

PURE BIOSCIENCE, INC.  
Form 10-Q  
December 11, 2014  
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**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 OCTOBER 31, 2014**

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

**Commission File Number 001-14468**

**Pure Bioscience, Inc.**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**33-0530289**  
**(I.R.S. Employer**  
**Identification No.)**

**1725 Gillespie Way**  
**El Cajon, California**  
**(Address of principal executive offices)**

**92020**  
**(Zip Code)**

**Registrant's telephone number, including area code: (619) 596-8600**

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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 December 11, 2014, there were 39,788,465 shares of the registrant's common stock, \$0.01 par value per share, outstanding.

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**Pure Bioscience, Inc.**

**Form 10-Q**

**for the Quarterly Period Ended October 31, 2014**

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**Table of Contents****Item 1. Financial Statements****Pure Bioscience, Inc.****Condensed Consolidated Balance Sheets**

	<b>October 31, 2014 (Unaudited)</b>	<b>July 31, 2014</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 5,331,000	\$ 86,000
Accounts receivable, net	47,000	47,000
Inventories, net	231,000	249,000
Prepaid expenses	154,000	96,000
<b>Total current assets</b>	<b>5,763,000</b>	<b>478,000</b>
Property, plant and equipment, net	28,000	36,000
Patents, net	1,305,000	1,345,000
<b>Total assets</b>	<b>\$ 7,096,000</b>	<b>\$ 1,859,000</b>
<b>Liabilities and stockholders equity</b>		
Current liabilities		
Accounts payable	\$ 510,000	\$ 1,096,000
Restructuring liability	201,000	323,000
Accrued liabilities	154,000	401,000
Derivative liability	10,000	9,000
<b>Total current liabilities</b>	<b>875,000</b>	<b>1,829,000</b>
Deferred rent	12,000	13,000
<b>Total liabilities</b>	<b>887,000</b>	<b>1,842,000</b>
Commitments and contingencies (See Note 6)		
Stockholders equity		
Preferred stock, \$0.01 par value: 5,000,000 shares authorized, no shares issued		
Common stock, \$0.01 par value: 100,000,000 shares authorized, 39,788,465 shares issued and outstanding at October 31, 2014, and 29,394,940 shares issued and outstanding at July 31, 2014		
	398,000	295,000
Additional paid-in capital	88,966,000	80,943,000
Accumulated deficit	(83,155,000)	(81,221,000)

Total stockholders' equity	6,209,000	17,000
Total liabilities and stockholders' equity	\$ 7,096,000	\$ 1,859,000

*See accompanying notes.*

Table of Contents**Pure Bioscience, Inc.****Condensed Consolidated Statements of Operations****(Unaudited)**

	<b>Three months ended October 31,</b>	
	<b>2014</b>	<b>2013</b>
Net product sales	\$ 117,000	\$ 115,000
Operating costs and expenses		
Cost of goods sold	45,000	36,000
Selling, general and administrative	1,192,000	925,000
Research and development	176,000	213,000
Share-based compensation	503,000	89,000
Other share-based expenses	131,000	
Restructuring costs		2,684,000
Total operating costs and expenses	2,047,000	3,947,000
Loss from operations	(1,930,000)	(3,832,000)
Other income (expense)		
Change in derivative liability	(1,000)	(58,000)
Interest expense, net	(2,000)	(3,000)
Other income (expense), net	(1,000)	49,000
Total other income (expense)	(4,000)	(12,000)
Net loss	\$ (1,934,000)	\$ (3,844,000)
Basic and diluted net loss per share	\$ (0.05)	\$ (0.19)
Shares used in computing basic and diluted net loss per share	37,029,203	20,701,547

*See accompanying notes.*

**Table of Contents****Pure Bioscience, Inc.****Condensed Consolidated Statements of Cash Flows****(Unaudited)**

	<b>Three months ended October 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Operating activities</b>		
Net loss	\$ (1,934,000)	\$ (3,844,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	503,000	89,000
Amortization of stock issued for services	22,000	614,000
Stock issued under severance agreements		805,000
Stock issued to investors to amend subscription agreements	131,000	
Depreciation and amortization	51,000	73,000
Change in fair value of derivative liability	1,000	58,000
Changes in operating assets and liabilities:		
Accounts receivable		(13,000)
Inventories	18,000	(65,000)
Prepaid expenses	(80,000)	(4,000)
Accounts payable and accrued liabilities	(955,000)	42,000
Deferred rent	(1,000)	(1,000)
Net cash used in operating activities	(2,244,000)	(2,246,000)
<b>Investing activities</b>		
Investment in patents	(4,000)	(12,000)
Purchases of property, plant and equipment		(11,000)
Net cash used in investing activities	(4,000)	(23,000)
<b>Financing activities</b>		
Net proceeds from the sale of common stock	7,493,000	3,163,000
Net proceeds from the exercise of warrants		163,000
Payment on note payable		(21,000)
Net cash provided by financing activities	7,493,000	3,305,000
Net increase in cash and cash equivalents	5,245,000	1,036,000
Cash and cash equivalents at beginning of period	86,000	32,000

Cash and cash equivalents at end of period	\$ 5,331,000	\$ 1,068,000
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for taxes	\$	\$
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Common stock issued for prepaid services	\$	\$ 175,000
Common stock issued in connection with financing	\$	\$ 252,000
Settlement of warrant liability	\$	\$ 56,000

*See accompanying notes.*



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**Pure Bioscience, Inc.**

**Notes to Consolidated Financial Statements**

(Unaudited)

**1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements include the consolidated accounts of Pure Bioscience, Inc. and its wholly owned subsidiary, ETIH2O Corporation, a Nevada corporation. ETIH2O Corporation currently has no business operations and no material assets or liabilities and there have been no significant transactions related to ETIH2O Corporation during the periods presented in the condensed consolidated financial statements. All inter-company balances and transactions have been eliminated. All references to PURE, we, our, us and the Company refer to Pure Bioscience, Inc. and our wholly owned subsidiary.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, for interim financial information pursuant to the instructions to Form 10-Q and Article 10/Rule 8-03 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three months ended October 31, 2014 are not necessarily indicative of the results that may be expected for other quarters or the year ending July 31, 2015. The July 31, 2014 balance sheet was derived from audited financial statements but does not include all disclosures required by GAAP and included in our Annual Report on Form 10-K. For more complete information, these unaudited financial statements and the notes thereto should be read in conjunction with the audited financial statements for the year ended July 31, 2014 included in our Annual Report on Form 10-K covering such period filed with the Securities and Exchange Commission, or SEC, on October 28, 2014.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

**2. Liquidity**

Since our inception, we have financed our operations primarily through public and private offerings of securities, debt financings, and revenue from product sales and license agreements. We have a history of recurring losses, and as of October 31, 2014 we have incurred a cumulative net loss of \$83,155,000.

As of October 31, 2014, we had \$5,331,000 in cash and cash equivalents, and \$875,000 of current liabilities. As of October 31, 2014, we had no long term debt.

Our future capital requirements depend on numerous forward-looking factors. These factors may include, but are not limited to, the following: the acceptance of, and demand for, our products; our success and the success of our partners in selling our products; our success and the success of our partners in obtaining regulatory approvals to sell our products; the costs of further developing our existing products and technologies; the extent to which we invest in new product and technology development; and the costs associated with the continued operation, and any future growth, of

our business. The outcome of these and other forward-looking factors will substantially affect our liquidity and capital resources.

We expect that we will need to increase our liquidity and capital resources by one or more measures. These measures may include, but are not limited to, the following: reducing operating expenses; obtaining financing through the issuance of equity, debt, or convertible securities; entering into partnerships, licenses, or other arrangements with third parties; and reducing the exercise price of outstanding warrants. Any one of these measures could substantially reduce the value to us of our technology and its commercial potential. If we issue equity, debt or convertible securities to raise additional funds, our existing stockholders may experience dilution, and the new equity, debt or convertible securities may have rights, preferences and privileges senior to those of our existing stockholders. There is no guarantee that we would be able to obtain capital on terms acceptable to us, or at all.

If we are unable to obtain sufficient capital, it would have a material adverse effect on our business and operations. It could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to competitive pressures or customer requirements. It also may require us to delay, scale back or eliminate some or all of our research and development programs, to license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, or to reduce or cease operations. If adequate funds are not available when needed, we may be required to significantly modify our business model and operations to reduce spending to a sustainable level.

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We believe our available cash, our current efforts to market and sell our products, and our ability to significantly reduce expenses, will provide sufficient cash resources to satisfy our needs over the next 12 months. However, we do not yet have, and we may never have, significant cash inflows from product sales or from other sources of revenue to offset our ongoing and planned investments in, research and development projects, regulatory submissions, business development activities, and sales and marketing, among other investments. Some or all of our ongoing or planned investments may not be successful. In addition, irrespective of our cash resources, we may be contractually or legally obligated to make certain investments which cannot be postponed.

**3. Net Loss Per Share**

Basic net loss per common share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Our diluted net loss per common share is the same as our basic net loss per common share because we incurred a net loss during each period presented, and the potentially dilutive securities from the assumed exercise of all outstanding stock options, restricted stock units, and warrants would have an anti-dilutive effect. As of October 31, 2014 and 2013, the number of shares issuable upon the exercise of stock options, the vesting of restricted stock units, and the exercise of warrants, none of which are included in the computation of basic net loss per common share, was 10,681,167 and 7,450,766, respectively.

**4. Comprehensive Loss**

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on marketable securities and foreign currency translation adjustments. For the three months ended October 31, 2014 and 2013, our comprehensive loss consisted only of net loss.

**5. Inventory**

Inventories are stated at the lower of cost or net realizable value, and net of a valuation allowance for potential excess or obsolete material. Cost is determined using the average cost method. Depreciation related to manufacturing is systematically allocated to inventory produced, and expensed through cost of goods sold at the time inventory is sold.

Inventories consist of the following:

	<b>October 31, 2014</b>	<b>July 31, 2014</b>
Raw materials	\$ 95,000	\$ 102,000
Finished goods	136,000	147,000
	<b>\$ 231,000</b>	<b>\$ 249,000</b>

During the three months ended October 31, 2013, we received \$20,000 from the sale of inventory which was previously reserved during the fiscal year ended July 31, 2013. The \$20,000 gain is reflected in the other income (expense) section of the condensed consolidated statement of operations.



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**6. Commitments and Contingencies**

**Severance Agreements**

On August 13, 2013, the Company entered into Purchase, Severance and Release Agreements with Michael L. Krall, our former Chief Executive Officer, Donna Singer, our former Executive Vice President, and Dennis Brovarone, a former Board member.

In connection with Mr. Krall's separation from the Company, the Company entered into a Purchase, Severance, and Release Agreement effective August 13, 2013 with Mr. Krall (the "Krall Release Agreement"). The Krall Release Agreement provides for a mutual release of all claims between Mr. Krall and the Company. Mr. Krall is also prohibited from engaging in certain competitive activities until July 2017. Pursuant to the Krall Release Agreement, Mr. Krall (i) was paid \$25,000 on August 13, 2013; and, (ii) is entitled to receive \$30,000 per month until February 2015, during which time Mr. Krall shall provide consulting services to the Company. In consideration of Mr. Krall's transfer to the Company of certain enumerated intellectual property rights, the Company also (i) paid Mr. Krall the sum of \$125,000 on August 13, 2013; and, (ii) issued to Mr. Krall 850,000 shares of common stock on August 21, 2013 (the "Krall Shares"). The Krall Shares are subject to certain registration rights intended to register the Krall Shares. The Krall Shares are also subject to a Voting Support Agreement and Irrevocable Proxy (the "Krall Proxy"). The Krall Proxy gives our CEO the right to vote the Krall Shares for so long as Mr. Krall owns the Krall Shares. Mr. Krall will also continue to receive health insurance coverage over the term of the severance period, which will cost the Company \$20,000.

