

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.  
Form 10-Q  
April 28, 2016

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2014**

**. 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  .

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

Accelerated Filer  .

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 April 27, 2016, the Registrant had 672,951,000 outstanding shares of Common Stock with a par value of \$0.001 per share.



### **IMPORTANT PREFATORY NOTE**

On April 28, 2014, we received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated. The ostensible reason given was our failure to make certain unspecified payments due under the license agreement to his clients. We disputed the termination, but believed that the costs involved with litigating the termination of the license was not in the best interest of the Company and its shareholders. Therefore, the Company decided to move in a new direction.

### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

The following factors are among those that may cause actual results to differ materially from our forward-looking statements:

Need for additional capital;

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Limited operating history in our new business model;

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Limited experience introducing new products;

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Our ability to successfully expand our operations and manage our future growth;

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Difficulty in managing our growth and expansion;

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Dilutive effects of any raising of additional capital;

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The deterioration of global economic conditions and the decline of consumer confidence and spending;

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Material weaknesses reported in our internal control over financial reporting;

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Our ability to protect intellectual property rights and the value of our products;

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The potential for product liability claims against us;

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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, 2013.

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

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

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

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## PART I Financial Information

## Item 1. Financial Statements

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

	<b>March 31, 2014</b>	<b>December 31, 2013</b>
	<b>(Unaudited)</b>	<b>(Audited)</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 7,635	\$ 12,513
Accounts receivable, net	23,758	21,391
Inventories	24,878	26,798
Prepaid expenses and other current assets	79,234	68,569
<b>Total current assets</b>	<b>135,506</b>	<b>129,271</b>
Other non-current assets	12,441	12,441
Property and equipment, net	63,850	69,133
<b>Total assets</b>	<b>\$ 211,796</b>	<b>\$ 210,844</b>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 289,084	\$ 298,521
Accrued expenses and other current liabilities	269,442	251,354
Due to related parties	226,964	236,324
<b>Total current liabilities</b>	<b>785,489</b>	<b>786,199</b>
<b>Shareholders' Deficit</b>		
Preferred stock, \$.001 par value; 5,000,000 shares authorized	-	-
Common stock, \$.001 par value; 699,999,999 shares authorized,	106,466	94,466

106,466,400 issued and outstanding at  
 March 31, 2014 and 699,999,999 shares  
 authorized, 94,466,400 issued and  
 outstanding at December 31, 2013

Capital in excess of par	1,699,475	1,665,725
Deficit accumulated	(2,379,634)	(2,335,546)
<b>Total shareholders' deficit</b>	<b>(573,693)</b>	<b>(575,355)</b>
<b>Total liabilities and shareholders' deficit</b>	<b>\$ 211,796</b>	<b>\$ 210,844</b>

*See accompanying notes to financial statements.*

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

	<b>For the Three Months End March 31, 2014</b>	<b>For the Three Months End March 31, 2013</b>
Net international revenues	\$ 75,419	\$ 107,956
Cost of goods sold	1,920	3,604
<b>Gross profit</b>	<b>73,499</b>	<b>104,352</b>
<b>Operating expenses:</b>		
Selling	2,580	3,215
General and administrative	14,476	18,026
Salaries, wages, and related costs	26,628	159,308
Royalties	-	4,158
Amortization and depreciation	5,283	5,830
Consulting fees	31,303	5,033
Legal and professional fees	42,615	77,431
<b>Total operating expenses</b>	<b>122,885</b>	<b>273,002</b>
<b>Loss from operations</b>	<b>(49,386)</b>	<b>(168,650)</b>
<b>Other income (expense):</b>		
Net other income (expense)	7,481	2,770
Interest expense	(2,184)	(408)
<b>Total other income (expense)</b>	<b>5,298</b>	<b>2,362</b>
<b>Net loss</b>	<b>\$ (44,088)</b>	<b>\$ (166,288)</b>
<b>Basic and diluted loss per common share</b>	<b>\$ (0.00)</b>	<b>\$ (0.00)</b>
<b>Weighted average shares outstanding</b>	<b>94,446,400</b>	<b>81,913,067</b>

*See accompanying notes to financial statements.*



**Therapeutic Solutions International, Inc.**  
**Condensed Consolidated Statement of Changes in Shareholders' (Deficit) (Unaudited)**  
**For the Period from December 31, 2012 to March 31, 2014**

	Common Stock	Common Stock Amount	Additional Paid-in Capital	Earnings (Deficit) Accumulated	Total
<b>Balance, December 31, 2012</b>	<b>305,458,333</b>	<b>\$ 305,458</b>	<b>\$ 1,285,533</b>	<b>\$ (1,783,888)</b>	<b>\$ (192,897)</b>
Stock returned & cancelled due to MDRA on January 17, 2013	(223,991,933)	(223,992)	223,992	-	-
Stock issued for service on May 8, 2013	2,000,000	2,000	28,200	-	30,200
Stock options granted June 29, 2013			78,000	-	78,000
Stock issued for service on July 10, 2013	2,000,000	2,000	10,000	-	12,000
Stock issued for service on July 15, 2013	4,000,000	4,000	20,000	-	24,000
Stock issued for service on December 2, 2013	5,000,000	5,000	20,000	-	25,000
Net Loss, December 31, 2013	-	-	-	(551,658)	(551,658)
<b>Balance, December 31, 2013</b>	<b>94,466,400</b>	<b>\$ 94,466</b>	<b>\$ 1,665,725</b>	<b>\$ (2,335,546)</b>	<b>\$ (575,355)</b>
Stock issued for service on March 31, 2014	12,000,000	12,000	33,750	-	45,750
Net Loss, March 31, 2014	-	-	-	(44,088)	(44,088)
<b>Balance, March 31, 2014</b>	<b>106,466,400</b>	<b>\$ 106,466</b>	<b>\$ 1,699,475</b>	<b>\$ (2,379,634)</b>	<b>\$ (573,693)</b>

