

THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.  
Form 10-Q  
August 23, 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 SEPTEMBER 30, 2015**

**. 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 August 16, 2016, the Registrant had 682,751,000 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;

.  
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, 2014.

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

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

**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

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## PART I Financial Information

## Item 1. Financial Statements

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

	<b>September 30, 2015</b> <b>(Unaudited)</b>	<b>December 31, 2014</b> <b>(Audited)</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 8,495	\$ 2,894
Accounts Receivable, net	-	-
Inventories	28,572	-
Prepaid expenses and other current assets	6,868	139,016
Assets from discontinued operations	-	46,845
<b>Total current assets</b>	<b>43,936</b>	<b>188,756</b>
Other non-current assets	12,476	12,461
Property and equipment, net	-	-
<b>Total assets</b>	<b>\$ 56,411</b>	<b>\$ 201,217</b>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 289,489	\$ 290,554
Accrued expenses and other current liabilities	18,163	14,777
Due to related parties	26,364	27,174
<b>Total current liabilities</b>	<b>334,016</b>	<b>332,505</b>
<b>Shareholders' Equity</b>		
Preferred stock, \$.001 par value; 5,000,000 shares authorized	-	-

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Common stock, \$.001 par value;  
699,999,999 shares authorized,

484,000,000 issued and outstanding at  
September 30, 2015 and

699,999,999 shares authorized,  
400,000,000 issued and outstanding at

December 31, 2014	484,000	400,000
Capital in excess of par	2,240,309	2,093,009
Deficit accumulated	(3,001,914)	(2,624,296)
<b>Total shareholders' equity</b>	<b>(277,605)</b>	<b>(131,288)</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 56,411</b>	<b>\$ 201,217</b>

*See accompanying notes to financial statements.*

## THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.

## Condensed Consolidated Statements of Operations

(Unaudited)

	For the Three Months ended September 30, 2015	For the Three Months ended September 30, 2014	For the Nine Months ended September 30, 2015	For the Nine Months ended September 30, 2014
<b>Net Sales</b>	\$ 325	\$ -	\$ 745	\$ -
Cost of Goods Sold	166	-	263	-
<b>Gross Profit</b>	159	-	481	-
<b>Operating expenses:</b>				
General and administrative Salaries, wages, and related costs	25,727	13,421	58,673	55,500
Selling expenses	71,323	26,019	193,489	112,150
Amortization and depreciation	429	-	911	-
Consulting	-	5,283	-	15,850
Legal and professional	55,467	3,383	83,800	37,253
<b>Total operating     expenses</b>	25,708	16,081	30,046	91,209
<b>Loss from operations</b>	178,655	64,187	366,919	311,961
<b>Other income (expense):</b>				
Net other income/(expense)	178,496	64,187	366,438	311,961
Interest expense	-	888	1,682	108
<b>Total other income     (expense)</b>	(1,301)	(3,084)	(4,140)	(8,162)
<b>Net income (loss) from continuing operations</b>	(1,301)	(2,196)	(2,458)	(8,054)
Net income from discontinued operations	(179,797)	(66,383)	(369,377)	(320,015)
<b>Net income (loss)</b>	-	101,277	(8,722)	249,849
<b>Basic and diluted loss per common share</b>				
Continuing operation	\$ (179,797)	\$ 34,894	\$ (377,618)	\$ (70,167)
Discontinued operation.	\$ (0.00)	\$ (0.00)	\$ (0.00)	\$ (0.00)
<b>Weighted average shares outstanding</b>	\$ -	\$ 0.00	\$ (0.00)	\$ 0.00
	467,869,565	196,466,400	440,619,048	152,290,576

*See accompanying notes to financial statements.*

**Therapeutic Solutions International, Inc.**  
**Condensed Consolidated Statement of Changes in Shareholders' (Deficit)**  
**For the Period from December 31, 2013 to September 30, 2015**

	Common Stock	Common Stock Amount	Additional Paid-in Capital	Earnings (Deficit) Accumulated	Total
<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
Stock issued for note conversion on June 30, 2014	90,000,000	90,000	180,000	-	270,000
Stock issued for note conversion on September 30, 2014	103,533,600	103,534	103,534	-	207,067
Stock issued for a material definitive agreement	100,000,000	100,000	110,000	-	210,000
Net Loss, December 31, 2014	-	-	-	(288,750)	(288,750)
<b>Balance, December 31, 2014</b>	<b>400,000,000</b>	<b>\$ 400,000</b>	<b>\$ 2,093,009</b>	<b>\$ (2,624,296)</b>	<b>\$ (131,288)</b>
Stock issued on March 27, 2015	20,000,000	20,000	30,000	-	50,000
Stock issued on April 17, 2015	20,000,000	20,000	30,000	-	50,000
Stock issued on June 8, 2015	1,000,000	1,000	1,500	-	2,500
Stock issued on July 15, 2015	1,000,000	1,000	1,500	-	2,500
Stock issued for services on February 27, 2015	2,000,000	2,000	3,000	-	5,000
Stock issued for services on April 1, 2015	10,000,000	10,000	15,000	-	25,000
Stock issued for services on June 1, 2015	7,000,000	7,000	10,500	-	17,500
Stock issued for services on June 1, 2015	3,000,000	3,000	4,800	-	7,800
Stock issued for services on August 31, 2015	10,000,000	10,000	15,000	-	25,000
Stock issued for services on September 25, 2015	10,000,000	10,000	36,000	-	46,000
Net Loss, June 30, 2015	-	-	-	(377,618)	(377,618)
<b>Balance, September 30, 2015 (Unaudited)</b>	<b>484,000,000</b>	<b>\$ 484,000</b>	<b>\$ 2,240,309</b>	<b>\$ (3,001,914)</b>	<b>\$ (277,605)</b>