In connection with Ms. Singer's separation from the Company, we entered into a Purchase, Severance, and Release Agreement effective August 13, 2013 with Ms. Singer (the "Singer Release Agreement"). The Singer Release Agreement provides for a mutual release of all claims between Ms. Singer and the Company. Ms. Singer is also prohibited from engaging in certain competitive activities until August 2017. Pursuant to the Singer Release Agreement, Ms. Singer (i) was paid \$45,000 on August 13, 2013; (ii) was due the amount of her continued health insurance coverage until August 2014; and, (iii) was paid \$17,000 per month for 12-months following August 13, 2013, during which time Ms. Singer was to provide consulting services to the Company. In consideration of Ms. Singer's transfer to the Company of certain enumerated intellectual property rights, the Company also issued to Ms. Singer 300,000 shares of common stock on August 21, 2013 (the "Singer Shares"). The Singer Shares are subject to certain registration rights intended to register the Singer Shares. The Singer Shares are also subject to a Voting Support Agreement and Irrevocable Proxy (the "Singer Proxy"). The Singer Proxy gives our CEO the right to vote the Singer Shares for so long as Ms. Singer owns the Singer Shares.

In connection with Mr. Brovarone's separation from the Company, we entered into a Severance and Release Agreement effective August 13, 2013 with Mr. Brovarone (the "Brovarone Release Agreement"). The Brovarone Release Agreement provides for a mutual release of all claims between Mr. Brovarone and the Company. In addition, Mr. Brovarone will receive \$91,000, payable in 60 monthly installments of approximately \$1,600, commencing December 11, 2013 for amounts previously accrued as of July 31, 2013.

Approximately \$201,000 remains payable under the severance agreements and is included in the accrued restructuring liability section of the condensed consolidated balance sheets as of October 31, 2014. During the three months ended October 31, 2013, we expensed approximately \$1,789,000 to restructuring costs related to the Purchase, Severance, and Release Agreements.

**7. Promissory Note**

On January 25, 2013, we entered into a Letter Agreement (the Agreement ) with Morrison & Foerster LLP ( Morrison ). Under the terms of the Agreement, we issued a Promissory Note (the Note ) in favor of Morrison in the principal amount of \$1,125,000. In consideration for the Note, Morrison agreed to waive \$1,519,000 of amounts due and payable to Morrison for legal services rendered. The Note bore interest at the rate of 7.5% per annum, but the then outstanding balance would accrue interest at the rate of 10% per annum upon the occurrence of an event of default (as defined in the Note). During the quarter ended October 31, 2013, we paid \$21,000 under the terms of the Note.

In consideration for Morrison's acceptance of the Note, we issued Morrison a warrant to purchase 375,000 shares of our common stock at an exercise price of \$0.83 per share. The warrant was exercisable immediately and expires on January 24, 2018. The warrant may be exercised by Morrison with a cash payment or, in lieu thereof, at its election, through a net exercise, as set forth in the warrant agreement. Neither the warrant nor the shares to be issued upon exercise thereof are registered for sale or resale under the Securities Act of 1933, as amended (the Securities Act ), and have been or will be issued in reliance on an exemption from registration under the Securities Act pursuant to Section 4(a)(2) thereof based on the offering of such securities to one investor and the lack of any general solicitation or advertising in connection with such issuance. We determined that the warrants issued in connection with the Note were equity instruments and did not represent derivative instruments. The fair value of the warrants issued to Morrison was \$245,000, based on the Black-Scholes valuation method assuming no dividend yield, volatility of 134%, a risk-free interest rate of 0.35%, and an expected life of 5 years.

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During the fiscal year ended July 31, 2014, we entered into a Promissory Note Payoff Agreement ( Payoff Agreement ) with Morrison. Under the Payoff Agreement, we paid \$500,000 in cash to Morrison to extinguish \$1,227,000 in unsecured debt owed to Morrison under the Note, dated January 25, 2013. We have no further obligations or liability under the Note. As a result of the Payoff Agreement, we recorded a gain of \$727,000 that is reflected in the other income (expense) section of the consolidated statement of operations.

**8. Impairment of Long-Lived Assets**

In accordance with GAAP, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and we record the impairment as a reduction in the carrying value of the related asset and a charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment, and assumptions could differ materially from actual results. During the three months ended October 31, 2014 and 2013, no impairment of long-lived assets was indicated or recorded.

**9. Convertible Note and Derivative Liability**

On June 26, 2012, and July 10, 2012 we received an aggregate of \$1,200,000 in cash consideration from nine lenders in exchange for our issuance to such lenders of secured convertible promissory notes, or the Notes, in an aggregate principal amount of \$1,333,000 and certain other consideration (including shares of our common stock and warrants to acquire shares of our common stock). We refer to such transaction as the Bridge Loan . Pursuant to the terms of the Notes and the other agreements entered in connection with the Bridge Loan, all amounts owed thereunder became due and payable upon the closing of our underwritten public offering on September 17, 2012, and accordingly all such amounts were repaid during the three months ended October 31, 2012.

We accounted for the 132,420 warrants issued in connection with the Bridge Loan in accordance with the accounting guidance for derivatives. The applicable accounting guidance sets forth a two-step model to be applied in determining whether a financial instrument is indexed to an entity's own stock, which would qualify such financial instruments for a scope exception. This scope exception specifies that a contract that would otherwise meet the definition of a derivative financial instrument would not be considered as such if the contract is both (i) indexed to the entity's own stock and (ii) classified in the stockholders' equity section of the entity's balance sheet. We determined the warrants were ineligible for equity classification due to anti-dilution provisions set forth therein.

We recorded the fair value of the warrants issued in connection with the Bridge Loan as a warrant liability due to anti-dilution provisions requiring the strike price of the warrants to be adjusted if we subsequently issue common stock at a lower stock price. The Company revalues the warrants as of the end of each reporting period. The fair value of the warrants at October 31, 2014 and July 31, 2014 was \$10,000 and \$9,000, respectively. The change in fair value of the warrant liability for the three months ended October 31, 2014 was an increase of \$1,000, which was recorded as a change in derivative liability in the consolidated statement of operations.

During the three months ended October 31, 2013, there were net exercises on an aggregate of 90,699 of the warrants issued in connection with the Bridge Loan, which resulted in the issuance of 73,290 shares of our common stock. As these warrants were net exercised, as permitted under the respective warrant agreements, we did not receive any cash proceeds. The warrants were revalued as of the settlement dates, and the change in fair value was recognized to earnings. The Company also recognized a reduction in the warrant liability based on the fair value as of the settlement

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date for the warrants exercised, with a corresponding increase in additional paid-in capital. As of October 31, 2014 there are 9,709 warrants outstanding issued in connection with the Bridge Loan. No warrants issued in connection with the Bridge Loan were exercised during the three months ended October 31, 2014.

The estimated fair value of the derivative liability was computed using a Monte Carlo option pricing model based the following assumptions:

	<b>October 31, 2014</b>	<b>July 31, 2014</b>
Volatility	186.4%	163.5%
Risk-free interest rate	0.49%	0.98%
Dividend yield	0.0%	0.0%
Expected life	2.2 years	2.4 years



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Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the authoritative guidance establishes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In connection with the Bridge Loan, we issued warrants and convertible notes that are accounted for as derivative liabilities.

We used Level 3 inputs for the valuation methodology of the derivative liabilities. The estimated fair values were computed using a Monte Carlo option pricing model based on various assumptions. Our derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the fair value of the derivative liabilities.

The following table provides a reconciliation of the beginning and ending balances of the derivative liabilities for the three months ended October 31, 2014:

	<b>Warrant Liability</b>	<b>Conversion Feature Liability</b>	<b>Total</b>
Balance at July 31, 2013	\$ 51,000	\$	\$ 51,000
Issuances			
Settlement of warrant liability	(97,000)		(97,000)
Adjustments to estimated fair value	55,000		55,000
Balance at July 31, 2014	\$ 9,000	\$	\$ 9,000
Issuances			
Settlement of warrant liability			
Adjustments to estimated fair value	1,000		1,000
Balance at October 31, 2014	\$ 10,000	\$	\$ 10,000

## **11. Stockholders Equity**

### **Private Placements**

During the three months ended October 31, 2014, we issued a total of 9,958,032 shares of common stock and warrants to purchase 4,004,259 shares of common stock for gross proceeds of approximately \$7.49 million. The warrants have a five-year term, are exercisable immediately, and have an exercise price of \$0.75 per share. A fair value of \$3,746,000 was estimated for the warrants using the Black-Sholes valuation method using a volatility of 133.74%, an interest rate of 1.50% and a dividend yield of zero. We determined that the warrants issued in connection with the private placements were equity instruments and did not represent derivative instruments.

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Additionally, in connection with the price adjustment terms in subscription agreements we previously entered into with investors in prior private placements, we issued an aggregate of 127,993 shares of common stock and warrants to purchase up to an aggregate of 648,053 shares of common stock. The warrants have a five-year term, are exercisable immediately, and have exercise prices ranging from \$0.01 to \$0.75 per share. A fair value of \$651,000 was estimated for the warrants using the Black-Scholes valuation method using a volatility of 133.74%, an interest rate of 1.50% and a dividend yield of zero. We determined that the warrants issued in connection with prior private placements were equity instruments and did not represent derivative instruments.

We recorded a one-time expense of \$131,000 associated with the issuance of the additional 127,993 shares of common stock discussed above. The expense is reflected in the other share-based expense section of the consolidated statement of operations.

In August 2013, we completed a private placement pursuant to which we sold 5,500,000 shares of our common stock. The shares were sold at a per share purchase price of \$0.20, resulting in approximately \$1,100,000 in aggregate gross proceeds to the Company. After deducting fees of \$43,000, the net proceeds to us were \$1,057,000.

On October 14 and October 16, 2013, we completed private placements pursuant to which we sold 2,441,270 shares of our common stock. The shares were sold at a per share purchase price of \$0.75 per share, resulting in approximately \$1,831,000 in aggregate gross proceeds to the Company. After deducting fees of \$49,000, the net proceeds to us were \$1,782,000. In addition, between October 17, 2013 and October 31, 2013, we sold 442,667 shares of our common stock in private placements. The shares were sold at a per share purchase price of \$0.75 per share, resulting in approximately \$332,000 in aggregate gross proceeds to the Company. After deducting fees of \$8,000, the net proceeds to us were \$324,000.

During the three months ended October 31, 2014 and 2013, the shares of common stock issued under the private placements were offered and sold without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws, based on the lack of any general solicitation or advertising in connection with the sale of the securities; the representation of each investor to the Company that it is an accredited investor (as that term is defined in Rule 501 of Regulation D) and that it was purchasing the securities for its own account and without a view to distribute them. The securities may not be offered or sold in the United States without an effective registration statement or pursuant to an exemption from applicable registration requirements.