*See accompanying notes to financial statements.*



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

	<b>For the</b>	<b>For the</b>
	<b>Three</b>	<b>Three</b>
	<b>Months</b>	<b>Months</b>
	<b>Ended</b>	<b>Ended</b>
	<b>March 31,</b>	<b>March 31,</b>
	<b>2014</b>	<b>2013</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (44,088)	\$ (166,288)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Non-cash expenses:		
Depreciation	5,283	5,830
Stock based compensation to consultants	45,750	30,200
Changes in operating assets and liabilities:		
(Increase) decrease in inventory	1,920	861
(Increase) decrease in accounts receivable	(2,367)	(23,110)
(Increase) decrease in prepaid expenses and other current assets	(10,665)	(30,694)
(Increase) decrease in other assets	-	-
Increase (decrease) in accounts payable	(9,437)	46,700
Increase (decrease) in accrued expenses and other current liabilities	18,087	112,319
Increase (decrease) in other related party liabilities	4,640	(15,652)
<b>Net cash provided by operating activities</b>	<b>9,122</b>	<b>(39,835)</b>
<b>Cash flows from investing activities</b>		
Acquisition of fixed assets	-	-
<b>Net cash used by investing activities</b>	<b>-</b>	<b>-</b>
<b>Cash flows from financing activities</b>		
Advance from Related Party	-	15,000
Repayments	(14,000)	-
<b>Net cash provided by financing activities</b>	<b>(14,000)</b>	<b>15,000</b>
Increase in cash	(4,878)	(24,835)
Cash at beginning of period	12,513	35,011
Cash at end of period	\$ 7,635	\$ 10,176

**Supplemental disclosure of non-cash investing and financing activities:**

Increase in fixed assets and due to related parties	\$	-	\$	-
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**Supplemental Cash Flow Information:**

Cash paid for interest	\$	734	\$	408
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*See accompanying notes to financial statements.*



**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO THE FINANCIAL STATEMENTS**

**As of and for the three ended March 31, 2014**

**(Unaudited)**

These unaudited Financial Statements and Notes should be read in conjunction with the audited financial statements and notes of Therapeutic Solutions International, Inc. as of and for the year ended December 31, 2013 included in its Annual Report on Form 10-K.

**Note 1 Organization and Presentation Basis**

The consolidated financial statements included herein have been prepared by Therapeutic Solutions International, Inc. (the Company), without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). In the opinion of the management of the Company, these interim Financial Statements include all adjustments, consisting of normal recurring adjustments, that are considered necessary for a fair presentation of the Company's financial position as of March 31, 2014 and the results of operations for the three months ended March 31, 2014 and 2013. Interim results are not necessarily indicative of results for a full year or for any future period.

The consolidated financial statements and notes included herein are presented as required by Form 10-Q, and do not contain certain information included in our audited financial statements and notes for the fiscal year ended December 31, 2013 pursuant to the rules and regulation of the SEC. For further information, refer to the financial statements and notes thereto as of and for the year ended December 31, 2013, and included in the Annual Report on Form 10-K on file with the SEC.

Therapeutic Solutions International, Inc. (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 organized September 21, 2010 (Splint). Splint is treated as the accounting acquirer in the accompanying financial statements.

Until April 28, 2014 the Company sold (directly and through distributors and sublicensees), in non-US countries, plastic intraoral devices known as Anterior Midpoint Stop Appliances (AMPSA Products). Our customers were dentists and doctors. The AMPSA Products, which are used for the treatment and prevention of common neurological and temporomandibular disorders including migraine headaches, migraine pain and bruxism.

On April 28, 2014, we received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated. The ostensible reason given was our failure to make certain unspecified payments due under the license agreement to his clients. We disputed the termination, but believed that the costs involved with litigating the termination of the New License was not in the best interest of the Company and its shareholders. Therefore, the Company moved in a new direction.

Currently the Company is involved in the medical sciences market. We are focused on three different areas within the same market. They are outlined as follows:

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Dietary Supplements

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Immunotherapy, and

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Fetal - Maternal Health

## **Note 2 Significant Accounting Policies**

### Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### Cash

For the Statements of Cash Flows, all highly liquid investments with maturity of three months or less are considered to be cash equivalents. There were no cash equivalents as of March 31, 2014 and 2013. Other assets include restricted cash of \$10,000 that is used to secure a company credit card.

### Inventory

Inventory consists of finished goods, and is stated at the lower of cost or market. The Company records cost of sales using the moving average cost method. There was no excess or obsolete inventory reserve at March 31, 2014 and 2013.

### Depreciation and Amortization

Depreciation is calculated using the straight line method over the estimated useful lives of the assets. Amortization is computed using the straight line method over the term of the agreement.

### Intangible Assets

Intangible assets consisted primarily of intellectual properties such as regulatory product approvals and patents. The Company does not own any such intangible assets as of March 31, 2014. On August 24, 2012, the Company entered into a New License Agreement, which terminated a prior Exclusive Agreements and continued, for the remainder of 2012, the exclusive worldwide license to make and sell the chairside AMPSA Products, as well as (other than in the United States) dental-laboratory semi-custom AMPSA Products. Beginning on January 1, 2013, the New License Agreement granted the Company a royalty-free nonexclusive worldwide license to make and sell certain products under certain Boyd Parties patent rights and related technology (but excluding the United States market). On April 28, 2014, the Company received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated See Note 5 License Agreements.