*See Accompanying Notes to Financial Statements*



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

	<b>For the Nine Months Ended September 30, 2015</b>	<b>For the Nine Months Ended September 30, 2014</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (377,618)	\$ (70,167)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Non-cash expenses:		
Depreciation	-	15,850
Stock based compensation to consultants	126,300	-
Stock based note conversion to officers	-	522,817
Changes in operating assets and liabilities:		
(Increase) decrease in inventory	(28,572)	-
(Increase) decrease in accounts receivable	-	-
(Increase) decrease in prepaid expenses and other current assets	132,148	(48,501)
(Increase) decrease in other assets	(15)	(20)
(Increase) decrease in bank overdraft	-	312
Increase (decrease) in accounts payable	(1,065)	(9,618)
Increase (decrease) in accrued expenses and other current liabilities	3,387	(211,576)
Increase (decrease) in other related party liabilities	(810)	(149,906)
Cash used by operating activities-continuing operations	(146,244)	49,191
Cash provided (used) by operating activities-discontinued operations	46,845	(56,703)
<b>Net cash used by operating activities</b>	<b>(99,399)</b>	<b>(7,511)</b>
<b>Cash flows from investing activities</b>		
Acquisition of fixed assets	-	-
<b>Net cash used by by investing activities</b>	<b>-</b>	<b>-</b>
<b>Cash flows from financing activities</b>		
Stock issuance	105,000	-
Repayments	-	(5,000)
<b>Net cash provided by financing activities</b>	<b>105,000</b>	<b>(5,000)</b>
Increase in cash	5,601	(12,513)
Cash at beginning of period	2,894	12,513
Cash at end of period	\$ 8,495	\$ -
<b>Supplemental Cash Flow Information:</b>		
Cash paid for interest	\$ 2,478	\$ 2,153

Cash paid for income taxes	\$	800	\$	800
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*See accompanying notes to financial statements.*



**THERAPEUTIC SOLUTIONS INTERNATIONAL, INC.**

**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**As of and for the nine months ended September 30, 2015**

**(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, 2014 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 September 30, 2015 and the results of operations for the three and nine months ended September 30, 2015 and 2014. 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, 2014 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, 2014, 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 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. The following outlines our relationships and divisions to focus on each of these programs:

**Nutraceutical Division** TSI has been producing high quality nutraceuticals. Its flagship product, ProJuvenol<sup>®</sup>, is a proprietary mixture containing pterostilbene – one of the most potent antioxidants known. TSOI filed a patent application for ProJuvenol<sup>®</sup> on 07-08-2015 titled: Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions .

**OmniBiome, Inc.,** ( OMNI ) - is a partially-subsiary of TSI, incorporated in the State of Delaware on October 20, 2015, where the intellectual property surrounding probiotics is housed.

On November 18, 2015 the Company licensed to OmniBiome, Inc. certain intellectually property. The License agreement in its entirety may be read as an exhibit filed with Form 8 K: [https://www.sec.gov/Archives/edgar/data/1419051/000107878215001890/f8k111715\\_ex10z1.htm](https://www.sec.gov/Archives/edgar/data/1419051/000107878215001890/f8k111715_ex10z1.htm)



Licensed Patent Rights: Shall mean:

- a. Patent Application Serial No. 62/213260 filed 9-02-2015 by Licensor.
- b. Patent Application Serial No. 62/219020 filed 9-15-2015 by Licensor.
- c. Patent Application Serial No. 62/232722 filed 9-25-2015 by Licensor.

1. Initial Payment and Royalty Rate. For the licensed herein granted:

(a) Licensee agrees to pay a sign-up fee of \$ 50,000.00.

(b) Licensee shall pay on earned royalty of Five Percent (5 %) of Licensee s Gross Sales of Products and fifty percent (50%) of the sublicensing receipts.

(c) Licensee shall pay an annual minimum royalty fee of Fifteen Thousand Dollars (\$15,000.00) for each licensed Product.

On December 4, 2015 the Company licensed to OmniBiome, Inc. certain intellectually property. The License agreement in its entirety may be read as an exhibit filed with Form 8 K: [https://www.sec.gov/Archives/edgar/data/1419051/000107878215001971/f8k120815\\_ex10z2.htm](https://www.sec.gov/Archives/edgar/data/1419051/000107878215001971/f8k120815_ex10z2.htm)

1. Licensed Patent Rights: Shall mean:

- a. Patent Application Serial No. 62/194990 filed 7-21-2015 by Licensor.

1. Initial Payment and Royalty Rate. For the licensed herein granted:

(a) Licensee agrees to pay a sign-up fee of \$ 50,000.00.

(b) Licensee shall pay on earned royalty of Five Percent (5 %) of Licensee s Gross Sales of Products and fifty percent (50%) of the sublicensing receipts.

(c) Licensee shall pay an annual minimum royalty fee of Fifteen Thousand Dollars (\$15,000.00) for each licensed Product.

Current programs focus on the use of probiotics to prevent pre-term labor and on using probiotics to reverse periodontal disease. The Officers and Directors of the Company are also officers and Directors of Omni. As of August 16, 2016 TSI owns approximately 73.75% of the outstanding shares of Omni. Website: <http://omnibiomeinc.com>

**MolecuVax, Inc., ( MVAX )** is a partially-owned subsidiary of TSI, incorporated in the State of Delaware on October 28, 2015, where the intellectual property surrounding immune-oncology is housed.

On February 8, 2016 the Company licensed to MolecuVax, Inc. certain intellectually property. The License agreement in its entirety may be read as an exhibit filed with Form 8 K : [https://www.sec.gov/Archives/edgar/data/1419051/000107878216002281/f8k020816\\_ex10z1.htm](https://www.sec.gov/Archives/edgar/data/1419051/000107878216002281/f8k020816_ex10z1.htm)

Licensed Patent Rights: Shall mean:

a. Patent Application Serial No. 62/258007 filed 11-20-2015 by Licensor.