## Corporate Governance Restructuring Activity

The following transactions occurred on August 13, 2013:

We entered into a two-year service agreement with Pillar Marketing Group, Inc. for general advisory services with respect to corporate finance and capital raising activities, merger and acquisition transactions, and other related endeavors. In accordance with the agreement with Pillar we issued 250,000 shares of common stock, with a value of \$175,000. The value was capitalized to prepaid expense and is being amortized over the term of the agreement. During the three months ended October 31, 2014, we recognized \$22,000 of expense related to these services. We also issued 300,000 shares of registered common stock to the principal of Pillar for certain corporate reorganization services, valued at \$210,000. Pillar also received a onetime payment of \$150,000 for certain corporate reorganization activities previously provided. The fair value of the stock issued and the onetime payment was expensed to restructuring costs.

We issued 300,000 shares of common stock to Bibicoff & McInnis for investor relations services related to restructuring activities, valued at \$210,000. On issuance, the \$210,000 was expensed to restructuring costs.

We issued 250,000 shares of common stock, with a value of \$175,000, for corporate finance and restructuring activities to Wulff Services, Inc. Wulff Services, Inc. is primarily owned by our current Chief Financial Officer / Chief Operation Officer, Peter C. Wulff. In addition, Wulff Services, Inc. received a onetime payment of \$75,000 related to the corporate finance and restructuring efforts. The fair value of the stock issued and the onetime payment was expensed to restructuring costs.

We issued 300,000 shares of common stock, with a value of \$210,000, to Donna Singer, per Ms. Singer's separation agreement, pursuant to an exemption from registration provided by Section 4(a)(2) of the Securities Act. Ms. Singer was the Company's Executive Vice President and served as a member of the Board. Additionally, as part of this issuance, we granted certain registration rights with respect to the shares issued to Ms. Singer. On issuance, the \$210,000 was expensed to restructuring costs (See Note 6).

We issued 850,000 shares of common stock, with a value of \$595,000, to Michael L. Krall, per Mr. Krall's separation agreement, pursuant to an exemption from registration provided by Section 4(a)(2) of the Securities Act. Mr. Krall was the Company's Chief Executive Officer and served as a member of the Board. Additionally, as part of this issuance, we granted certain registration rights with respect to the shares issued to Mr. Krall. On issuance, the \$595,000 was expensed restructuring costs (See Note 6).

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### **Other Activity**

During the three months ended October 31, 2013, we issued 212,500 shares of common stock, to Gary D. Cohee and/or his affiliates for investor relations and financial advisor services, valued at \$149,000, pursuant to the terms of the director service agreement with Mr. Cohee. The fair value of \$149,000 was offset to additional paid-in capital. Mr. Cohee is a member of our Board.

### **Warrants**

During the three months ended October 31, 2013, we received \$163,000 from the exercise of a warrant to purchase 250,000 shares of our common stock. No warrants were exercised during the three months ended October 31, 2014.

In addition, during the three months ended October 31, 2013, there were net exercises on an aggregate of 90,699 warrants, which resulted in the issuance of 73,290 shares of our common stock. As these warrants were net exercised, as permitted under the respective warrant agreements, we did not receive any cash proceeds.

## **12. Share-Based Compensation**

On October 24, 2014, we appointed Tom Y. Lee, CPA, to the Board of Directors, or Board. In accordance with the Company's non-employee director compensation program, the Board granted Mr. Lee restricted stock units for 200,000 shares of the Company's Common Stock (RSUs). The agreement for the RSUs is the same as the RSU agreement form entered into with other non-employee Company directors. The RSUs vest as follows: fifty percent (50%) of the shares of Common Stock vest on the earlier of (i) the date of the Company's Annual Meeting of Stockholders in 2016 or January 15, 2016 and (ii) the remaining fifty percent (50%) of the shares of Common Stock vest on the earlier of the date of the annual meeting in 2017 or January 15, 2017. None of the RSUs granted to Mr. Lee were granted pursuant to any compensatory, bonus, or similar plan maintained or otherwise sponsored by the Company.

During the three months ended October 31, 2014, 307,500 RSUs vested based on service conditions that were satisfied during the period. Of the 4,717,500 RSUs outstanding we currently expect 3,657,500 to vest. As of October 31, 2014, there was \$3,852,000 of unrecognized non-cash compensation cost related to RSUs we expect to vest, which will be recognized over a weighted average period of 1.34 years.

As of October 31, 2014, there was \$127,000 of unrecognized non-cash compensation cost related to unvested stock options, which will be recognized over a weighted average period of 2.12 years. No options were granted during the three months ended October 31, 2014 and 2013.

For the three months ended October 31, 2014 and 2013, share-based compensation expense for outstanding RSUs and stock options was \$503,000 and \$89,000 respectively.

## **13. Recent Accounting Pronouncements**

No recent accounting pronouncements or other authoritative guidance have been issued that management considers likely to have a material impact on our consolidated financial statements.

**14. Subsequent Events**

None

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**Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations**

All references in this Item 2 and elsewhere in this Quarterly Report to PURE, we, our, us and the Company refer to Pure Bioscience, Inc. and our wholly owned subsidiary, ETIH2O Corporation, a Nevada corporation. ETIH2O Corporation currently has no business operations and no material assets or liabilities and there have been no significant transactions related to ETIH2O Corporation during the periods presented in the consolidated financial statements contained elsewhere in this Quarterly Report.

The discussion in this section contains forward-looking statements. These statements relate to future events or our future financial performance. We have attempted to identify forward-looking statements by terminology such as anticipate, believe, can, continue, could, estimate, expect, intend, may, plan, potential, predict, or the negative of these terms or other comparable terminology, but their absence does not mean that a statement is not forward-looking. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which could cause our actual results to differ from those projected in any forward-looking statements we make. Several risks and uncertainties we face are discussed in more detail under Risk Factors in Part II, Item 1A of this Quarterly Report or in the discussion and analysis below. You should, however, understand that it is not possible to predict or identify all risks and uncertainties and you should not consider the risks and uncertainties identified by us to be a complete set of all potential risks or uncertainties that could materially affect us. You should not place undue reliance on the forward-looking statements we make herein because some or all of them may turn out to be wrong. We undertake no obligation to update any of the forward-looking statements contained herein to reflect future events and developments, except as required by law. The following discussion should be read in conjunction with the consolidated financial statements and the notes to those financial statements included elsewhere in this Quarterly Report on Form 10-Q.

**Overview**

***Company Overview***

We are focused on developing and commercializing our proprietary antimicrobial products primarily in the food safety arena that provide solutions to the health and environmental challenges of pathogen and hygienic control. Our technology platform is based on patented stabilized ionic silver, and our initial products contain silver dihydrogen citrate, or SDC. SDC is a broad-spectrum, non-toxic antimicrobial agent, which offers 24-hour residual protection and formulates well with other compounds. As a platform technology, SDC is distinguished from existing products in the marketplace because of its superior efficacy, reduced toxicity and the inability of bacteria to form a resistance to it. SDC is manufactured as a liquid delivered in various concentrations. We currently distribute and contract the manufacture and distribution of, our SDC-based disinfecting and sanitizing products, which are registered by the Environmental Protection Agency, or EPA. We also contract manufacture and sell SDC-based formulations to manufacturers for use as a raw material ingredient in the production of personal care products. We believe our technology platform has potential application in a number of industries. We intend to focus our current resources on providing food safety solutions to the food industry.

Our goal is to become a sustainable company by commercializing our proprietary technology platform to deliver leading antimicrobial products through our sales and marketing efforts focused on the food industry and through licensing collaborations in other industries. Our current products are as follows:

Product Name	Product Use	EPA Registration
PURE Complete Solution:		

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PURE® Hard Surface	Disinfectant and sanitizer	SDC3A
PURE Multi-Purpose Cleaner Concentrate	Cleaner	Not applicable
PURE Multi-Purpose Hi-Foam Cleaner Concentrate	Cleaner	Not applicable
Axen® 30(1)	Disinfectant	Axen30
Axenohl®	Raw material ingredient	Axenohl
Silvérion®	Raw material ingredient	Not applicable

(1) We intend to phase out Axen® 30

***PURE Complete Solution***

Our PURE Complete Solution is comprised of PURE® Hard Surface and concentrated cleaning products that were launched as companion products to PURE® Hard Surface. The PURE Complete Solution offers a comprehensive, cost-effective and user-friendly cleaning, disinfecting and sanitizing product line to end-users including our targeted foodservice, food manufacturing and food processing customers. We can also target this product line to hospital and medical care facilities; janitorial service providers and the distributors that supply them.



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### ***PURE® Hard Surface Disinfectant and Sanitizer (Ready-to-Use)***

PURE® Hard Surface is our SDC-based, patented and EPA-registered, ready-to-use hard surface disinfectant and food contact surface sanitizer. We manufacture both consumer and commercial versions of the product. PURE Hard Surface combines high efficacy and low toxicity with 30-second bacterial and viral kill times and 24-hour residual protection. The product completely kills resistant pathogens such as MRSA and Carbapenem-resistant *Klebsiella pneumoniae* (NDM-1), and effectively eliminates dangerous fungi and viruses including HIV, Hepatitis B, Hepatitis C, Norovirus, Influenza A, Avian Influenza and H1N1. It also eradicates hazardous food pathogens such as *E. coli*, *Salmonella*, *Campylobacter* and *Listeria*. PURE® Hard Surface delivers broad-spectrum efficacy yet remains classified as least-toxic by the EPA. The active ingredient, SDC, has been designated as Generally Recognized as Safe, or GRAS, for use on food processing equipment, machinery and utensils.

### ***PURE Multi-Purpose Cleaner Concentrate (End-User Dilutable)***

PURE® Multi-Purpose Cleaner, is an environmentally responsible cleaning product that is protected by SDC. SDC ensures the quality and safety of PURE® Multi-Purpose Cleaner without human or environmental exposure to toxic chemical preservatives. PURE® Multi-Purpose Cleaner is non-toxic and non-flammable and contains no EDTA, phosphates, ammonia or bleach as well as no VOCs or NPEs. PURE Multi-Purpose Cleaner provides professional strength cleaning in a concentrate formula that yields a 1:96 – 1:256 use dilution that is safe for use on all resilient surfaces, including floors, glass and food contact surfaces.

### ***PURE Multi-Purpose Hi-Foam Cleaner Concentrate (End-User Dilutable)***

PURE® Multi-Purpose Hi-Foam Cleaner is an environmentally responsible, professional strength high foam forming cleaning product that is protected by SDC. SDC ensures the quality and safety of PURE Multi-Purpose Hi-Foam Cleaner without human or environmental exposure to toxic chemical preservatives. PURE Multi-Purpose Hi-Foam Cleaner is non-toxic and non-flammable and contains no EDTA, phosphates, ammonia or bleach as well as no VOCs or NPEs. PURE Multi-Purpose Hi-Foam Cleaner provides high foam cleaning in a concentrate formula that yields a 1:50 use dilution that is safe for use on stainless steel equipment, resilient floors, walls and painted surfaces.

### ***Axen® 30 (Ready-to-Use)***

Axen®30 is our patented and EPA-registered hard surface disinfectant and is a predecessor ready-to-use product to PURE® Hard Surface. Axen30 is currently sold on a limited basis by distributors under their respective private labels which we intend to phase out.

### ***Axenohl® (Raw Material Ingredient)***

Axenohl® is our patented and EPA-registered SDC-based antimicrobial formulation for use as a raw material ingredient in the manufacturing of EPA-registered products. Axenohl is a colorless, odorless and stable solution that provides fast acting efficacy against bacteria, viruses and fungi when manufactured into consumer and commercial disinfecting and sanitizing products.