### Income Taxes

The Company accounts for income taxes under ASC 740 "*Income Taxes*," which codified SFAS 109, "*Accounting for Income Taxes*" and FIN 48 "*Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109*." Under the asset and liability method of ASC 740, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period the enactment occurs. A valuation allowance is provided for certain deferred tax assets if it is more likely than not that the Company will not realize tax assets through future operations.

### Going Concern

The Company's financial statements are prepared using accounting principles generally accepted in the United States of America applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has experienced recurring losses over the past years which have resulted in stockholders' accumulated deficits of approximately \$2,379 thousand and a working capital deficit of approximately \$649 thousand at March 31 2014. These conditions raise uncertainty about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is contingent upon its ability to secure additional financing, increase sales of its products and attain profitable operations. It is the intent of management to continue to raise additional capital.

However, there can be no assurance that the Company will be able to secure such additional funds or obtain such on terms satisfactory to the Company, if at all.

The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

### Share Based Expenses

ASC 718 "*Compensation - Stock Compensation*," which codified SFAS 123, prescribes accounting and reporting standards for all stock-based payments awarded to employees, including employee stock options, restricted stock, employee stock purchase plans and stock appreciation rights. Such payments may be classified as either equity or liabilities. The Company should determine if a present obligation to settle the share-based payment transaction in cash or other assets exists. A present obligation to settle in cash or other assets exists if: (a) the option to settle by issuing equity instruments lacks commercial substance or (b) the present obligation is implied because of an entity's past practices or stated policies. If a present obligation exists, the transaction should be recognized as a liability; otherwise, the transaction should be recognized as equity. See also Note 6 Equity Transactions.

The Company accounts for stock-based compensation issued to non-employees and consultants in accordance with the provisions of ASC 505-50 "*Equity-Based Payments to Non-Employees*," which codified SFAS 123, and the Emerging Issues Task Force consensus in Issue No. 96-18, "*Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods or Services*". Measurement of share-based payment transactions with non-employees shall be based on the fair value of whichever is more reliably measurable: (a) the goods or services received; or (b) the equity instruments issued. The fair value of the share-based payment transaction should be determined at the earlier of the performance commitment date or performance completion date. See also Note 6 Equity Transactions.

### Recently Implemented Standards

The Company has implemented all new accounting pronouncements that are in effect that may impact its financial statements and does not believe that there are any new accounting pronouncements that have been issued that might have a material impact on its financial statements.

**Note 3 Restricted Cash**

Other non-current asset is a \$10,000 certificate of deposit with an annual interest rate of 0.6%. This certificate matures on June 17, 2016, and is used as collateral for a Company credit card, pursuant to a security agreement dated June 20, 2011.

**Note 4 Equipment**

The cost and accumulated depreciation of fixed assets and equipment at March 31, 2014 and December 31, 2013 are summarized below:

	March 31, 2014	December 31, 2013
Computer Hardware	\$ 10,747	\$ 10,747
Office Furniture and Equipment	3,639	3,639
Shipping and Other Equipment	1,575	1,575
Molding Equipment Interests	90,000	90,000
Total	105,961	105,961
Accumulated Depreciation	(42,101)	(36,828)
Property and Equipment, net	\$ 63,850	\$ 69,133

Depreciation is calculated using the straight line method over the estimated useful lives of the assets. Depreciation expenses for the three months ended March 31, 2014 and year ended December 31, 2013 were \$5,283 and \$23,320, respectively.

## **Note 5 License Agreements**

The Company had a New License Agreement for the period from August 24, 2012 to December 31, 2012, an exclusive worldwide license with a 30% royalty on net sales (subject to reduction under certain conditions). Also, the New License Agreement granted the Company, for the period from January 1, 2013 forward, a royalty-free nonexclusive worldwide license to make and sell certain products, but excluding the United States market. On April 28, 2014, the Company received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated.

## **Note 6 Equity Transactions**

### Preferred Stock

The Company is authorized to issue 5,000,000 shares of \$.001 par value preferred stock. The Company has not issued any preferred stock.

### Common Stock

The Company is authorized to issue 699,999,999 shares of \$.001 par value common stock. All shares have equal voting rights, are non-assessable, and have one vote per share. Voting rights are not cumulative and, therefore, the holders of more than 50% of the common stock could, if they choose to do so, elect all of the directors of the Company.

On March 31, 2014, we issued 2,500,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On March 31, 2014, we issued 2,500,000 shares of common stock, valued at \$.004 per share, for consulting services.



On March 31, 2014, we issued 2,000,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On March 31, 2014, we issued 5,000,000 shares of common stock, valued at \$.006 per share, for legal services.

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500, shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,476,435 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,250,000 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 7,682,165 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On December 9, 2014, we issued 100,000,000 shares of common stock, valued at \$.0035 per share, in regard to a Material Definitive Agreement (Form 8-K filed on December 10, 2014).

On April 1, 2015, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On April 11, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On April 11, 2015, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On April 17, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On June 1, 2015, we issued 3,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On June 1, 2015, we issued 7,000,000 shares of common stock, valued at \$.0025 per share, for legal services

On June 8, 2015, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On August 31, 2015, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 9, 2015, we issued 3,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 16, 2015, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 17, 2015, we issued 4,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 17, 2015, we issued 31,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On November 17, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 30, 2015, we issued 5,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On November 30, 2015, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for legal services.