1. Initial Payment and Royalty Rate. For the licensed herein granted:

(a) Licensee agrees to pay a sign-up fee of \$ 100,000.00.

(b) Licensee shall pay on earned royalty of Five Percent (5 %) of Licensee's Gross Sales of Products and fifty percent (50%) of the sublicensing receipts.

(c) Licensee shall pay an annual minimum royalty fee of Thirty Thousand Dollars (\$30,000.00) for each licensed Product.

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. The Officers and Directors of the Company are also officers and Directors of MVAX. As of August 16, 2016 TSI owns approximately 21.5% of the outstanding shares of MVAX. Website: [www.molecuvax.com](http://www.molecuvax.com)

### **Capo Therapeutics, Inc.**

Capo Therapeutics, Inc., ( CAPO ) is a Delaware Corporation incorporated on March 28, 2016. The main focus of Capo Therapeutics is the development of an effective and safe vaccine against Alzheimer's Disease (AD), one of the most devastating diseases of the century. Amyloid-beta (Ab) immunotherapy is considered to be a promising approach to reducing the level of Ab in the CNS of AD patients. However, data from the first clinical trial AN1792 indicated that vaccine should be designed not to induce autoreactive cellular responses and to be effective in the majority of the individuals from the risk groups. The Officers and Directors of the Company are also officers and Directors of CAPO. As of August 16, 2016 TSI owns approximately 6.5% of the outstanding shares of CAPO. Website: [www.capotherapeutics.com](http://www.capotherapeutics.com)

## **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 September 30, 2015 and 2014. 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 September 30, 2015 and December 31, 2014.

### 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 proprietary nutraceutical formulations. Intellectual assets are capitalized in accordance with ASC Topic 350 Intangibles Goodwill and Other.

### Long-lived Assets

In accordance with ASC 360, Property, Plant and Equipment, the carrying value of intangible assets and other long-lived assets is reviewed on a regular basis for the existence of facts or circumstances that may suggest impairment. The Company recognizes impairment when the sum of the expected undiscounted future cash flows is less than the carrying amount of the asset. Impairment losses, if any, are measured as the excess of the carrying amount of the asset over its estimated fair value. During the year ended December 31, 2014, the Company recognized an impairment charge of \$210,000 for intangible assets.



### 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 accumulated deficits of approximately \$3,001 thousand and a working capital deficit of approximately \$290 thousand at September 30, 2015. 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, 2017, 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 September 30, 2015 and December 31, 2014 are summarized below:

	September 30, 2015		December 31, 2014
Computer Hardware	\$ 10,747	\$	10,747
Office Furniture and Equipment	3,639		3,639
Shipping and Other Equipment	1,575		1,575
Total	15,961		15,961
Accumulated Depreciation	(15,961)		(15,961)
Property and Equipment, net	\$ -	\$	-

Depreciation is calculated using the straight line method over the estimated useful lives of the assets. Depreciation expenses for the nine months ended September 30, 2015 and year ended December 31, 2014 were \$0 and \$21,133, respectively.

**Note 5 - Intangible Asset**

On December 9, 2014 the Company contractually obtained the rights, 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, 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. The Company issued 100,000,000 shares for this rights, title and interest. The fair value of the 100,000,000 shares of common stock of \$210,000 has been recorded as intangible assets. On December 31, 2014, the Company performed an impairment test

on the intellectual property, and the Company recorded an impairment of \$210,000.

## **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

As of July 27, 2016 the Company is authorized to issue 990,000,000 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 \$.004 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 \$.0021 per share, in regard to a Material Definitive Agreement (Form 8-K filed on December 10, 2014).

On March 27, 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 March 27, 2015, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for consulting services.

On April 1, 2015, we issued 10,000,000 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 \$.0026 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 July 15, 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 September 25, 2015, we issued 10,000,000 shares of common stock, valued at \$.0046 per share, for consulting services.

On October 1, 2015, we issued 23,000,000 shares of common stock, valued at \$.0063 per share, for consulting services.

On October 13, 2015, we issued 2,500,000 shares of common stock, valued at \$.0060 per share, for consulting services.

On October 14, 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 October 16, 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 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 23, 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 2,500,000 shares of common stock, valued at \$.01 per share, for legal services.

On January 4, 2016, we issued 2,500,000 shares of common stock, valued at \$.004 per share, for consulting services.



On January 22, 2016, we issued 2,500,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On February 1, 2016, we issued 2,500,000 shares of common stock, valued at \$.003 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 \$.004 per share, for consulting services.

On March 21, 2016, we issued 100,800,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 2, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement and 1,000,000 shares of common stock, valued at \$.0053 per share, for consulting services.

On May 26, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for consulting services.

On May 26, 2016, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 31, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for legal services.

On July 27, 2016, we filed with the Nevada Secretary of State a Certificate of Amendment to Articles of Incorporation to effect an amendment (the Amendment ) changing the number of authorized shares of our common stock to 990,000,000.