### ***SILVÉRION® (Raw Material Ingredient)***

SILVÉRION® is our patented SDC-based antimicrobial formulation for use as a raw material ingredient in the manufacturing of personal care products. It can be used as either an active ingredient or a preservative. SILVÉRION is a colorless, odorless and stable solution that provides ionic silver in a water-soluble form. It provides fast acting

efficacy at low concentrations against a broad-spectrum of bacteria, viruses, yeast and molds. SILVÉRION is currently sold outside of the United States in various personal care products.

We were incorporated in the state of California in August 1992 as Innovative Medical Services. In September 2003, we changed our name to Pure Bioscience. In March 2011, we reincorporated in the state of Delaware under the name Pure Bioscience, Inc. We operate in one business segment.

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### ***Recent Corporate Developments***

During July 2014, we submitted a Food Contact Notification (FCN) to the Food and Drug Administration (FDA) for Salmonella reduction in processing of raw poultry. In November 2014, we withdrew, without prejudice, our FCN for raw poultry due to receipt of a Deficiency Letter from the FDA stating that the agency has developed new data that is currently under review. That data calls into question the long established safety levels of the dietary intake of silver in the U.S. from food contact uses previously approved by the FDA. As a result, the FDA indicated that it would not approve our FCN absent new data or additional information that adequately addresses its new toxicity concerns. Because the FDA is unlikely to approve any new uses of silver in food processing at this time, we believe we will likely receive a similar Deficiency Letter from the FDA for the FCN we submitted in October 2014 for the use of SDC to reduce Salmonella, E. coli and Listeria in the processing of produce. We are currently in discussions with the FDA to assess the additional data we need to provide to support our FCNs. We also intend to delay the filing of our FCN for the use of SDC as a processing aid for beef and pork until we receive guidance from the FDA.

On October 24, 2014, we appointed Tom Y. Lee, CPA, to the Board of Directors, or the Board. The Board now consists of six members who provide professional experience in business and finance; food science and food safety; foodservice and food manufacturing; and distribution.

### ***Financial Overview***

This financial overview provides a general description of our revenue and expenses.

#### **Revenue**

We manufacture and sell SDC-based products for end use, and as a raw material for manufacturing use. We also license our products and technology to development and commercialization partners. Revenue is recognized when realized or realizable and earned. Any amounts received prior to satisfying revenue recognition criteria are recorded as deferred revenue.

#### **Cost of Goods Sold**

Cost of goods sold for product sales includes direct and indirect costs to manufacture products, including materials consumed, manufacturing overhead, shipping costs, salaries, benefits, reserved inventory, and related expenses of operations. Depreciation related to manufacturing is systematically allocated to inventory produced, and expensed through cost of goods sold at the time inventory is sold.

#### **Selling, General and Administrative**

Selling, general and administrative expense consists primarily of salaries and other related costs for personnel in business development, sales, finance, accounting, information technology, and executive functions. Other selling, general and administrative costs include product marketing, advertising, and trade show costs, as well as public relations and investor relations, facility costs, and legal, accounting and other professional fees.

#### **Research and Development**

Our research and development activities are focused on leveraging our technology platform to develop additional proprietary products and applications. Research and development expense consists primarily of personnel and related costs, product registration expenses, and third-party testing. We expense research and developments costs as incurred.

Other Income (Expense)

We record interest income, interest expense, change in derivative liabilities, as well as other non-operating transactions, as other income (expense) in our consolidated statements of operations.

**Results of Operations**

*Fluctuations in Operating Results*

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our results of operations will be affected for the foreseeable future by several factors that may contribute to these periodic fluctuations, including the demand for our products, the timing and amount of our product sales, and the progress and timing of expenditures related to sales and marketing, as well as product development. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a reliable indication of our future performance.

*Comparison of the Three Months Ended October 31, 2014 and 2013*

Net Product Sales

Net product sales were \$117,000 and \$115,000 for the three months ended October 31, 2014 and 2013, respectively. Our domestic net product sales were \$99,000 and \$115,000 for the three months ended October 31, 2014 and 2013, respectively. The \$16,000 decrease in domestic net product sales was related to fluctuations within our legacy customer base. Our foreign net product sales were \$18,000 and zero for the three months ended October 31, 2014 and 2013, respectively. The increase in foreign net product sales was related to a new customer contract.

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For the three months ended October 31, 2014, three individual customers each accounted for 10% or more of our net product sales. One customer accounted for 22%, another for 20%, and the other for 16%. No other individual customer accounted for 10% or more of our net product sales. The geographic breakdown of net product sales was as follows: 84% U.S. and 16% foreign, with foreign sales occurring in the United Kingdom.

For the three months ended October 31, 2013, three individual customers each accounted for 10% or more of our net product sales. One customer accounted for 33%, another for 23%, and the other for 19%. No other individual customer accounted for 10% or more of our net product sales. The geographic breakdown of net product sales was as follows: 100% U.S. and 0% foreign.

### **Cost of Goods Sold**

Cost of goods sold was \$45,000 and \$36,000 for the three months ended October 31, 2014 and 2013, respectively. The increase of \$9,000 was primarily attributable to periodic inventory adjustments that took place during the current quarter, as well as, the sale of higher margin products during the prior quarter.

Gross margin as a percentage of net product sales, or gross margin percentage, was 62% and 69% for the three months ended October 31, 2014 and 2013, respectively. This decrease in gross margin percentage was primarily attributable to the sale of higher margin formulations and packaging configurations of our products during the quarter ended October 31, 2013 as compared to current quarter.

### **Selling, General and Administrative Expense**

Selling, general and administrative expense was \$1,192,000 and \$925,000 for the three months ended October 31, 2014 and 2013, respectively. The increase of \$267,000 was primarily attributable to increased personnel and related costs, offset by reductions in facility costs and professional services.

### **Research and Development Expense**

Research and development expense was \$176,000 and \$213,000 for the three months ended October 31, 2014 and 2013, respectively. The decrease of \$37,000 was primarily attributable to decreases in personnel costs and related expenses, offset by increased third-party research and testing activities.

### **Share-Based Compensation**

Share-based compensation expense was \$503,000 and \$89,000 for the three months ended October 31, 2014 and 2013, respectively. The increase of \$414,000 is primarily due to the restricted stock units granted to employees and directors supporting our selling, general and administrative, and research and development functions during the prior fiscal year and current quarter.

### **Other Share-Based Expenses**

Other share-based expense was \$131,000 and zero for the three months ended October 31, 2014 and 2013, respectively. The increase is due to \$131,000 of expense incurred from the amendment of the subscription agreements for investors who participated in prior private placements (See Note 11).

### **Restructuring Expense**

Restructuring expense was zero and \$2,684,000 for the three months ended October 31, 2014 and 2013, respectively. On August 13, 2013, Michael L. Krall, Donna Singer, and Dennis Brovarone resigned all positions respectively held by them as officers and directors of the Company and a new management team and Board were appointed. Based on the corporate governance change we incurred the following expenditures in 2013:

Mr. Krall and Ms. Singer received a onetime separation payment of \$150,000 and \$45,000, respectively; Mr. Brovarone received \$91,000, payable in 60 monthly installments of approximately \$1,600, commencing December 2013; Mr. Krall is entitled to receive a cash severance of \$540,000 in aggregate, payable in monthly installments of \$30,000 until February 2015; Ms. Singer received a cash severance of \$204,000 in aggregate, which was payable until August 2014; Mr. Krall received 850,000 unregistered shares of common stock, valued at \$595,000; Ms. Singer received 300,000 unregistered shares of common stock, valued at \$210,000; and Mr. Krall and Ms. Singer each were entitled to receive the amount of their continued health insurance coverage until February 2015 and August 2014, respectively. Medical and dental insurance for Mr. Krall and Ms. Singer cost the Company \$20,000 and \$18,000, respectively. Per the terms of the agreements, we recorded a onetime expense of \$1,782,000 related to Mr. Krall's and Ms. Singer's separation payments, future severance payments, unregistered stock received, and future medical and dental insurance payments. All but \$7,000 due to Mr. Brovarone was accrued in prior periods for services previously provided.

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We issued 300,000 shares of unregistered common stock to Bibicoff & McInnis for investor relations services related to the corporate restructuring, valued at \$210,000.

We issued 250,000 shares of unregistered common stock, with a value of \$175,000, for corporate finance and restructuring activities to Wulff Services Inc. Wulff Services, Inc. is primarily owned by our current Chief Financial Officer / Chief Operation Officer, Peter Wulff. In addition, Wulff Services, Inc. received a onetime payment of \$75,000 related to the corporate finance and restructuring efforts.

We issued 300,000 shares of registered common stock, with a value of \$210,000, for corporate reorganization services previously provided by the principal of Pillar Marketing Group, Inc. In addition, Pillar also received a onetime payment of \$152,000 related to the reorganization efforts.

We incurred \$73,000 in legal fees associated with the corporate finance and restructuring activities.

### **Change in Derivative Liability**

Change in derivative liability for the three months ended October 31, 2014 and 2013 was an increase of \$1,000 and \$58,000, respectively. The change is primarily due to adjustments of the estimated fair value, and the settlement of derivative warrants exercised during the period ended October 31, 2013.

### **Other (Expense) Income**

Other expense for the three months ended October 31, 2014 was \$1,000, compared to other income of \$49,000 for the three months ended October 31, 2013. The decrease is primarily attributable to the sale of reserved inventory and accounts payable vendors settlements that occurred during the three months ended October 31, 2013.

## **Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily through public and private offerings of securities, debt financing, and revenue from product sales and license agreements. We have a history of recurring losses, and as of October 31, 2014 we have incurred a cumulative net loss of \$83,155,000.

During the three months ended October 31, 2014, we issued a total of 9,958,032 shares of common stock and warrants to purchase 3,996,259 shares of common stock for gross proceeds of approximately \$7.49 million. Additionally, in connection with the price adjustment terms in subscription agreements we previously entered into with investors in prior private placements, we issued an aggregate of 127,993 shares of common stock and warrants to purchase up to and aggregate of 648,053 shares of common stock. The shares of common stock and the warrants issued under the private placements were offered and sold without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws, based on the lack of any general solicitation or advertising in connection with the sale of the securities; the representation of each investor to the Company that it is an accredited investor (as that term is defined in Rule 501 of Regulation D) and that it was purchasing the securities for its own account and without a view to distribute them. The securities, including the shares underlying the warrants, may not be offered or sold in the United States without an effective registration statement or pursuant to an exemption from applicable registration requirements.

As of October 31, 2014, we had \$5,331,000 in cash and cash equivalents compared to \$86,000 in cash and cash equivalents as of July 31, 2014. The net increase in cash and cash equivalents was primarily attributable to proceeds from our issuance of common stock in the private placements noted above. Additionally, as of October 31, 2014, we had \$875,000 of current liabilities, including \$510,000 in accounts payable, compared to \$1,829,000 of current liabilities, including \$1,096,000 in accounts payable as of July 31, 2014. The net decrease in current liabilities was primarily due to the timing of accounts payable and reduced wage accruals.

In addition, from time to time we have entered into employment agreements with our executives that, under certain cases, provide for the continuation of salary and certain other benefits if these executives are terminated under specified circumstances. These agreements generally expire upon termination for cause or when we have met our obligations under these agreements. As of October 31, 2014, no events have occurred resulting in the obligation of any such payments. On August 13, 2013, we entered into Purchase, Severance, and Release Agreements with our named executive officers, which is further described in Note 6 above.