On January 4, 2016, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On January 22, 2016, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On February 1, 2016, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On February 5, 2016, we issued 8,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On February 22, 2016, we issued 5,451,000 shares of common stock, valued at \$.003 per share, in regard to a License Agreement (Form 8-K filed on February 25, 2016).

On February 26, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On March 7, 2016, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On March 21, 2016, we issued 100,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

#### Warrants

On February 20, 2009, the Company granted certain compensatory warrants. As of March 31, 2014 all warrants expired and no warrants were exercised. No warrants were granted by the Company in 2014 or 2015.

**Note 7 Related Party Transactions**

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500, shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,476,435 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,250,000 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 7,682,165 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

**Note 8 Subsequent Events**

On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

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On June 19, 2014, we issued 45,000,000 shares of common stock, valued at \$.003 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500, shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,476,435 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 26,562,500 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 21,250,000 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On September 30, 2014, we issued 7,682,165 shares of common stock, valued at \$.002 per share, to an officer of the Company for a conversion of notes payable for accrued wages.

On December 9, 2014, we issued 100,000,000 shares of common stock, valued at \$.0035 per share, in regard to a Material Definitive Agreement (Form 8-K filed on December 10, 2014).

On April 1, 2015, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On April 11, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On April 11, 2015, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On April 17, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.





On June 1, 2015, we issued 3,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On June 1, 2015, we issued 7,000,000 shares of common stock, valued at \$.0025 per share, for legal services

On June 8, 2015, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On August 31, 2015, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 9, 2015, we issued 3,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 16, 2015, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 17, 2015, we issued 4,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 17, 2015, we issued 31,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On November 17, 2015, we issued 20,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On November 30, 2015, we issued 5,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On November 30, 2015, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for legal services.

On January 4, 2016, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On January 22, 2016, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On February 1, 2016, we issued 2,500,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On February 5, 2016, we issued 8,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On February 22, 2016, we issued 5,451,000 shares of common stock, valued at \$.003 per share, in regard to a License Agreement (Form 8-K filed on February 25, 2016).

On February 26, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On March 7, 2016, we issued 10,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On March 21, 2016, we issued 100,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

The Company previously reported, on April 29, 2013 a former employee of the Company, Reid Jilek, sued the Company, its two directors and its three officers in San Diego County (California) Superior Court for breach of contract, retaliation, constructive discharge, failure to pay wages, failure to reimburse, conversion and fraudulent inducement. The complaint related to his employment agreement with the Company and his resignation which was effective in January 2013.

The trial was held in September 2014. On September 26, 2014 the Court ruled in favor of the Company and against all of Jilek's claims, and ruled that the Company was the prevailing party, and therefore was entitled to recover its attorney's fees and costs from Jilek. The Company did not prevail in its cross-claims against Jilek. Jilek's claims against the Company's directors and officers had previously been dismissed.

On December 9, 2014 the Company completed sales of its unregistered restricted common shares to Innovative Supplements, Inc., and Robert F. Graham. The Company sold a total of one hundred million (100,000,000) shares of unregistered restricted common stock at par value (\$0.001) per share in exchange for (i) an assignment of Seller and Shareholder's contractual right, title and interest in and to proprietary formulations for two nutritional supplement products known under the trade names: (a) T-Rx ; and, (b) Vital Female; and, (ii) the purchase of all legal right, title and interest, in and to intellectual property including, but not limited to, Innovative's nutritional supplement product known under the trade name: Projuvenol.

On July 8, 2015, the United States Patent and Trademark Office (the USPTO ) accepted U.S. Application No. 62/190170 titled Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions .

On July 21, 2015, the United States Patent and Trademark Office (the USPTO ) accepted U.S. Application No. 62/194990 titled Prevention of Pregnancy Complications by Probiotic Administration .

On September 02, 2015, the United States Patent and Trademark Office (the USPTO ) accepted U.S. Application No. 62/213260 titled Preventative Methods and Therapeutic or Pharmaceutical Compositions for the Treatment or Prevention of Pregnancy Complications .

On September 15, 2015, the United States Patent and Trademark Office (the USPTO ) accepted U.S. Application No. 62/219020 titled Diagnostic Methods For The Assessment Of Pregnancy Complications .

On September 25, 2015, the United States Patent and Trademark Office (the USPTO ) accepted U.S. Application No. 62/232722 titled A Medical Device For Reducing The Risk Of Preterm-Labor And Preterm-Birth .

On October 20, 2015, OmniBiome, Inc, a wholly owned subsidiary of the Company, was incorporated in the State of Delaware.

On October 28, 2015, MolecuVax, Inc, a wholly owned subsidiary of the Company, was incorporated in the State of Delaware.

On November 18, 2015, Therapeutic Solutions International, Inc. licensed certain intellectual property to OmniBiome, Inc., a wholly owned subsidiary of Therapeutic Solutions International, Inc., as follows:

(1) Application No. 62/213260 titled Preventative Methods and Therapeutic or Pharmaceutical Compositions for the Treatment or Prevention of Pregnancy Complications covers utility of vaccines and various agents to alter pathological conditions in which the maternal immune system induces a process of inflammation that culminates in placental alterations leading to either fetal loss or preterm labor;

(2) Application No. 62/219020 Diagnostic Methods For The Assessment Of Pregnancy Complications a cytokine-based diagnostic kit aimed at stratifying risk of preterm labor and other pregnancy associated complications; and

(3) Application No. 62/232722 A Medical Device For Reducing The Risk Of Preterm-Labor And Preterm-Birth covering various medical devices aimed at immune modulating the cervical microenvironment in order to prevent preterm labor.