## Note 7 Discontinued Operation

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 following are the summarized results of discontinued operations for the three and nine months ended September 30, 2015 and 2014 and the Balance Sheet as of September 30, 2015 and December 31, 2014:

	<b>For the Three Months ended September 30, 2015</b>	<b>For the Three Months ended September 30, 2014</b>	<b>For the Nine Months ended September 30, 2015</b>	<b>For the Nine Months ended September 30, 2014</b>
Net revenues	\$ -	\$ 124,593	\$ -	\$ 268,892
Cost of goods sold	-	(23,215)	-	(26,798)
Selling expenses	-	(1,101)	-	(5,678)
Bad debt	-	-	(4,670)	-
Obsolete inventory	-	-	(4,052)	-
Other income from discontinued operations	-	1,000	-	13,433
	\$ -	\$ 101,277	\$ (8,772)	\$ 249,849
	<b>September 30, 2015</b>	<b>December 31, 2014</b>		
Assets				
Accounts Receivable, net	\$ -	\$ 46,895		
Total assets of discontinued operations	\$ -	\$ 46,895		



## **Note 8 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.

As of September 30, 2015, the Company has advanced approximately \$5,900 to the officers of the company. Additionally the officers of the Company waived their monthly salary accrual from July 1, 2014 to December 31, 2014. The Company has accrued officer salaries of \$135,000 and \$154,150 and paid \$36,000 and \$15,288 for the nine months ended September 30, 2015 and 2014, respectively.

## **Note 9 Litigation**

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.

#### **Note 10 Subsequent Events**

On October 1, 2015, we issued 23,000,000 shares of common stock, valued at \$.0063 per share, for consulting services.

On October 13, 2015, we issued 2,500,000 shares of common stock, valued at \$.0060 per share, for consulting services.

On October 14, 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 October 16, 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 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 23, 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 2,500,000 shares of common stock, valued at \$.01 per share, for legal services.

On January 4, 2016, we issued 2,500,000 shares of common stock, valued at \$.004 per share, for consulting services.

On January 22, 2016, we issued 2,500,000 shares of common stock, valued at \$.0035 per share, for consulting services.

On February 1, 2016, we issued 2,500,000 shares of common stock, valued at \$.003 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). Add detail payment schedule. Euro 250,000, Euro 275,000, Euro 300,000, Euro 375,000, and Euro 500,000

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 \$.004 per share, for consulting services.

On March 21, 2016, we issued 100,800,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 2, 2016, we issued 1,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement and 1,000,000 shares of common stock, valued at \$.0053 per share, for consulting services.

On May 26, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for consulting services.

On May 26, 2016, we issued 2,000,000 shares of common stock, valued at \$.0025 per share, for an investment in the Company's Private Placement.

On May 31, 2016, we issued 2,500,000 shares of common stock, valued at \$.0066 per share, for legal services.

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

On October 28, 2015, MolecuVax, Inc., a partially-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 partially-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 partially-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 partially-owned subsidiary of Therapeutic Solutions International, Inc., Application No. 62/258,007 titled Exosome Mediated Innate and Adaptive Immune Stimulation for Treatment of Cancer.

On April 27, 2016, the United States Patent and Trademark Office (the USPTO ) accepted U.S. Application No. 62/327756 titled Augmentation Of Stem Cell Activity Using Pterostilbene And Compositions Containing Pterostilbene .

On July 27, 2016, we filed with the Nevada Secretary of State a Certificate of Amendment to Articles of Incorporation to effect an amendment (the Amendment ) changing the number of authorized shares of our common stock to 990,000,000.

On or about August 4, 2016 it was determined a shareholder had overcharged the Company in an inventory purchase in the amount of approximately \$5,100. As of September 30, 2015 we recorded an Accounts Receivable of \$5,100 and a corresponding contra account in the same amount. We intend to pursue collection of this amount from the shareholder.

## 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, 2014 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**

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

**Nutraceutical Division** TSI has been producing high quality nutraceuticals. Its flagship product, ProJuvenol<sup>®</sup>, is a proprietary mixture containing pterostilbene one of the most potent antioxidants known. TSOI filed a patent application for ProJuvenol<sup>®</sup> on 07-08-2015 titled: Augmentation of Oncology Immunotherapies by Pterostilbene Containing Compositions . On April 28, 2016 the Company announced the filing of a patent application covering the use of ProJuvenol<sup>®</sup> and its active ingredient pterostilbene for augmentation of stem cell activity.

**OmniBiome, Inc.,** ( OMNI ) - is a partially-subsiary of TSI, incorporated in the State of Delaware on October 20, 2015, where the intellectual property surrounding probiotics is housed.

On November 18, 2015 the Company licensed to OmniBiome, Inc. certain intellectually property. The License agreement in its entirety may be read as an exhibit filed with Form 8 K : [https://www.sec.gov/Archives/edgar/data/1419051/000107878215001890/f8k111715\\_ex10z1.htm](https://www.sec.gov/Archives/edgar/data/1419051/000107878215001890/f8k111715_ex10z1.htm)

Licensed Patent Rights: Shall mean:

- a. Patent Application Serial No. 62/213260 filed 9-02-2015 by Licensor.
- b. Patent Application Serial No. 62/219020 filed 9-15-2015 by Licensor.
- c. Patent Application Serial No. 62/232722 filed 9-25-2015 by Licensor.

1. Initial Payment and Royalty Rate. For the licensed herein granted:

(a) Licensee agrees to pay a sign-up fee of \$ 50,000.00.

(b) Licensee shall pay on earned royalty of Five Percent (5 %) of Licensee s Gross Sales of Products and fifty percent (50%) of the sublicensing receipts.

(c) Licensee shall pay an annual minimum royalty fee of Fifteen Thousand Dollars (\$15,000.00) for each licensed Product.

On December 4, 2015 the Company licensed to OmniBiome, Inc. certain intellectually property. The License agreement in its entirety may be read as an exhibit filed with Form 8 K : [https://www.sec.gov/Archives/edgar/data/1419051/000107878215001971/f8k120815\\_ex10z2.htm](https://www.sec.gov/Archives/edgar/data/1419051/000107878215001971/f8k120815_ex10z2.htm)

1. Licensed Patent Rights: Shall mean:

a. Patent Application Serial No. 62/194990 filed 7-21-2015 by Licensor.