Our future capital requirements depend on numerous forward-looking factors. These factors may include, but are not limited to, the following: the acceptance of, and demand for, our products; our success and the success of our partners in selling our products; our success and the success of our partners in obtaining regulatory approvals to sell our products; the costs of further developing our existing products and technologies; the extent to which we invest in new product and technology development; and the costs associated with the continued operation, and any future growth, of our business. The outcome of these and other forward-looking factors will substantially affect our liquidity and capital resources.



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We expect that we will need to increase our liquidity and capital resources by one or more measures. These measures may include, but are not limited to, the following: reducing operating expenses; obtaining financing through the issuance of equity, debt, or convertible securities; entering into partnerships, licenses, or other arrangements with third parties; and reducing the exercise price of outstanding warrants. Any one of these measures could substantially reduce the value to us of our technology and its commercial potential as it may be necessary to enter into arrangements with less favorable terms than otherwise possible. Additionally, a reduction in operating expenses will require a reduction in the sales, marketing, and other commercialization activities required to bring our products to market. If we issue equity, debt or convertible securities to raise additional funds, our existing stockholders may experience dilution, and the new equity, debt or convertible securities may have rights, preferences and privileges senior to those of our existing stockholders. There is no guarantee that we would be able to obtain capital on terms acceptable to us, or at all.

If we are unable to obtain sufficient capital, it would have a material adverse effect on our business and operations. It could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to competitive pressures or customer requirements. It also may require us to delay, scale back or eliminate some or all of our research and development programs, to license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, or to reduce or cease operations altogether. If adequate funds are not available when needed, we may be required to significantly modify our business model and operations to reduce spending to a sustainable level.

We believe our current efforts to raise capital, our current efforts to market and sell our products, and our ability to significantly reduce expenses, will provide sufficient cash resources to satisfy our needs over the next 12 months. However, we do not yet have, and we may never have, significant cash inflows from product sales or from other sources of revenue to offset our ongoing and planned investments in corporate infrastructure, research and development projects, regulatory submissions, business development initiatives, and sales and marketing activities, among other investments. Some or all of our ongoing or planned investments may not be successful and could result in further losses. In addition, irrespective of our cash resources, we may be contractually or legally obligated to make certain investments which cannot be postponed.

## **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies and estimates are critical to aid you in understanding and evaluating our reported financial results.

### ***Revenue Recognition***

We sell our products to distributors and end users. We record revenue when we sell products to our customers, rather than when our customers resell products to third parties. When we sell products to our customers, we reduce the balance of our inventory with a corresponding charge to cost of goods sold. We do not currently have any consignment sales.

Terms of our product sales are generally FOB shipping point. Product sales are recognized when delivery of the products has occurred (which is generally at the time of shipment), title has passed to the customer, the selling price is fixed or determinable, collectability is reasonably assured and we have no further obligations. Any amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. We record product sales net of discounts at the time of sale and report product sales net of such discounts.

We also license our products and technology to development and commercialization partners. License fee revenue consists of product and technology license fees earned. If multiple-element arrangements require on-going services or performance, then upfront product and technology license fees under such arrangements are deferred and recognized over the period of such services or performance. Non-refundable amounts received for substantive milestones are recognized upon achievement of the milestone. Any amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

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### ***Share-Based Compensation***

We grant equity-based awards under share-based compensation plans or stand-alone contracts. We estimate the fair value of share-based payment awards using the Black-Scholes option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected life of the option. Share-based compensation expense is based on awards ultimately expected to vest, and therefore is reduced by expected forfeitures. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

### ***Impairment of Long-Lived Assets***

In accordance with GAAP, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and we record the impairment as a reduction in the carrying value of the related asset and a charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment, and assumptions could differ materially from actual results.

For purposes of testing impairment, we group our long-lived assets at the lowest level for which there are identifiable cash flows independent of other asset groups. Currently, there is only one level of aggregation for our intangible assets. We assess the impairment of long-lived assets, consisting of property, plant, and equipment and our patent portfolio, whenever events or circumstances indicate that the carrying value may not be recoverable. Examples of such events or circumstances include:

an asset group's ability to continue to generate income from operations and positive cash flow in future periods;

loss of legal ownership or title to the asset(s);

significant changes in our strategic business objectives and utilization of the asset(s); and

the impact of significant negative industry or economic trends.

Additionally, on a quarterly basis we review the significant assumptions underlying our impairment assessment to determine whether our previous conclusions remain valid.

Recoverability of assets to be held and used in operations is measured by a comparison of the carrying amount of an asset to the future net cash flows expected to be generated by the assets. The factors used to evaluate the future net cash flows, while reasonable, require a high degree of judgment and the results could vary if the actual results are materially different than the forecasts. In addition, we base useful lives and amortization or depreciation expense on our subjective estimate of the period that the assets will generate revenue or otherwise be used by us. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying

amount or fair value less selling costs.

We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the assets. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

### ***Derivative Financial Instruments***

We do not use derivative instruments to hedge exposures to cash flow or market or foreign currency risks.

We review the terms of the common stock, warrants and convertible debt we issue to determine whether there are derivative instruments, including embedded conversion options, that are required to be bifurcated and accounted for separately as derivative financial instruments. In circumstances where the host instrument contains more than one embedded derivative instrument, including a conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument.

Derivatives are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as non-operating income or expense. When the equity or convertible debt instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds received are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the host instruments themselves, usually resulting in those instruments being recorded at a discount from their face value.

### **Recent Accounting Pronouncements**

See Note 13 to the consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

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**Off Balance Sheet Arrangements**

We do not have any off balance sheet arrangements.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

As a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, or the Exchange Act, and as provided in Item 10(f)(1) of Regulation S-K, we are electing scaled disclosure reporting obligations and therefore are not required to provide the information requested by this Item.

**Item 4. Controls and Procedures  
Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the Securities and Exchange Commission, or SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

As required by Rule 13a-15(b) under the Exchange Act, our management conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing evaluation, our principal executive officer and principal financial officer concluded that as of the end of the period covered by this report our disclosure controls and procedures were effective.

**Changes in Our Internal Controls**

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of any potential changes in our internal control over financial reporting during the fiscal quarter covered by this quarterly report on Form 10-Q.

There were no changes in our internal controls over financial reporting during the three months ended October 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

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**PART II Other Information**

**Item 1. Legal Proceedings**

From time to time, we may become involved in various lawsuits and legal proceedings that arise in the ordinary course of our business. The impact and outcome of litigation, if any, is subject to inherent uncertainties, and any adverse result in these or other matters may arise from time to time that could harm our business. We are not currently aware of any such legal proceedings or claims to which we or our wholly owned subsidiary is a party or of which any of our property is subject that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

**Item 1A. Risk Factors**

*You should carefully consider the following information about risks and uncertainties that may affect us or our business, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q, including our consolidated financial statements and the notes thereto, and the information in other reports we file with the SEC, including our Annual Report on Form 10-K for the year ended July 31, 2014 and our audited consolidated financial statements and the notes thereto included therein. If any of the following events, described as risks, actually occur, either alone or taken together, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment in our securities. An investment in our securities is speculative and involves a high degree of risk. You should not invest in our securities if you cannot bear the economic risk of your investment for an indefinite period of time and cannot afford to lose your entire investment. There may be additional risks that we do not presently know of or that we currently believe are immaterial which could also impair our business and financial position.*

**Risks Related to Our Business and Industry**

*We have a history of losses, and we may not achieve or maintain profitability.*

We had a loss of \$1.93 million for the quarter ended October 31, 2014, and a loss of \$3.84 million for the quarter ended October 31, 2013. As of October 31, 2014, we have incurred a cumulative net loss of approximately \$83 million. Although we expect to continue to have losses in future periods, we are unable to predict the extent of our future losses or when or if we will become profitable, and it is possible we will never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

None of our existing agreements, including with Subway, contain provisions that guarantee us any minimum revenues. If the penetration into the marketplace of silver dihydrogen citrate, or SDC, and SDC-based products is unsuccessful, revenue growth is slower than anticipated or operating expenses exceed expectations, it may take an unforeseen period of time to achieve or maintain profitability and we may never achieve or maintain profitability. Slower than anticipated revenue growth could force us to reduce research, testing, development and marketing of our technologies, and/or force us to reduce the size and scope of our operations, to sell or license our technologies to third parties, or to cease operations altogether.

The risks associated with our business may be more acute during periods of economic slowdown or recession. In addition to other consequences, these periods may be accompanied by decreased consumer and institutional spending

in general, as well as decreased demand for, or additional downward pricing pressure on, our products. Accordingly, any prolonged economic slowdown or a lengthy or severe recession with respect to either the U.S. or the global economy is likely to have a material adverse effect on our results of operations, financial condition and business prospects. As a result, given the current weakness and uncertainties in the U.S. and in certain overseas economies, we expect that our business will continue to be adversely affected for so long as, and to the extent that, such adverse economic conditions and uncertainty exist.

***Our future capital needs are uncertain, and we currently expect that we will need additional funds in the future which may not be available on acceptable terms or at all.***

Our capital requirements will depend on many factors, including, among other factors:

the acceptance of, and demand for, our products;

the success of our strategic partners in developing and selling products derived from our technology;

the costs of further developing our existing, and developing new, products or technologies;

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the extent to which we invest in new technology, testing and product development;

the timing of vendor payments and of the collection of receivables, among other factors affecting our working capital;

the exercise of outstanding options or warrants to acquire our common stock;

the number and timing of acquisitions and other strategic transactions, if any; and

the costs associated with the continued operation, and any future growth, of our business.

We believe that our current cash resources are sufficient to meet our anticipated needs during the next twelve months, however we do not yet have, and we may never have, significant cash inflows from product sales or from other sources of revenue to offset our ongoing and planned investments in corporate infrastructure, research and development projects, regulatory submissions, business development activities, and sales and marketing, among other investments. Some or all of our ongoing or planned investments may not be successful. In addition, irrespective of our cash resources, we may be contractually or legally obligated to make certain investments, which cannot be postponed.

We expect that we will need to increase our liquidity and capital resources by one or more measures, which may include reducing operating expenses, raising additional financing in future periods through the issuance of debt, equity, or convertible securities, entering into partnerships, licenses, or other arrangements with third parties, reducing the exercise price of outstanding warrants, or through other means, any one of which could reduce the value to us, perhaps substantially, of our technology and its commercial potential. There is no guarantee that we would be able to obtain capital on terms acceptable to us, or at all. Insufficient funds would result in a material adverse effect on our business and operations and could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to competitive pressures or customer requirements, and further may require us to delay, scale back or eliminate some or all of our research and product development programs, license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, or to reduce or cease operations. If adequate funds are not available when needed, we may be required to significantly modify our business model and operations to reduce spending to a sustainable level. Such modification of our business model and operations could also result in an impairment of assets which cannot be determined at this time. Furthermore, if we issue equity or convertible debt securities to raise additional funds, our existing shareholders may experience dilution, and in addition the new equity or debt securities may have rights, preferences and privileges senior to those of our existing shareholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization.

As of December 11, 2014, we have 50,469,632 shares of common stock issued and outstanding or reserved for issuance. Shares reserved for issuance include shares under equity compensation plans, vested and unvested options, warrants, and unvested restricted stock units. Our current authorized capital stock is limited to 100,000,000 shares of common stock and 5,000,000 shares of preferred stock. Any increase in our authorized capital stock would require the approval of a majority of our shareholders as well as the approval of our Board of Directors. If we were unable to increase our authorized capital stock for any reason, our ability to raise additional capital through the issuance of equity or convertible debt would be severely compromised and we may be unable to obtain equity or convertible debt capital at all.