On November 20, 2015, the United States Patent and Trademark Office (the USPTO ) accepted U.S. Application No. 62/258007 titled Exosome Mediated Innate and Adaptive Immune Stimulation for Treatment of Cancer .

On December 04, 2015, Therapeutic Solutions International, Inc. licensed certain intellectual property to OmniBiome, Inc., a wholly owned subsidiary of Therapeutic Solutions International, Inc., Application No. 62/194990 titled Prevention of Pregnancy Complications by Probiotic Administration.

On January 21, 2016, our Board of Directors elected Thomas E. Ichim, Ph.D, to fill a vacant seat on our Board of Directors.

On February 05, 2016, Therapeutic Solutions International, Inc. licensed certain intellectual property to MolecuVax, Inc., a wholly owned subsidiary of Therapeutic Solutions International, Inc., Application No. 62/258,007 titled Exosome Mediated Innate and Adaptive Immune Stimulation for Treatment of Cancer.



## **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, 2013 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**

### **Description of Business until April 28, 2014**

Until April 28, 2014 the Company sold (directly and through distributors and sublicensees), in non-US countries, plastic intraoral devices known as Anterior Midpoint Stop Appliances ( AMPSA Products ). Our customers were dentists and doctors. The AMPSA Products, which are used for the treatment and prevention of common neurological and temporomandibular disorders including migraine headaches, migraine pain and bruxism.

On April 28, 2014, we received a letter from Mr. J. Christopher Jaczko, a lawyer with the Procopio law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jaczko notified us that our license to use the international patents for our AMPSA device, pursuant to our license agreement with his clients effective January 1, 2013, was terminated. The ostensible reason given was our failure to make certain unspecified payments due under the license agreement to his clients. We disputed the termination, but believed that the costs involved with litigating the termination of the New License was not in the best interest of the Company and its shareholders. Therefore, the Company decided to move in a new direction.

## CURRENT BUSINESS DESCRIPTION

Therapeutic Solutions International, Inc. ( TSI ), is a public company (OTC:TSOI) 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 a well-accepted method to cure certain cancers, reduce recovery time from viral or bacterial infections and to prevent illness. On the other hand, inhibiting one s immune system is vital for reducing inflammation, autoimmune disorders and allergic reactions.

TSI is developing a range of immune-modulatory agents to target certain cancers, improve maternal and fetal health, fight periodontal disease, and for daily health. TSI has created several subsidiaries and divisions to focus on each of these programs:

**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 filed a patent application for ProJuvenol® on 07-08-2015 titled: Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions .



**OmniBiome, Inc.** - is a subsidiary of TSI, incorporated in the State of Delaware on October 20, 2015, where the intellectual property surrounding probiotics is housed. Current programs focus on the use of probiotics to prevent pre-term labor and on using probiotics to reverse periodontal disease.

**MolecuVax, Inc.** is a subsidiary of TSI, incorporated in the State of Delaware on October 28, 2015, where the intellectual property surrounding immune-oncology is housed. The programs within MolecuVax include using exosomes derived from various immune cells to attack cancers as well as developing a cancer vaccine against cancers that express a certain protein unique to them.

## **Summary**

TSI has assembled a first-rate scientific advisory board that is leading the company into the most exciting and potentially profitable fields of medicine - immune modulation. TSI expects to launch several products that improve people's health and well-being over the next several months.

## **Principle Products and Services**

### **Clinical Stage Dexosome**

TSOI recently licensed in 2015 a Dexosome Clinical Stage Cancer Immunotherapy Product from Gustave Roussy European Cancer Centre. Planning is still underway as to next steps.

Dexosomes are exosome nanoparticles generated by dendritic cells, which have previously been used by investigators at Anosys, Inc., in collaboration with researchers at Duke University, for treatment of cancer patients as part of an FDA-cleared Phase I clinical trial<sup>1</sup>. The licensed patent was invented by internationally-renowned immunologists Sebastian Amigorena, Doctor at the Curie Institute, and Laurence Zitvogel, Professor at Gustave Roussy. The patent covers means of generating therapeutically-effective dexosomes, which can act as a platform for loading any tumor antigen desired.

In the area of drug development, much of the risk is taking the technology from the lab to the patient. We are fortunate that the current technology has already been utilized in patients under FDA jurisdiction, and has demonstrated safety with signs of efficacy.

The in-licensing of the current patent augments previously filed patent applications by TSOI, including one filed in November 2015, covering uses of exosomes to stimulate both innate and adaptive arms of the immune response<sup>2</sup>. The Company plans to leverage the experience of its newest Board Member, Dr. Thomas Ichim, to lead the Dexosome program back into clinical trials. Dr. Ichim has previously patented the manipulation of exosomes in the area of cancer therapy for alleviation of immune suppression<sup>3</sup>, as well as being published in the peer-reviewed literature in this area<sup>4,5</sup>.

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1

Couzin-Frankel J. Breakthrough of the year 2013. Cancer immunotherapy. *Science*. 2013;342:1432-3. <https://www.sciencemag.org/content/342/6165/1432.summary>

2

Yang et al. Pterostilbene exerts antitumor activity via the Notch1 signaling pathway in human lung adenocarcinoma cells. *PLoS One*. 2013 May 3;8(5):e62652. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3643961/>

3

Li et al. Pterostilbene acts through metastasis-associated protein 1 to inhibit tumor growth, progression and metastasis in prostate cancer. *PLoS One*. 2013;8(3):e57542. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3586048/>

4

McCormack and McFadden. A review of pterostilbene antioxidant activity and disease modification. *Oxid Med Cell Longev*. 2013;2013:575482. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3649683/>

5

Qureshi et al. Inhibition of nitric oxide and inflammatory cytokines in LPS-stimulated murine macrophages by resveratrol, a potent proteasome inhibitor. *Lipids Health Dis*. 2012 Jul 10;11:76. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393619/>

6

Marcus et al. Severe hypovitaminosis C occurring as the result of adoptive immunotherapy with high-dose interleukin 2 and lymphokine-activated killer cells. *Cancer Res*. 1987 Aug 1;47(15):4208-12.