1. Initial Payment and Royalty Rate. For the licensed herein granted:

(a) Licensee agrees to pay a sign-up fee of \$ 50,000.00.

(b) Licensee shall pay on earned royalty of Five Percent (5 %) of Licensee s Gross Sales of Products and fifty percent (50%) of the sublicensing receipts.

(c) Licensee shall pay an annual minimum royalty fee of Fifteen Thousand Dollars (\$15,000.00) for each licensed Product.

Current programs focus on the use of probiotics to prevent pre-term labor and on using probiotics to reverse periodontal disease. The Officers and Directors of the Company are also officers and Directors of Omni. As of August 16, 2016 TSI owns approximately 73.75% of the outstanding shares of Omni. Website: <http://omnibiomeinc.com>

**MolecuVax, Inc., ( MVAX )** is a partially-owned subsidiary of TSI, incorporated in the State of Delaware on October 28, 2015, where the intellectual property surrounding immune-oncology is housed.

On February 8, 2016 the Company licensed to MolecuVax, Inc. certain intellectually property. The License agreement in its entirety may be read as an exhibit filed with Form 8 K :



Licensed Patent Rights: Shall mean:

a. Patent Application Serial No. 62/258007 filed 11-20-2015 by Licensor.

1. Initial Payment and Royalty Rate. For the licensed herein granted:

(a) Licensee agrees to pay a sign-up fee of \$ 100,000.00.

(b) Licensee shall pay on earned royalty of Five Percent (5 %) of Licensee's Gross Sales of Products and fifty percent (50%) of the sublicensing receipts.

(c) Licensee shall pay an annual minimum royalty fee of Thirty Thousand Dollars (\$30,000.00) for each licensed Product.

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. The Officers and Directors of the Company are also officers and Directors of MVAX. As of August 16, 2016 TSI owns approximately 21.5% of the outstanding shares of MVAX. Website: [www.molecuvax.com](http://www.molecuvax.com)

Capo Therapeutics, Inc.

Capo Therapeutics, Inc., ( CAPO ) is a Delaware Corporation incorporated on March 28, 2016. The main focus of Capo Therapeutics is the development of an effective and safe vaccine against Alzheimer's Disease (AD), one of the most devastating diseases of the century. Amyloid-beta (Ab) immunotherapy is considered to be a promising approach to reducing the level of Ab in the CNS of AD patients. However, data from the first clinical trial AN1792 indicated that vaccine should be designed not to induce autoreactive cellular responses and to be effective in the majority of the individuals from the risk groups. The Officers and Directors of the Company are also officers and Directors of CAPO. As of August 16, 2016 TSI owns approximately 6.5% of the outstanding shares of CAPO. Website: [www.capotheapeutics.com](http://www.capotheapeutics.com)

## 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 2016 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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<sup>1</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC551593/>

<sup>2</sup> <http://www.therapeuticsolutionsint.com/index.php/2015-04-19-16-05-26/228-therapeutic-solutions-international-files-patent-on>

<sup>3</sup> <http://www.google.com/patents/US8288172>



<sup>4</sup> Ichim et al. Exosomes as a tumor immune escape mechanism: possible therapeutic implications. J Transl Med. 2008 Jul 22;6:37. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504474/>

<sup>5</sup> Abusamra et al. Tumor exosomes expressing Fas ligand mediate CD8+ T-cell apoptosis. Blood Cells Mol Dis. 2005 Sep-Oct;35(2):169-73. <http://www.ncbi.nlm.nih.gov/pubmed/16081306>

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

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

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

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

### **Patents:**

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

Immuno-Oncology, described by Science Magazine as 'Breakthrough of the Year'<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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<sup>1</sup> Couzin-Frankel J. Breakthrough of the year 2013. Cancer immunotherapy. Science. 2013;342:1432-3. <https://www.sciencemag.org/content/342/6165/1432.summary>

<sup>2</sup> 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/>

<sup>3</sup> 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/>

<sup>4</sup> 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/>

<sup>5</sup> 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/>

<sup>6</sup> 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.

In addition on April 28, 2016 the Company filed a patent application covering the use of ProJuvenol<sup>®</sup> and its active ingredient pterostilbene for augmentation of stem cell activity. Diseases such as diabetes<sup>1</sup>, cardiovascular disease<sup>2</sup>, and neurodegenerative diseases<sup>3</sup> 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<sup>4</sup> and undergo accelerated neurological recovery after stroke<sup>5</sup> as compared to patients with lower numbers of such stem cells.

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<sup>1</sup> Moon et al. Circ J. 2012;76(9):2273-9. <http://www.ncbi.nlm.nih.gov/pubmed/22664650>

<sup>2</sup> Hill et al. N Engl J Med. 2003 Feb 13;348(7):593-600. <http://www.ncbi.nlm.nih.gov/pubmed/12584367>

<sup>3</sup> Lee et al. Neurology. 2009 May 26;72(21):1858-63 <http://www.ncbi.nlm.nih.gov/pubmed/19470969>

<sup>4</sup> Hill et al. N Engl J Med. 2003 Feb 13;348(7):593-600. <http://www.ncbi.nlm.nih.gov/pubmed/12584367>

<sup>5</sup> Sobrino et al. Stroke. 2007 Oct;38(10):2759-64. <https://www.ncbi.nlm.nih.gov/pubmed/17761925>

TSOI markets currently several other nutraceuticals, they include T-Rx<sup>®</sup>, a testosterone booster, and Vital<sup>®</sup> Female an estrogen enhancer, Liposomal CoQ10, Curcumin, and Vitamin-C, all powerful antioxidants.

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

**Coenzyme Q10 (CoQ10)** is a substance similar to a vitamin. It is found in every cell of the body. Your body makes CoQ10, and your cells use it to produce energy your body needs for cell growth and maintenance. It also functions as an antioxidant, which protects the body from damage caused by harmful molecules.