***The industries in which we operate are heavily regulated and we may be unable to compete effectively.***

We are focused on the marketing and continued development of our SDC antimicrobial technology. We believe that products derived from our SDC technology, or products that may be derived from our SDC technology in future periods, require or will require approval by government agencies prior to marketing or sale in the U.S. or in foreign markets. Complying with applicable government regulations and obtaining necessary approvals can be, and has historically been, time consuming and expensive, due in part, we believe, to the novel nature of our technology. Regulatory review could involve delays or other actions adversely affecting the development, manufacture, marketing and sale of our products. While we cannot accurately predict the outcome of any pending or future regulatory review processes or the extent or impact of any future changes to legislation or regulations affecting review processes, we expect such processes to remain time consuming and expensive as we, or our partners, apply for approval to make new or additional efficacy claims for current products or to market new product formulations. Obtaining approvals for new SDC-based products in the U.S., or in markets outside the U.S., could take several years, or may never be accomplished.

SDC is a platform technology rather than a single use applied technology. As such, products developed from the platform may fall under the jurisdiction of multiple U.S. and international regulatory agencies. Our disinfectant and sanitizer products are regulated in the U.S. by the EPA. In addition to the EPA, each of the 50 United States has its own government agencies that regulate the sale or shipment of our products into their state. We have obtained registration for these products from the EPA and all states into which such products are currently marketed and sold. We are required to meet certain efficacy, toxicity and labeling requirements and pay ongoing fees in order to maintain such registrations. We may not be able to maintain these registrations in the future, which may eliminate our continued ability to market and sell our products in some or all parts of the U.S. We also may not be able to obtain necessary registrations with the EPA and applicable states for other SDC disinfectant and sanitizer products that we or our partners may develop, which would limit our ability to sell any such products in the future.

Some potential applications of SDC, such as those aimed at healthcare, veterinary and certain food preparation markets, may require approval of other government agencies prior to marketing or sale in the U.S. or in foreign markets, such as the U.S. Food and Drug Administration, or FDA, or the United States Department of Agriculture, or USDA. Obtaining FDA and/or USDA approval is a complicated and expensive process and such approvals may never be obtained for any SDC products.

In November 2014, we withdrew, without prejudice, our FCN for raw poultry due to receipt of a Deficiency Letter from the FDA stating that the agency has developed new data that is currently under review, which data calls into question the long established safety levels of the dietary intake of silver in the U.S. from food contact uses previously approved by the FDA. As a result, the FDA indicated that it would not approve our FCN absent new data or additional information that adequately addresses its new toxicity concerns. Because the FDA is unlikely to approve any new uses of silver in food processing at this time, we believe we will likely receive a similar Deficiency Letter from the FDA for the FCN we submitted in October 2014 for the use of SDC to reduce Salmonella, E. coli and Listeria in the processing of produce. If we do receive such a Deficiency Letter, we intend to similarly withdraw that FCN until we can provide the FDA with the additional data and information necessary to address the FDA's concerns. We are currently in discussions with the FDA to assess the additional data we need to provide to support our FCNs. We also intend to delay the filing of our FCN for the use of SDC as a processing aid for beef and pork until we receive guidance from the FDA. These delays in achieving regulatory approvals will have a significant adverse effect on the timing of any anticipated revenues from sales of our SDC products and could significantly impact our product development costs and business. Additionally, if we fail to achieve regulatory approval of the SDC products, such failure would have a significant adverse effect on our business and we may not be able to support our continued operations.

If FDA and/or USDA approvals are obtained, the approvals may limit the uses for which SDC products may be marketed such that they may not be profitable to us, and the applicable products would be subject to pervasive and

continuing regulation by the FDA and/or USDA that could lead to withdrawal or limitation of any product approvals.

We intend to fund and manage certain of our EPA-regulated product development internally, in conjunction with engaging regulatory consultants and partnering with other third parties. We have partnered, or intend to partner, with third parties who are seeking, or intend to seek, approvals to market SDC-based products in markets outside the U.S., and with other third parties who are developing FDA-regulated SDC-based products who, upon such development, would seek FDA approvals of such products. Our ability to market and sell our products is dependent on our and our partners' ability to obtain and maintain required registrations and approvals of applicable regulatory agencies. Failure by our partners or us to comply with applicable regulations could result in fines or the withdrawal of approval for us or our partners and distributors to market our products in some or all jurisdictions or for certain indications, which could cause us to be unable to successfully commercialize SDC or otherwise achieve revenues from sales of such products.

***Raising additional funds by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

We expect that we will need to increase our liquidity and capital resources in future periods. We have a history of raising funds through offerings of our common stock, and we may in the future raise additional funds through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. To the extent that we raise additional capital by issuing equity securities, our stockholders' ownership will be diluted. Additionally, any debt financing we obtain may involve covenants that restrict our operations. These restrictive covenants may include, among other things, limitations on borrowing, specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens on our assets, pay dividends on or redeem our capital stock or make investments. In addition, if we raise funds through collaboration and licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to us or relinquish potentially valuable rights to our products or proprietary technologies. We may be required in future collaborations to relinquish all or a portion of our sales and marketing rights with respect to our products or license intellectual property that enable licensees to develop competing products in order to complete any such transaction.

As a result of the reverse stock split that we effected on August 14, 2012, the number of our outstanding shares of common stock was reduced at a ratio of one-for-eight, while the number of our authorized shares of common and preferred stock did not change. Accordingly, our authorized common stock remains 100,000,000 shares. In addition to capital raising activities, other possible business and financial uses for our authorized common stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of common stock, issuing shares of our common stock to partners in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our various equity compensation plans, satisfying any debt we may have by issuing equity securities, or other transactions and corporate purposes that our Board of Directors, or Board, deems are in our best interest. Additionally, shares of common stock could be used for anti-takeover purposes or to delay or prevent changes in control or management of the Company. For example, without further stockholder approval, our Board could approve the sale of shares of common stock in a private transaction to purchasers who may oppose a takeover or favor our current Board. We cannot provide assurances that any issuances of common stock will be consummated on favorable terms or at all, that they will enhance stockholder value, or that they will not adversely affect our business or the trading price of our common stock.

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Under our Certificate of Incorporation, our Board could also authorize the issuance of up to 5,000,000 shares of preferred stock on terms determined by the Board. If any common or preferred stock is issued, the interests of holders of our common stock could be diluted, and shares of preferred stock could be issued in a financing in which investors purchase preferred stock with rights, preferences and privileges that may be superior to those of the common stock, and the market price of our common stock could decline.

*If outstanding options and warrants to purchase shares of our common stock are exercised, the interests of our stockholders could be diluted.*

As of December 11, 2014, in addition to 39,788,465 shares of common stock issued and outstanding, we had 462,343 shares reserved for issuance under equity compensation plans for vested and unvested stock options and 4,717,500 shares reserved for issuance for vested and unvested restricted stock units. We also had 5,501,324 shares reserved for issuance on the exercise of outstanding warrants.

We may elect to reduce the exercise price of outstanding warrants as a means of providing additional financing to us. The exercise of options and warrants, and the sale of shares underlying such options or warrants, could have an adverse effect on the market for our common stock, including the price that an investor could obtain for their shares. Investors may experience dilution in the net tangible book value of their investment upon the exercise of options and warrants currently outstanding, as well as options and warrants that may be granted or issued in the future.

*Because we are an early stage company, it is difficult to evaluate our prospects and our financial results may fluctuate, which may cause our stock price to fall.*

Since acquiring the rights to our SDC technology, we have encountered and likely will continue to encounter risks and difficulties associated with introducing or establishing our products in rapidly evolving markets. These risks include the following, among others:

we may not increase our sales to our existing customers and/or expand our customer base;

we may not succeed in materially penetrating markets and applications for our SDC technology;

our new sales and marketing strategy, which is built on our direct control of the sales and marketing of our products, may not be successful;

we may not be successful in obtaining any required regulatory approvals on a timely basis, or at all;

we or our partners and/or distributors may not establish or maintain effective marketing programs to create product awareness or brand identity;

our partners and/or distributors goals and objectives may not be consistent with our own;

we may not attract and retain key business development, technical and management personnel;

we may not maintain existing, or obtain new, regulatory approvals for our technology and products;

we may not succeed in locating strategic partners and licensees of our technology;

we may not effectively manage our anticipated growth, if any; and

we may not be able to adequately protect our intellectual property.

Any failure to successfully address these risks and uncertainties could seriously harm our business and prospects. We may not succeed given the technological, marketing, strategic and competitive challenges we face. In addition, because of our limited operating history and the early stage of market development for our SDC technology, we have limited insight into trends that may emerge and affect our business. Forecasting future revenues is difficult, especially because our technology is novel, and market acceptance of our products could change rapidly. In addition, our customers and potential customers in the foreseeable future are highly concentrated. Fluctuations in the buying patterns of our current or potential customers could significantly affect the level of our sales on a period to period basis. As a result, our financial results could fluctuate to an extent that may adversely affect our stock price. There are a number of other factors that could cause our financial results to fluctuate unexpectedly, including product sales, the mix of product sales, the cost of product sales, our ability for any reason to be able to meet demand, the achievement and timing of research and development and regulatory milestones, changes in expenses, including non-cash expenses such as the fair value of stock options granted, and manufacturing or supply issues, among other factors.

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***A loss of one or more of our key customers could adversely affect our business.***

From time to time, one or a small number of our customers may represent a significant percentage of our revenue. Our three largest customers accounted for 58% of our revenue for the months ended October 31, 2014. One customer accounted for 22%, one 20%, and the other for 16%. Although we have agreements with many of our customers, these agreements typically do not prohibit customers from purchasing products and services from competitors. A decision by any of our major customers to significantly reduce the amount of product ordered or license fees paid, or their failure or inability to pay amounts owed to us in a timely manner, or at all, could have a significant adverse effect on our business.

***We are dependent on our core SDC technology and if our efforts to achieve or maintain market acceptance of our core SDC technology are not successful, we are unlikely to attain profitability.***

We have and are currently focusing substantially all of our time and financial resources in the development and commercialization of our core SDC technology. We believe SDC has applications in multiple industries and we expect that sales of SDC and SDC-based products will constitute a substantial portion, or all, of our revenues in future periods. Any material decrease in the overall level of sales or expected sales of, or the prices for, SDC or SDC-based products, whether as a result of competition, change in customer demand, or any other factor, would have a materially adverse effect on our business, financial condition and results of operations. We are marketing our antimicrobial silver ion technology to industrial and consumer markets. These technologies and the products that incorporate them have not yet been accepted into the marketplace, and may never be accepted. In addition, even if our products achieve market acceptance, we may not be able to maintain product sales or other forms of revenue over time if new products or technologies are introduced that are more favorably received than our products, are more cost-effective or otherwise render our products less attractive or obsolete.