**Nutraceutical Division (TSOI)**

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

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

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

**Projuvenol includes:**

**Pterostilbene** (trans-3,5-dimethoxy-4-hydroxystilbene) is a natural dietary compound and the primary antioxidant component of blueberries. It has increased bioavailability in comparison to other stilbene compounds, which may enhance its dietary benefit and possibly contribute to a valuable clinical effect. Multiple studies have demonstrated the antioxidant activity of pterostilbene in both in vitro and in vivo models illustrating both preventative and therapeutic benefits. The antioxidant activity of pterostilbene has been implicated in anticarcinogenesis, modulation of neurological disease, anti-inflammation, attenuation of vascular disease, and amelioration of diabetes.

**Alpha lipoic acid (ALA)**, a coenzyme that is essential for producing cellular energy, assists in deactivating cell-damaging free radicals and renewing the body's antioxidant defense system. ALA supports a healthy liver function and enhanced insulin sensitivities.

**Superoxide dismutase (SOD)**, an essential enzyme found in all living cells, it is a powerful cellular protector which helps break down potentially harmful oxygen molecules in cells, assisting in the prevention of damage to tissues. Green coffee bean extract, which contains antioxidant polyphenols and plant compounds that help support a variety of biological processes including fat and glucose metabolism. Projuvenol uses the only known, patented coated source of Superoxide dismutase, to ensure that your body has the ability to absorb and utilize this ingredient. Uncoated versions of SOD have not been shown to be effective when taken orally.

**DMAE, 2-dimethylaminoethanol**, an ingredient known to help promote choline production, which is required for healthy neurological and cognitive function. DMAE has been shown to have the ability to scavenge specific types of free radicals, it is also has been shown to assist in improving memory and mood; boosting thinking skills and intelligence; and increasing physical energy, oxygen efficiency, athletic performance, and muscle reflexes.

**Piperine** for bio-enhanced nutrient absorption. Piperine has been clinically tested in the United States. Piperine significantly enhances the bioavailability of various supplement nutrients through increased absorption. We have included this in ProJuvenol because we believe that it significantly increases the absorption of the amazing active ingredients found in ProJuvenol.

**Curcumin** is an anti-inflammatory molecule in the turmeric root, a relative of ginger.

**Patent:**

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

Immuno-Oncology, described by Science Magazine as 'Breakthrough of the Year'<sup>1</sup> offers the possibility of not only killing tumor cells in a non-toxic manner, but also establishing immunological memory, which patrols the body and destroys recurrent tumor cells. While great progress has been made in developing drugs that stimulate the immune system to recognize and kill tumors, a major pitfall of current approaches is that tumors produce chemicals and oxidative stress that suppresses the immune system, thus limiting efficacy of immune therapies.

Pterostilbene, which is chemically related to resveratrol, has been published to possess anticancer<sup>2,3</sup>, antioxidant<sup>4</sup>, and anti-inflammatory activities<sup>5</sup>. Through the filing of the recent patent, the company is exploring whether its lead product, ProJuvenol®, may be useful as a nutraceutical adjuvant to conventional cancer immunotherapies.

The importance of proper nutrition in the context of immunotherapy cannot be overstated. Studies on one of the original cancer immunotherapies, interleukin-2, demonstrated that efficacy was related to anti-oxidant content in the patients at time of therapy<sup>6</sup>. Accordingly, we are seeking through the current work to identify whether our currently marketed product, ProJuvenol®, may be utilized as part of an integrative approach to building up the immune response of cancer patients.

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1.

Couzin-Frankel J. Breakthrough of the year 2013. Cancer immunotherapy. Science. 2013;342:1432-3. <https://www.sciencemag.org/content/342/6165/1432.summary>

2

Yang et al. Pterostilbene exerts antitumor activity via the Notch1 signaling pathway in human lung adenocarcinoma cells. PLoS One. 2013 May 3;8(5):e62652. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3643961/>

3

Li et al. Pterostilbene acts through metastasis-associated protein 1 to inhibit tumor growth, progression and metastasis in prostate cancer. PLoS One. 2013;8(3):e57542. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3586048/>

4

McCormack and McFadden. A review of pterostilbene antioxidant activity and disease modification. Oxid Med Cell Longev. 2013;2013:575482. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3649683/>

5

Qureshi et al. Inhibition of nitric oxide and inflammatory cytokines in LPS-stimulated murine macrophages by resveratrol, a potent proteasome inhibitor. Lipids Health Dis. 2012 Jul 10;11:76. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393619/>

6

Marcus et al. Severe hypovitaminosis C occurring as the result of adoptive immunotherapy with high-dose interleukin 2 and lymphokine-activated killer cells. Cancer Res. 1987 Aug 1;47(15):4208-12.

TSOI markets currently two other nutraceuticals, T-Rx®, a testosterone booster, and Vital® Female, an estrogen booster and has plans to introduce a line of oncologist friendly nutraceuticals in liposome formula.

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

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

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

**OmniBiome, Inc.**

OmniBiome, Inc. is focused on therapeutic / Rx approaches to either utilize or intervene with the systemic effects of the vaginal, lactal-duct and oral microbiomes for improving maternal healthcare and resulting birth outcomes.