**Curcumin** is an anti-inflammatory molecule in the turmeric root, a relative of ginger. The properties of curcumin can best be summarized as protective of the integrity of bio molecules in the body by being both a fabulous antioxidant and anti-inflammatory all rolled up in one.

**Vitamin-C** is absorbed at approximately 19%, the balance remains in the gastrointestinal tract to attract water and loosen the bowels. Liposomalized vitamin C is absorbed much more efficiently than traditional delivery methods. A huge advance in both efficiency and effectiveness of supplemental nutrients.

On June 22, 2016 the Company announced the addition of four new consumer products to our nutraceutical division.

The four new products will all be in Liposome formulas. Many orally consumed nutrients are absorbed from 4% to 19%! Those same nutrients in a Liposomal Delivery System are absorbed at a much higher level in the bloodstream. Liposomes have layers that can encapsulate an ingredient and serve to protect the ingredient from the environment as well as act as a slow release mechanism. A liposome is a microscopic, fluid-filled pouch whose walls are made of layers of phospholipids identical in makeup to the phospholipids that make up cell membranes.

Liposomes represent a versatile and advanced nanodelivery system for a wide range of biologically active compounds. Liposomes have been used to improve the therapeutic index of new or established ingredients by modifying their absorption, reducing metabolism, and prolonging biological half-life.

Liposomes can be used to deliver substances to the blood stream and even target cells much more efficiently than normal. The liposomes offer a unique delivery system for nutrients because these microscopic spheres are so tiny that absorption becomes almost perfect.

The four new high absorption formulas will be Liposomal Vitamin-C, CoQ10, Curcumin, and Glutathione, sold in 16oz bottles.

### **Fetal-Maternal Health**

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

OmniBiome, Inc. ( OMNI ), a partially-subsiary of TSI, is focused on therapeutic / Rx approaches to either utilize or intervene with the systemic effects of the vaginal, lactal-duct and oral microbiomes for improving maternal healthcare and resulting birth outcomes. The Officers and Directors of the Company are also officers and Directors of OMNI. As of August 16, 2016 TSI owns approximately 73.75% of the outstanding shares of OMNI. Website: <http://omnibiomeinc.com>

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.

### **Immune-Oncology**

#### **MolecuVax, Inc.**

MolecuVax is a partially-owned 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. The Officers and Directors of the Company are also officers and Directors of MVAX. As of August 16, 2016 TSI owns approximately 6.5% of the outstanding shares of MVAX. Website: [www.molecuvax.com](http://www.molecuvax.com)

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.

On April 11, 2016 the Company announced the signing of an agreement between its subsidiary, MolecuVax, Inc., (MVAX) and the Pan Am Cancer Treatment Center covering production and clinical implementation of a novel cancer immunotherapy based around MVAX's proprietary BORISome (Brother of the Regulator of Imprinted Sites (BORIS)) peptide/exosome technology.

In November of last year, the Company filed a patent on technologies covering novel means of stimulating the immune system to kill cancer using naturally made nanoparticles termed exosomes<sup>1</sup> which was subsequently licensed to MVAX<sup>2</sup>. In contrast to previous exosome-based cancer therapeutic approaches, the strategy being pursued by MVAX involves focusing the immune system to attack the protein BORIS, which is selectively found on cancer stem cells<sup>3</sup>.

BORIS represents a unique target in the fight against cancer because it is only found on cancer cells and not healthy tissues. Additionally, because it is selectively found on cancer stem cells, we possess the possibility of inducing an immune response that would strike cancer at its roots, which are the cancer stem cells. By leveraging dendritic cell technology to generate BORIS-expressing exosomes in vivo, we believe the current therapeutic approach possesses a possibility of inducing a potent and selective immune response against cancer.

The Pan Am Cancer Treatment Center is a clinical research and treatment facility, which has been offering dendritic cell therapy for treatment of cancer patients. The current collaboration will leverage existing cellular therapy manufacturing expertise to develop, and clinically apply, the BORIS-peptide loaded dendritic cell therapy to patients.

Thomas Ichim, Ph.D, Board Member of TSOI co-authored three of the scientific peer reviewed papers demonstrating efficacy of BORIS-targeting immunotherapy in animal models, some of the papers together with scientists from the National Institutes of Health<sup>4,5,6</sup>.

The importance of BORIS is difficult to overstate, not only is it a marker that is found on cancer stem cells, but when the protein is blocked from expressing by using gene silencing, we have previously published that cancer cells die<sup>7</sup>. Accordingly, there is a possibility that it will be difficult for tumors to become resistant to BORIS-based immunotherapies.

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<sup>1</sup> [http://therapeuticsolutionsint.com/?page\\_id=60](http://therapeuticsolutionsint.com/?page_id=60)

<sup>2</sup> [http://therapeuticsolutionsint.com/?page\\_id=39](http://therapeuticsolutionsint.com/?page_id=39)

<sup>3</sup> Asano et al. Oncotarget. 2016 Feb 3. <https://www.ncbi.nlm.nih.gov/pubmed/?term=26849232>

<sup>4</sup> Loukinov et al. J Cell Biochem. 2006 Aug 1;98(5):1037-43. <https://www.ncbi.nlm.nih.gov/pubmed/16741971>

<sup>5</sup> Ghochikyan et al. J Immunol. 2007 Jan 1;178(1):566-73. <https://www.ncbi.nlm.nih.gov/pubmed/17182597>

<sup>6</sup> Mkrtychyan et al. Gene Ther. 2008 Jan;15(1):61-4. <https://www.ncbi.nlm.nih.gov/pubmed/17972923>

<sup>7</sup> Dougherty et al. Biochem Biophys Res Commun. 2008 May 23;370(1):109-12. <https://www.ncbi.nlm.nih.gov/pubmed/18355444>

On May 09, 2016 the Company announced the signing of an exclusive license agreement between its subsidiary, MolecuVax, Inc., (MVAX) and UniVax, LLC covering composition of matter of a new cancer vaccine that targets a molecule found in cancer stem cells of a variety of types of cancers. The vaccine target, termed CTCFL or Brother of the Regulator of Imprinted Sites (BORIS), was discovered by researchers at the National Institutes of Health (NIH)<sup>1</sup>, and has been shown in numerous peer-reviewed studies to be essential for cancer survival and progression<sup>2,3,4</sup>.