***We are subject to intense competition.***

Our SDC-based products compete in highly competitive markets dominated by prominent chemical and pharmaceutical companies. Most of our competitors have been in business for a longer period of time than we have, and have a greater number of products on the market and greater financial and other resources than we do. Many of our competitors already have well established brands and distribution capabilities, and in some cases are able to leverage the sale of other products with more favorable terms for products competing with our own. We also have significantly fewer employees than virtually all of our competitors. Furthermore, recent trends in this industry are for large chemical and pharmaceutical companies to consolidate into a smaller number of very large entities, which further concentrates financial, technical and market strength and increases competitive pressure in the industry. If we directly compete with these very large entities for the same markets and/or products, their financial strength could prevent us from capturing a share of those markets. It is also possible that developments by our competitors will make our technologies or products noncompetitive or obsolete. Our ability to compete will depend upon our ability, and the ability of our distributors and other partners, to develop brand recognition and novel distribution methods, and to displace existing, established and future products in our relevant target markets. We, or our distributors and partners, may not be successful in doing so, which would have a materially adverse effect on our business, financial condition and results of operations.

***We have limited sales, marketing and product distribution experience.***

We have limited experience in the sales, marketing and distribution of our products. While we previously relied primarily on product distribution arrangements and/or sales and marketing services provided by third parties, we have now developed and obtained registration by the Environmental Protection Agency, or EPA, of our proprietary brand,

PURE® Hard Surface disinfectant and food contact surface sanitizer, and have resumed direct control of our sales of this product through a restructuring of our sales strategy and operations. Our new sales and marketing strategy requires that we enact various operational changes in our business, including making significant investments in our own sales and marketing organization. We intend to market and sell our PURE® Hard Surface and related SDC-based products into consumer, commercial and institutional markets through both traditional and alternative distribution channels. Additionally, Subway has agreed to make the Pure Hard Surface disinfectant available in its franchised locations in the U.S.; however, we cannot assure you whether any franchisees will choose to purchase and use the product.

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We have commenced the launch of a multi-channel national sales program, which involves our development of an internal team of industry sales experts to manage each of our key channels and our deployment of contract sales representatives within each of those channels. Our current sales, distribution and marketing strategies and programs may not be successful, and we may not be able to establish the sales, marketing, and distribution capabilities necessary to directly control and manage these aspects of our operations. If we are not able to successfully sell, market and distribute these products directly, we may seek to establish product distribution arrangements with third parties, which may not be available on terms acceptable to us, if at all.

***We rely on third parties to develop SDC-based products, and they may not do so successfully or diligently.***

On December 11, 2013, we entered into a five-year strategic collaboration agreement with St. Louis-based Intercon Chemical Company (ICC) where we granted ICC distribution and certain development rights and rights to be the exclusive manufacturer for all our SDC-based products.

We may also rely in part, on other third parties to whom we license rights to our technology to develop and commercialize products containing SDC for many of the applications for which we believe SDC-based products have, or may have, market opportunities.

Our reliance on ICC and other third parties for development activities reduces our control over these activities. In such arrangements, we have relied, and expect in the future to rely, on the third party to fund and direct product development activities and appropriate regulatory filings. Any of these third parties may not be able to successfully develop such SDC-based products due to, among other factors, a lack of capital, a lack of appropriate diligence, insufficient devotion to sales efforts, a change in the evaluation by the third party of the market potential for SDC-based products, technical failures, and poorer than expected results from testing or trial use of any products that may be developed. If the third parties on which we rely are not successful in such development activities, our business and operating results would be adversely affected.

***If we are unable to successfully develop or commercialize new applications of our SDC technology, or if such efforts are delayed, our operating results will suffer.***

In addition to its use on hard surfaces, we are pursuing potential applications of our SDC technology as a broad-spectrum antimicrobial for use as a direct food contact processing aid where it is applied as a wash for produce, meat and poultry as an intervention to prevent or kill various food-borne pathogens. Any product that may be developed in these fields may be delayed or may never achieve regulatory approval or be commercialized. For example, as discussed above, in November 2014, we withdrew, without prejudice, our FCN for raw poultry due to receipt of a Deficiency Letter from the FDA stating that the agency has developed new data that is currently under review, which data calls into question the long established safety levels of the dietary intake of silver in the U.S. from food contact uses previously approved by the FDA. Because the FDA is unlikely to approve any new uses of silver in food processing at this time, we believe we will likely receive a similar Deficiency Letter from the FDA for the FCN we submitted in October 2014 for the use of SDC to reduce Salmonella, E. coli and Listeria in the processing of produce. We also intend to delay the filing of our FCN for the use of SDC as a processing aid for beef and pork until we receive guidance from the FDA. Delays in achieving regulatory approvals for particular applications of our products could significantly impact our product development costs. If indications are commercialized, we may not receive a share of future revenues that provides an adequate return on our historical or future investment.

***We are dependent on third-party manufacturers, over whom we have limited control, to manufacture our products.***

We do not have any manufacturing facilities ourselves and we currently rely on ICC to manufacture our SDC-based products and may in the future rely on one or more third-party manufacturers to properly manufacture our products. We may not be able to quickly replace our manufacturing capacity if ICC is unable to manufacture our products as a result of a fire, natural disaster (including an earthquake), equipment failure or other difficulty, or if such ICC facilities are deemed not in compliance with current good manufacturing practices, and the noncompliance could not be rapidly rectified. ICC is our single manufacturer for our SDC-based products and may not be replaced without significant effort and delay in production. A supply interruption or an increase in demand beyond our current manufacturer's capabilities could harm our ability to manufacture such products until new manufacturers are identified and qualified, which would have a significant adverse effect on our business and results. Any third-party manufacturer that we find may not match our quality standards or be able to meet customer requirements.

Additionally, our inability or reduced capacity to have our products manufactured would prevent us from successfully evaluating or commercializing our proposed products. Our dependence upon third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop and deliver proposed products on a timely and competitive basis.

***If we are not able to manage any growth we achieve effectively, we may not become profitable.***

If our efforts to achieve and maintain market acceptance of our SDC technology are successful, we will need to expand our business operations. We may not have sufficient resources to do so. If we invest in additional infrastructure, we may not be effective in expanding our operations and our systems, procedures or controls may not be adequate to support any such expansion. In addition, we would need to provide additional sales and support services to our partners, potentially in multiple markets, which we may not be able to do. Failure to properly manage increased customer demands, if any, could result in a material adverse effect on customer satisfaction, our ability to meet our contractual obligations, and our operating results.



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*We are subject to substantial regulation related to quality standards applicable to our manufacturing and quality processes, and our partners, including our third-party manufacture, failure to comply with applicable quality standards could affect our ability to commercialize SDC products.*

The EPA and other applicable U.S. and foreign government agencies regulate our and our partners' systems and processes, including those of ICC, for manufacturing SDC-based products. These regulations require that we and our partners observe good manufacturing practices in order to ensure product quality, safety and effectiveness. Failure by us or our partners to comply with current or future government regulations and quality assurance guidelines could lead to temporary manufacturing shutdowns, product recalls or related field actions, product shortages, and/or delays in product manufacturing, any or all of which could cause significant cost to us. Further, efficacy or safety concerns and/or manufacturing quality issues with respect to our products or those of our partners could lead to product recalls, fines, withdrawal of approvals, and/or declining sales, any or all of which could result in our failure to successfully commercialize SDC or otherwise achieve revenue growth.

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***Pricing and supply issues may have a material impact on our margins and our ability to supply our customers.***

All of the supply ingredients used to manufacture our products are available from multiple suppliers. However, commodity prices for some ingredients can vary significantly and the margins that we are able to generate could decline if prices rise. For example, both silver and citric acid prices have been volatile in recent periods.

In addition to such commodities, for finished products we also rely on producers of specialized packaging inputs such as bottles and labels. Due to their specialized nature, the supply of such inputs can be periodically constrained and result in additional costs to obtain these items, which may in turn inhibit our ability to supply products to our customers.

We are generally unable to raise our product prices to our customers, partners and distributors quickly to maintain our margins, and significant price increases for key inputs could therefore have an adverse effect on our results of operations. Price increases can also result in lost sales, and any inability to supply our customers' orders can lead to lost future sales to such customers.

While we expect to be the sole source supplier of SDC concentrate, in future periods we may use third parties to blend, package and provide fulfillment activities for our finished products. We expect that our margins would be reduced by using such third parties, and our ability to maintain product quality may not be as extensive or effective as when we produce these products in our own facility(ies). Any quality control issues could lead to product recalls and/or the loss of future sales, which would reduce our revenues and/or profits.

***If we suffer negative publicity concerning the safety or efficacy of our products, our sales may be harmed.***

If concerns should arise about the safety or efficacy of any of our products that are marketed, regardless of whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research, such concerns could adversely affect the market for those products. Similarly, negative publicity could result in an increased number of product liability claims, whether or not those claims are supported by applicable law.

***Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.***

Our manufacture, use and sale of SDC-based products may subject us to lawsuits relating to the validity and infringement of patents or other proprietary rights of third parties. Litigation may be costly and time-consuming, and could divert the attention of our management and technical personnel. If we are found to have violated the trademark, trade secret, copyright, patent or other intellectual property or proprietary rights of others, such a finding could result in the need to cease use of a trademark, trade secret, copyrighted work or patented invention in our business and our obligation to pay a substantial amount for past infringement. If the rights holders are willing to permit us to continue to use their intellectual property rights, it may be necessary for us to enter into license arrangements with unfavorable terms and pay substantial amounts in royalty and other license fees. Either having to cease use or pay such fees could prevent us, or our third-party manufacture, from manufacturing and selling our products, which could make us much less competitive in our industry and have a material adverse impact on our business, operating results and financial condition.

***We may become subject to product liability claims.***

As a business that manufactures and markets products for use by consumers and institutions, we may become liable for any damage caused by our products, whether used in the manner intended or not. Regardless of merit or potential

outcome, product liability claims against us may result in, among other effects, the inability to commercialize our products, impairment of our business reputation, and distraction of management's attention from our primary business. If we cannot successfully defend ourselves against product liability claims we could incur substantial liabilities. Although we maintain general and product liability insurance, our insurance may not cover potential claims and may not be adequate to indemnify for liabilities that may be imposed. Any imposition of liability that is not covered by insurance or is in excess of insurance coverage could harm our business and operating results.

***Litigation or the actions of regulatory authorities may harm our business or otherwise distract our management.***

Substantial, complex or extended litigation could cause us to incur major expenditures and would distract our management. For example, lawsuits against us or our officers or directors by employees, former employees, stockholders, partners, customers, or others, or actions taken by regulatory authorities, could be very costly and substantially disrupt our business. Such lawsuits and actions are not uncommon, and we may not be able to resolve such disputes or actions on terms favorable to us, and there may not be sufficient capital resources available to defend such actions effectively, or at all.