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

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

**MicroBiome Targets**

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

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

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

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

**The Human Microbiome Link**



The following microbiomes combined recapitulate approximately 75 - 80 % of the gut microbiome, hence OmniBiome sees no need to focus on the gut microbiome

***The Vaginal Microbiome*** comprises approximately 300 - 600 species of bacteria. 100s of species are transferred to the newborn child orally as the baby passes thru the birth canal. C-section-born children miss this important microbiome transfer

***The Breast Milk Microbiome*** contains between 200 - 700 species of bacteria and is transferred to the child via nursing. Babies of non-nursing mothers miss this equally important transfer.

***The Oral Microbiome*** diversity spectrum also covers 600 species shared with the baby via kissing and sharing eating utensils with both the mother & the father.

### **Licensed Patents**

Patent titled "Prevention of Pregnancy Complications by Probiotic Administration." Press Release of 7/22/2015.

Patent titled "Preventative Methods and Therapeutic or Pharmaceutical Compositions for the Treatment or Prevention of Pregnancy Complications" covers utility of vaccines and various agents to alter pathological conditions in which the maternal immune system induces a process of inflammation that culminates in placental alterations leading to either fetal loss or preterm labor. Press Release of 9/8/2015.

Patent titled "Diagnostic Methods For The Assessment Of Pregnancy Complications" a cytokine-based diagnostic kit aimed at stratifying risk of preterm labor and other pregnancy associated complications. Press Release of 9/21/2015.

Patent titled "A Medical Device For Reducing The Risk Of Preterm-Labor And Preterm-Birth" covering various medical devices aimed at immune modulating the cervical microenvironment in order to prevent preterm labor. Press Release of 9/29/2015.



**MolecuVax, Inc.**

MolecuVax is a subsidiary of the Company where the intellectual property surrounding immune-oncology is housed. The programs within MolecuVax include using exosomes derived from various immune cells to attack cancers as well as developing a cancer vaccine against cancers that express a certain protein unique to them.

On February 08, 2016 TSOI licensed its exosome patent filed on 11-20-2015 to MolecuVax titled Exosome Mediated Innate and Adaptive Immune Stimulation for Treatment of Cancer as part of a future generation of immune cell derived nanoparticles, as a means of selectively stimulating the body's own natural defense mechanisms to seek and destroy cancer cells by company collaborators. The patent is focused on a means of manufacturing exosomes that possess high concentrations of proteins found on tumors, which are specifically optimized to stimulate the immune system of cancer patients as a new form of immunotherapy.

This patent was collaboration between Dr. Michael Agadjanyan, Head of the Department of Immunology at the Institute for Molecular Medicine, and Dr. Santosh Kesari, Head of Neuro-Oncology at the John Wayne Cancer Center, both of whom are members of the Scientific Advisory Board of TSOI.

Exosomes are one of the means by which immune system cells communicate with each other. In the current patent we disclose means of generating exosomes in the laboratory, which can be utilized as a nanoparticle-based cancer vaccine to stimulate immune response to tumors in patients suffering from cancer.

Immunotherapy of cancer offers the possibility of selectively treating cancer without the side effects of radiation and chemotherapy. The recent FDA approval of immune stimulatory drugs such as checkpoint inhibitors strongly supports the advancement of this natural means of using the body's own immune system to treat the cancer. Immunotherapy offers possibility to help patients in which chemotherapy and radiotherapy no longer work, without the side effects of these approaches.

**E-COMMERCE WEBSITE**

The Company's current e-commerce website seeks to speak directly and clearly to the user with the Company's established brand platform and function as a tactical extension of the Company's sales message.

In developing and implementing the Company's website, the Company will continue to:

·  
Establish and integrate an enterprise solution that allows it to sell products securely over the Internet, [www.youcanordernow.com](http://www.youcanordernow.com);

·  
Provide a mobile interface that allows customers and medical professionals to acquire product data and purchase from a mobile device such as an iPhone;

·  
Publish articles, news and white papers containing relevant information;

·  
Allow customers and medical professionals accessing the website to create a contact form with database capture; and,

·  
Provide for links to other Social Media websites where the Company will establish its brand identity, including Face Book, Twitter, et al.

### **OTHER MARKETING EFFORTS**

The Company currently uses a number of other marketing efforts using the growing social media channels, FaceBook, YouTube, Twitter, Instagram, etc, which currently are becoming increasing more relevant for our marketing strategy.

### **MANUFACTURING AND ORDER FULLFILLMENT**

The Company has located and vetted redundant Certified Good Manufacturing Practices (cGMP) manufacturing and production facilities and the Company's initial products will be produced, warehoused and shipped through its existing corporate offices.

## 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.

### **Results of Operations**

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

#### **For the three months ended March 31, 2014 and March 31, 2013**

Net revenues for the three month periods ended March 31, 2014 and 2013 were \$75,419 and \$107,956, a decrease of \$32,537. Our international sales are made upon distributors orders and can be bunched, so quarter to quarter

comparisons are not necessary instructive.

Operating expenses for the three month periods ended March 31, 2014 and 2013 were \$122,885 and \$273,002, a decrease of \$150,117. This decrease was mainly due headcount reductions, and the nonrecurrence of legal fees.

Selling expenses decreased \$635 from \$3,215 to \$2,580 and General and Administrative costs decreased \$3,550, from \$18,026 to \$14,476, for the three months ended March 31, 2013 and 2014, respectively. These decreases were mainly due to reduction in overhead costs.