The patent covers vaccines that stimulate the immune system to selectively kill tumor cells that are expressing this universal cancer specific protein. In contrast to other vaccines, our vaccine is targeting BORIS protein that is critical for the growth of histologically different cancers. This possesses important implications in that if a cancer cell mutates to lose expression of the target, then the cancer cell will no longer be cancerous.

The technology licensed positions MolecuVax in an ideal situation given the rapidly expanding interest in cancer immunotherapy clinical trials. The great successes of CAR-T cells and checkpoint inhibitors have already saved many lives and are testimony to the efficacy of this approach to cancer. We aim to utilize the licensed technology to enter clinical trials, in part through our existing collaboration with the Pan Am Cancer Treatment Center<sup>5</sup>, as well as our planned FDA Investigational New Drug (IND) submission.

This vaccine was developed at the Institute for Molecular Medicine in Huntington Beach, California by Michael Agadjanyan, Ph.D. D.Sc., Head of the Cancer Vaccines Laboratory and member of TSOI's Scientific Advisory Board, and Anahit Ghochikyan, Ph.D., Head of the Alzheimer's Disease Vaccines Laboratory. The vaccine is important because it not only prevents onset of cancer, but can also be used in patients that have cancer, thus it is termed a therapeutic vaccine. Additionally, the vaccine can be used as part of dendritic cell immunotherapy, which the inventors previously published as being extremely effective against breast cancer in animal models.

Our collaborators have been working on the concept of selectively killing cancer by immunologically targeting BORIS / CTCFL for over a decade. This work is now translated from a scientific hypothesis, to issued US and International patents, and now on the road to commercialization and to patients. Thomas Ichim, Ph.D., Board Member of TSOI has co-authored publications on BORIS / CTCFL with Dr. Agadjanyan and researchers at the NIH on this technology<sup>7,8,9</sup>.

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<sup>1</sup> Loukinov et al. Proc Natl Acad Sci U S A. 2002 May 14;99(10):6806-11, <http://www.ncbi.nlm.nih.gov/pubmed/12011441>

<sup>2</sup> Asano et al. Oncotarget. 2016 Mar 8;7(10):11223-37. <http://www.ncbi.nlm.nih.gov/pubmed/26849232>

<sup>3</sup> Alberti et al. PLoS One. 2015 Jul 17;10(7):e0132977.

<sup>4</sup> Dougherty et al. Biochem Biophys Res Commun. 2008 May 23;370(1):109-12. <http://www.ncbi.nlm.nih.gov/pubmed/18355444>

<sup>5</sup> <http://cancerimmunotherapy.mx/web/>

<sup>6</sup> Mkrtychyan et al. Cell Immunol. 2011;270(2):188-97. <http://www.ncbi.nlm.nih.gov/pubmed/21641588>

<sup>7</sup> Loukinov et al. J Cell Biochem. 2006 Aug 1;98(5):1037-43. <http://www.ncbi.nlm.nih.gov/pubmed/16741971>

<sup>8</sup> Ghochikyan et al. J Immunol. 2007 Jan 1;178(1):566-73. <http://www.ncbi.nlm.nih.gov/pubmed/17182597>

<sup>9</sup> Mkrtychyan et al. Gene Ther. 2008 Jan;15(1):61-4. <http://www.ncbi.nlm.nih.gov/pubmed/17972923>



**Capo Therapeutics, Inc.**

Capo Therapeutics, Inc., ( CAPO ) is a Delaware Corporation incorporated on March 28, 2016. The main focus of Capo Therapeutics is the development of an effective and safe vaccine against Alzheimer's disease (AD), one of the most devastating diseases of the century. Amyloid-beta (Ab) immunotherapy is considered to be a promising approach to reducing the level of Ab in the CNS of AD patients. However, data from the first clinical trial AN1792 indicated that vaccine should be designed not to induce autoreactive cellular responses and to be effective in the majority of the individuals from the risk groups. The Officers and Directors of the Company are also officers and Directors of CAPO. As of August 16, 2016 TSI owns approximately 6.5% of the outstanding shares of CAPO. Website: [www.capotherapeutics.com](http://www.capotherapeutics.com)

**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:

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

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

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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,

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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:

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product claims and advertising;

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product labels;

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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:

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the identification of dietary or nutritional supplements and their nutrition and ingredient labeling;

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requirements related to the wording used for claims about nutrients, health claims, and statements of nutritional support;

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labeling requirements for dietary or nutritional supplements for which high potency and antioxidant claims are made;

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notification procedures for statements on dietary and nutritional supplements; and

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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 and nine months ended September 30, 2015 and September 30, 2014**

On April 28, 2014, we received a letter from Mr. J. Christopher Jack, a lawyer with the Procopius law firm in San Diego who represents Boyd Research, Inc. and related parties. In his letter, Mr. Jack 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 7, Discontinued Operation in Notes to the Financial Statements.

