.

Selling expenses decreased \$119, from \$712 to \$593, for the three months ended September 30, 2017 and 2018, respectively. This was mainly due a decrease in selling and marketing expenses related to the Company's products during the period. Selling expenses decreased \$767, from \$2,538 to \$1,771, for the nine months ended September 30, 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 \$28,396 from \$22,950 to \$51,346 for the three months ended September 30, 2017 and 2018, respectively, due to an increase in overall consulting services. Consulting fees increased \$51,067 from \$29,650 to \$80,717 for the nine months ended September 30, 2017 and 2018, respectively, due to an increase in overall consulting services.

Legal and professional fees decreased \$21,554, from \$64,226 to \$42,672 for the three months ended September 30, 2017 and September 30, 2018, respectively, due to a decrease in legal expenses. Legal and professional fees decreased \$46,046, from \$216,945 to \$170,899 for the nine months ended September 30, 2017 and September 30, 2018, respectively, due to a decrease in legal expenses.

Research and development costs increased \$31,858, from \$2,038 to \$33,896, for the three months ended September 30, 2017 and 2018, respectively. This increase was mainly due to increased research and development expenses related our NanoStilbene products for the comparable three month periods. Research and development costs increased \$49,616, from \$24,144 to \$73,760, for the nine months ended September 30, 2017 and 2018, respectively. This increase was mainly due to increased research and development expenses for the comparable nine month periods.

Loss on derivatives liability increased \$55,253, from \$83,968 to \$139,221 for the three months ended September 30, 2017 and September 30, 2018, respectively. This increase was due to a derivative liability loss from additional convertible notes outstanding at September 30, 2018 compared to September 30, 2017. Loss on derivatives liability increased \$176,708, from \$83,968 to \$260,676 for the nine months ended September 30, 2017 and September 30, 2018, respectively. This increase was due to a derivative liability loss from certain convertible notes at September 30, 2018 compared to September 30, 2017.

Change in fair value of derivative liabilities increased \$264,163 from \$35,285 to \$299,448 for the three months ended September 30, 2017 and September 30, 2018, respectively. This increase was due to a derivative liability revaluation change from all outstanding convertible notes for the three months ended September 30, 2018 compared to September 30, 2017. Change in fair value of derivative liabilities increased \$17,067 from \$35,285 to \$52,352 for the nine months ended September 30, 2017 and September 30, 2018, respectively. This increase was due to a derivative liability revaluation change from all outstanding convertible notes for the nine months ended September 30, 2018 compared to September 30, 2017.

Net interest expense increased \$61,043 from \$10,363 to \$71,406 for the three months ended September 30, 2017 and September 30, 2018, respectively. This increase was mainly due to increased debt balances. Net interest expense increased \$135,754 from \$24,675 to \$160,429 for the nine months ended September 30, 2017 and September 30, 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 \$6.3 million and a working capital deficit of approximately \$1.5 million at September 30, 2018. These conditions raise significant doubt about the Company's ability to continue as a going concern for the 12 months subsequent to the issuance of the September 30, 2018 financial statements. 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 September 30, 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 September 30, 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 September 30, 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 September 30, 2018 our internal control over financial reporting was not effective, and that material weaknesses existed in the following areas as of September 30, 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.

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

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

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

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

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

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

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

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

On September 10, 2018, we issued 3,262,222 shares of common stock for the partial conversion of \$13,000 and \$1,680 of interest for convertible note dated January 3, 2018.

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

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

On October 3, 2018, we issued a nine month convertible note in the amount of \$33,000 with an annual interest rate of 12%.

On October 25, 2018, the officers and a director were granted a Restricted Stock Award (“RSA”) for 15,000,000 shares each of Company’s common stock in accordance with a Restricted Stock Award Agreement dated October 25, 2018.

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**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 13a-14(a)/Section 302 Certification of Principal Executive Officer |
| <u>31.2</u> | Rule 13a-14(a)/Section 302 Certification of Principal Financial Officer |
| <u>32.1</u> | Certification pursuant to 18 U.S.C. Section 1350/Rule 13a-14(b)         |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

Date: November 14, 2018 By: */s/ Timothy G. Dixon*  
Timothy G. Dixon  
President and Chief Executive Officer  
  
(Principal Executive Officer)

Date: November 14, 2018 By: */s/ Gerry B. Berg*  
Gerry B. Berg  
  
Chief Financial Officer  
  
(Principal Financial Officer)

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