Salaries, wages and related costs decreased \$132,680, from \$159,308 to \$26,628 for the three months ended March 31, 2013 and 2014, respectively. This decrease was due reduction in officers salaries and reduced employee headcount.

Royalties decreased from \$4,158 to \$0- for the three months ended March 31, 2013 and 2014, respectively. The decrease in Royalty expense was due to sales being royalty free effective January 1, 2013.

Amortization and depreciation decreased \$547 from \$5,830 to \$5,283 for the three months ended March 31, 2013 and 2014, respectively.

Consulting fees increased \$26,270 from \$5,033 to \$31,310 for the three months ended March 31, 2013 and 2014, due to new consulting agreements entered into during the quarter.

Legal and professional fees decreased \$34,816, from \$77,431 to \$42,615 for the three months ended March 31, 2013 and 2014. This decrease was mainly due to a reduction of legal services in 2014.

### **Liquidity and Capital Resources**

Net cash provided in operating activities totaled \$9,123 for the three months ended March 31, 2014 and our loss for the three months ended March 31, 2014 was \$44,088. We had no material commitments for capital expenditures at March 31, 2014.

As of March 31, 2014, we had approximately \$7,600 of cash. We had no cash equivalents at the end of the quarter. Clearly, such a cash level is untenable. Based upon our current plans, we believe that our existing capital resources will be sufficient to meet our operating expenses through 2014. However, changes in our product development or marketing plans or other events affecting our operating expenses may result in the expenditure of such cash before that time.

We believe we will need outside financing to execute our business plan in 2014 and beyond. There is no guarantee we will receive the required financing to complete our business strategies, and it is uncertain whether future financing will be available to us on acceptable terms. If financing is not available on satisfactory terms, we may be unable to continue, develop or expand our operations. Our auditor has stated in their opinion on our 2013 annual financial statements that there is substantial doubt about our ability to continue as a going concern.



## **Off Balance Sheet Arrangements**

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

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

No disclosure required.

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

### *A. Disclosure Controls and Procedures*

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, or Exchange Act, our principal executive officer and principal financial officer evaluated our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of March 31, 2014. 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 adequate to ensure that the information required to be disclosed by the Company in reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and include controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

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

*B. Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended March 31, 2014 that materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**

None

**Item 1A. Risk Factors**

No disclosure required.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

EXHIBIT

NUMBER	DESCRIPTION
3.1	Articles of Incorporation
3.1.1	Certificate of Merger, filed February 22, 2011
3.1.2	Certificate of Amendment to Articles of Incorporation filed October 15, 2012 (incorporated herein by reference to Form 8-K, filed on October 17, 2012)
3.2	Bylaws (incorporated herein by reference to Form SB-2, filed on November 21, 2007)
3.2.1	Bylaws amendments adopted August 22, 2012, August 24, 2012 and September 26, 2012
10.1	2009 Stock Incentive Plan (as amended on August 31, 2011) (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.2	Common Stock Share Exchange Agreement dated November 16, 2010 (incorporated herein by reference to Exhibit E to Regulation 14C information statement filed on February 15, 2011)
10.3	Exclusive License Agreement between Boyd Research, Inc. and us, dated April 1, 2011 (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.4	Investor Relations Consulting Agreement, between us and Constellation Asset Advisors, Inc., dated June 17, 2011 (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.5	Employment Agreement between Timothy Dixon and us, dated November 15, 2011 (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.6	Employment Agreement between Gerry Berg and us, dated November 15, 2011 (incorporated herein by reference to Form 10-K, filed on October 31, 2012)
10.7	Master Dispute Resolution Agreement, by and among us, James P. Boyd, Boyd Research, Inc., TMD Courses, Inc., Timothy G. Dixon and Gerry B. Berg, dated August 24, 2012 (incorporated herein by reference to Exhibit 10.1 to Form 8-K filed August 30, 2012)
10.8	License Agreement, by and among us, Boyd Research, Inc. and TMD Courses, Inc., dated August 24, 2012 (incorporated herein by reference to Exhibit 10.2 to Form 8-K filed August 30, 2012)
10.9	Escrow Agreement, by and among us and James P. Boyd and Chicago Title Company (as escrow agent), dated August 24, 2012 (incorporated herein by reference to Exhibit 10.3 to Form 8-K filed August 30, 2012)
10.10	Voting Agreement, by and between us and James P. Boyd, dated August 24, 2012 (incorporated herein by reference to Exhibit 10.4 to Form 8-K filed August 30, 2012)
10.11	License Agreement, by and among us, Innovative Supplements, Inc. and Robert F. Graham, dated December 9, 2014 (incorporated herein by reference to Form 8-K filed December 10, 2014)
10.12	License Agreement, by us and OmniBiome, Inc., a wholly owned subsidiary, dated November 18, 2015, 2015 (incorporated herein by reference to Form 8-K filed November 18, 2015)
10.13	License Agreement, by us and OmniBiome, Inc., a wholly owned subsidiary, dated December 4, 2015, 2015 (incorporated herein by reference to Form 8-K filed December 8, 2015)
10.14	License Agreement, by us and MolecuVax, Inc., a wholly owned subsidiary, dated February 5, 2016, 2015 (incorporated herein by reference to Form 8-K filed February 8, 2015)
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a)/Section 302 Certification of Principal Executive Officer
31.2	Rule 13a-14(a)/Section 302 Certification of Principal Financial Officer
32.1	Certification pursuant to 18 U.S.C. Section 1350/Rule 13a-14(b)



SIGNATURES

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

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

Date: April 28, 2016

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

(Principal Executive Officer)

Date: April 28, 2016

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

(Principal Financial Officer)