Net sales increased \$325 from \$0 to \$325 for the three months ended September 30, 2014 and September 30, 2015, respectively. This was due to the Company's sales in its Nutraceutical Division. Net sales for the three months ended September 30, 2014 of \$124,593 were reclassified as Discontinued Operations. Net sales increased \$745 from \$0 to \$745 for the nine months ended September 30, 2014 and September 30, 2015, respectively. This was due to the Company's sales in its Nutraceutical Division. Net sales of \$268,892 for the nine months ended September 30, 2014 were reclassified as Discontinued Operations.

Cost of Goods Sold increased \$166 from \$0 to \$166 for the three months ended September 30, 2014 and September 30, 2015, respectively. Cost of Goods Sold for the three months ended September 30, 2014 of \$23,215 were reclassified as Discontinued Operations. Cost of Goods Sold increased \$263 from \$0 to \$263 for the nine months ended September 30, 2014 and September 30, 2015, respectively. This was due to the Company's costs related to sales in its Nutraceutical Division. Cost of Goods Sold for the nine months ended September 30, 2014 of \$26,798 were reclassified as Discontinued Operations.

Operating expenses for the three month periods ended September 30, 2015 and 2014 were \$178,655 and \$64,187, an increase of \$114,468. This was mainly due to increased General and Administrative costs, Salaries, wages, and related costs, increased consulting fees and decreased legal expenses. Operating expenses for the nine month periods ended September 30, 2015 and 2014 were \$366,919 and \$311,961, an increase of \$54,958. This was mainly due to increased Salaries, wages, and related costs, increased consulting fees and decreased legal expenses.

General and Administrative costs increased \$12,306, from \$13,421 to \$25,727, for the three months ended September 30, 2014 and 2015, respectively. General and Administrative costs increased \$3,173, from \$55,500 to \$58,673, for the nine months ended September 30, 2014 and 2015, respectively. These increases were mainly due to increased rent, marketing and insurance costs.

Salaries, wages and related costs increased \$45,304, from \$26,019 to \$71,323 for the three months ended September 30, 2014 and 2015, respectively. Salaries, wages and related costs increased \$81,339, from \$112,150 to \$193,489 for

the nine months ended September 30, 2014 and 2015, respectively. This increase for the nine months was mainly due to an increase in officers' salary accruals.

Selling expenses increased \$429, from \$0 to \$429, for the three months ended September 30, 2014 and 2015, respectively. Selling expenses increased \$911, from \$0 to \$911, for the nine months ended September 30, 2014 and 2015, respectively. This increase was mainly due to a reclassification of all selling and marketing expenses for last year to discontinued operation.

Amortization and depreciation decreased \$5,283 from \$5,283 to \$0 for the three months ended September 30, 2014 and 2015, respectively. Amortization and depreciation decreased \$15,850 from \$15,850 to \$0 for the nine months ended September 30, 2014 and 2015, respectively.

Consulting fees increased \$52,084 from \$3,383 to \$55,467 for the three months ended September 30, 2014 and 2015, due to an increase in overall consulting services. Consulting fees increased \$46,547 from \$37,253 to \$83,800 for the nine months ended September 30, 2014 and 2015, due to an increase in overall consulting services.

Legal and professional fees increased \$9,627, from \$16,081 to \$25,708 for the three months ended September 30, 2014 and 2015. This increase was mainly due to an increase in overall legal services from 2015 vs 2014.

Legal and professional fees decreased \$61,163, from \$91,209 to \$30,046 for the nine months ended September 30, 2014 and 2015. This decrease was mainly due to a reduction of overall legal services from 2015 vs 2014.

Net other income/expense decreased \$888 from \$888 to \$0 for the three months ended September 30, 2014 and 2015, respectively. Net other income/expense increased \$1,574 from \$108 to \$1,682 for the nine months ended September 30, 2014 and 2015, respectively. These changes were mainly due to fluctuations in quarterly seminar tuition and related expenses.

Net interest expense decreased \$1,783 from \$3,084 to \$1,301 for the three months ended September 30, 2014 and 2015. Net interest expense decreased \$4,022 from \$8,162 to \$4,140 for the nine months ended September 30, 2014 and 2015. This decrease was mainly due to a reduction in note payables,

Net income from discontinued operation for the three month periods ended September 30, 2015 and 2014 were \$0 and \$101,277, a decrease of \$101,277. Net income from discontinued operation for the nine month periods ended September 30, 2015 and 2014 were \$(8,722) and \$249,849, a decrease of \$258,571. This decrease was primarily due to the final sales of inventory from the notification that our license to use the international patents for our AMPSA device, pursuant to our license agreement, that was terminated on April 28, 2014 and the write off of accounts receivable,

Net income (loss) for the three months ended September 30, 2015 was \$(179,797) compared with \$34,894 for the three months ended September 30, 2014. In addition to operating expenses, we had Net income from discontinued operations of \$101,277 for the three months ended September 30, 2014. Net income (loss) for the nine months ended September 30, 2015 was \$(377,618) compared with \$(70,167) for the nine months ended September 30, 2014. In addition to operating expenses, we had a Net loss from discontinued operations of \$8,722 for the nine months ended September 30, 2015 and a Net income from discontinued operations of \$249,849 for the nine months ended September 30, 2014.

### **Liquidity and Capital Resources**

Net cash used in operating activities totaled \$99,399 for the nine months ended September 30, 2015. We had no material commitments for capital expenditures at September 30, 2015.

As of September 30, 2015, we had cash of \$8,495. We had no cash equivalents at the end of the quarter. Clearly, such a cash level is untenable. We believe we will need outside financing to execute our business plan in 2015 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 2014 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 September 30, 2015. 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 September 30, 2015 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 partially-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 partially-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 partially-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: August 22, 2016 By: */s/ Timothy G. Dixon*  
Timothy G. Dixon  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 22, 2016 By: */s/ Gerry B. Berg*  
Gerry B. Berg  
  
Chief Financial Officer  
(Principal Financial Officer)