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***Maintaining compliance with our obligations as a public company may strain our resources and distract management, and if we do not remain compliant our stock price may be adversely affected.***

Our common stock is registered under the Exchange Act. It is therefore subject to the information, proxy solicitation, insider trading and other restrictions and requirements of the SEC under the Exchange Act. Both the U.S. Congress and the SEC continue to issue new and proposed rules, and complying with existing and new rules has caused, and will continue to cause, us to devote significant financial and other resources to maintain our status as a public company. These regulatory costs and requirements will continue to increase our losses in future periods, and we expect that an increasing amount of management time and effort will be needed to meet our regulatory obligations. In addition, in April 2008 we obtained a listing of our common stock on The NASDAQ Capital Market, adding the additional cost and administrative burden of maintaining such a listing. Such costs significantly increased during the period between September 2011 and September 2012 due to a series of notices and a lengthy appeal process in connection with the potential delisting of our common stock from The NASDAQ Capital Market. However, NASDAQ delisted us and suspended trading in our securities effective with the open of business on Friday, May 17, 2013 as a result of our determination that we would be unable to evidence compliance with the \$2.5 million stockholders' equity requirement for continued listing on The NASDAQ Capital Market by June 18, 2013. On May 17, 2013 our common stock began trading on the OTCQB marketplace.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate our internal control systems and that management report on and attest to the adequacy of our internal controls. Recent SEC pronouncements suggest that in the next several years we may be required to report our financial results using new International Financial Reporting Standards, replacing GAAP, which would require us to make significant investments in training, hiring, consulting and information technology, among other investments. All of these and other reporting requirements and heightened corporate governance obligations that we face, or may face in the future, will further increase the cost to us, perhaps substantially, of remaining compliant with our obligations under the Exchange Act and other applicable laws, including the Sarbanes-Oxley Act and the Dodd-Frank Act of 2010. In order to meet these incremental obligations, we will need to invest in our corporate and accounting infrastructure and systems, and acquire additional services from third party auditors and advisors. As a result of these requirements and investments, we may incur significant additional expenses and may suffer a significant diversion of management's time. There is no guarantee that we will be able to continue to meet these obligations in a timely manner. If we fail to do so, we could be subject to sanctions or investigation by regulatory authorities such as the SEC. Any such actions could adversely affect the market price of our common stock, perhaps significantly.

***Our publicly filed reports are reviewed from time to time by the SEC, and any significant changes or amendments required as a result of any such review may result in material liability to us and may have a material adverse impact on the trading price of our common stock.***

The reports and other securities filings of publicly traded companies are subject to review by the SEC from time to time for the purpose of assisting companies in complying with applicable disclosure requirements. The SEC is required, pursuant to the Sarbanes-Oxley Act of 2002, to undertake a comprehensive review of a company's reports at least once every three years, although an SEC review may be initiated at any time. While we believe that our previously filed SEC reports comply, and we intend that all future reports will comply, in all material respects with the published rules and regulations of the SEC, we could be required to modify, amend or reformulate information contained in our filings as a result of any SEC review. Any modification, amendment or reformulation of information contained in such reports could be significant and result in material liability to us and have a material adverse impact on the trading price of our common stock.

***If we are unable to build and integrate our new management team, our business could be harmed.***

As previously announced on our Form 8-K filed with the SEC on August 20, 2013 and as described elsewhere in this Quarterly Report, on August 13, 2013, Michael L. Krall, Donna Singer, and Dennis Atchley resigned all positions respectively held by them as officers of the Company and as members of the Board. Mr. Krall previously served as our Chief Executive Officer and interim Chief Financial Officer and on the Board. Ms. Singer served as our Executive Vice President and as a member of the Board and Mr. Atchley served as Corporate Secretary. Simultaneously with the resignations, Dave J. Pfanzelter was appointed by the Board to serve as Interim Chief Executive Officer and Chairman of the Board, Peter C. Wulff was appointed by the Board to serve as Chief Financial Officer, Chief Operating Officer, and Corporate Secretary and Gary D. Cohee was appointed by the Board to serve as a member of the Board.

On September 10, 2013, the Board appointed Henry R. Lambert to serve as Chief Executive Officer and a member of the Board. In connection with the hiring of Henry R. Lambert to serve as our Chief Executive Officer, Dave J. Pfanzelter resigned his position as our Interim Chief Executive Officer, but continues to serve as a member of the Board.

In October 2013, we appointed three additional members to the Board: Dr. David Theno, Jr., Craig Culver and William Otis.

On April 9, 2014, Mr. Culver resigned from our Board. There were no disagreements between Mr. Culver and the Company relative to his resignation.

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On October 24, 2014, we appointed Tom Y. Lee, CPA, to the Board.

Our success depends largely on the development and execution of our business strategy by our Board and management team. Management will be evaluating how to best execute our near-term strategy to drive customer adoption in the food industry by addressing food safety solutions across the supply chain in order to prevent or mitigate food contamination or the potential for food-borne illness with specific customer focus in foodservice providers, food processors and food manufacturers. However, we cannot assure you that management will succeed in driving customer adoption in the food industry or generally execute on our business strategy in the near-term or at all, which could harm our business and financial prospects. Further, integrating new management into existing operations may be challenging. If we are unable to effectively integrate our new management, our operations and prospects could be harmed.

***We depend on key personnel for our continued operations and future success, and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.***

Our success depends largely upon the continued services of our executive officers and other key personnel. Our executive officers and key personnel could terminate their employment with us at any time without notice and without penalty.

We do not maintain key person life insurance policies on our executive officers or other employees. The loss of one or more of our executive officers or key employees could seriously harm our business, results of operations, financial condition, and/or the market price of our common stock. We cannot assure you that in such an event we would be able to recruit qualified personnel able to replace these individuals in a timely manner, or at all, on terms acceptable to either us or to any qualified candidate.

***Because competition for highly qualified business development and bioengineering personnel is intense, we may not be able to attract and retain the employees we need to support our potential growth.***

To successfully meet our objectives, we must attract and retain highly qualified business development and bioengineering personnel with specialized skill sets focused on the industries in which we compete, or intend to compete. Competition for qualified business development and bioengineering personnel can be intense. Our ability to meet our business development objectives will depend in part on our ability to recruit, train and retain top quality people with advanced skills who understand our technology and business. In addition, it takes time for our new personnel to become productive and to learn our business. If we are unable to hire or retain qualified business development and bioengineering personnel, it will be difficult for us to sell our products or to license our technology or to achieve or maintain regulatory approvals, and we may experience a shortfall in revenue and not achieve our anticipated, or any, growth.

***We have recently had significant changes to the composition of our Board of Directors.***

On August 13, 2013, Michael L. Krall, Donna Singer, and Dennis Brovarone resigned as members of the Board. Subsequently on September 10, 2013, the Board appointed Henry R. Lambert to serve as Chief Executive Officer and a member of the Board. In October 2013, the Board appointed three additional members to the Board: Dr. David Theno, Craig Culver and Bill Otis. On April 9, 2014, Mr. Culver resigned from our Board. On October 24, 2014, we appointed Tom Y. Lee, CPA, to the Board. Following such resignations and appointments, the Board consists of six directors, three of whom are independent within the meaning of the applicable listing standards of the NYSE MKT.

The transition in the composition of our Board and its committees may result in inefficiencies in Board activity, disagreements regarding our business models or other operational strategies, and disruptions to our business, which may have an adverse effect on our business strategy and results of operations.

***We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.***

From time to time we may consider engaging in strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including, among others, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies, difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel, and inability to retain key employees of any acquired businesses. Accordingly, although we may not choose to undertake or may not be able to successfully complete any transactions of the nature described above, any transactions that we do undertake or complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

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***We may invest or spend our cash in ways with which you may not agree or in ways which may not yield a significant return.***

Our management has considerable discretion in the use of our cash. Our cash may be used for purposes that do not increase our operating results or market value. Until the cash is used, it may be placed in investments that do not produce significant income or that may lose value. The failure of our management to invest or spend our cash effectively could result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

***We may not be able to utilize all, or any, of our tax net operating loss carry-forwards and our future after-tax earnings, if any, could be reduced.***

At July 31, 2014, we had federal and California tax net operating loss carry-forwards of approximately \$83.6 million and \$71.8 million, respectively. Utilization of these net operating loss carry-forwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred, including with respect to our recent private placements, or that could occur in the future, as required by Section 382 of the Internal Revenue Code as well as similar state provisions. These ownership changes may limit the amount of net operating loss carry-forwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 of the Internal Revenue Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Since our formation, we have raised capital through the issuance of capital stock on several occasions (both before and after our initial public offering in 1996) which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future based upon subsequent disposition. While we believe that we have not experienced an ownership change, the pertinent tax rules related thereto are complex and subject to varying interpretations, and thus the applicable taxing authorities may take an alternative position.

Our current federal tax loss carry-forwards began expiring in the year ended July 31, 2011 and, unless previously utilized, will completely expire in the year ending July 31, 2034. The balance of our current federal net operating loss carry-forwards will expire between July 31, 2019 and July 31, 2034. Our California tax loss carry-forwards will begin to expire in the year ending July 31, 2015, and will completely expire in the year ending July 31, 2034. If we are unable to earn sufficient profits to utilize the carry-forwards by these dates, they will no longer be available to offset future profits, if any.

***We are subject to tax audits by various tax authorities in multiple jurisdictions.***

From time to time we may be audited by tax authorities to whom we are subject. Any assessment resulting from such audits, if any, could result in material changes to our past or future taxable income, tax payable or deferred tax assets, and could require us to pay penalties and interest that could materially adversely affect our financial results.

## **Risks Related to Our Intellectual Property**

***If we are unable to obtain, maintain or defend the patent and other intellectual property rights relating to our technology, we or our collaborators and distributors may not be able to develop and market proprietary products based on our technology, which would have a material adverse impact on our results of operations.***

We rely and expect in the future to continue to rely on a combination of patent, trademark, trade secret and copyright protections, as well as contractual restrictions, to protect the proprietary aspects of our technology and business.



Legal protections of our intellectual property and proprietary rights afford only limited protection. For instance, we currently own twelve U.S. patents related to our SDC technology. The lives of these patents, and any patents that we may obtain in the future, are not indefinite, and the value to us of some or all of our patents may be limited by their terms. Further, although we have a number of U.S. and international patent applications pending, some or all of those applications may not result in issued patents, and the intellectual property claims therein would be unprotected. Additionally, obtaining and maintaining patent protection depends on our compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Furthermore, the patent positions of bioscience companies can be highly uncertain and often involve complex legal, scientific and factual questions, and, therefore, we cannot predict with certainty whether we will be able to ultimately enforce our patents or other intellectual property rights. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents.

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From time to time, U.S. and other policymakers have proposed reforming the patent laws and regulations of their countries. In September 2011, after years of Congressional debate regarding patent reform legislation, President Obama signed into law the America Invents Act (the Act) considered by many to be the most substantial revision of U.S. patent law since 1952. The Act's various provisions will go into effect over an 18-month period. The Act changes the current first-to-invent system to a system that awards a patent to the first-inventor-to-file for an application for a patentable invention. This change alters the pool of available materials that can be used to challenge patents and eliminates the ability to rely on prior research work in order to lay claim to patent rights. Disputes as to whether the first filer is in fact the true inventor will be resolved through newly implemented derivation proceedings. The Act also creates mechanisms to allow challenges to newly issued patents in the patent office in post-grant proceedings and new inter partes reexamination proceedings. Although many of the changes bring U.S. law into closer harmony with European and other national patent laws, the new bases and procedures may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our product sales, business and results of operations. The changes may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention.

In addition, to the extent that we operate internationally, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the U.S. As stated above, many countries have a first-to-file trademark registration system, which may prevent us from registering or using our trademarks in certain countries if third parties have previously filed applications to register or have registered the same or similar trademarks. Additionally, changes in the patent and/or trademark laws or interpretations of such laws in the U.S. or other countries could diminish the value of our intellectual property rights. Moreover, our competitors may develop competing technologies that are not covered by the claims of, and therefore do not infringe upon, our issued patents, which could render our patents less valuable to us. If certain of our proprietary rights cannot be, or are not sufficiently, protected by patent and trademark registrations, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products.

Our own efforts to protect our intellectual property and other proprietary rights may also be insufficient. Despite efforts to protect our proprietary rights, including without limitation through confidentiality and other similar contractual restrictions, our means of protecting such rights may not be adequate and unauthorized parties may attempt to copy aspects of our proprietary technology, obtain and use information that we regard as proprietary, or otherwise misappropriate our intellectual property. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. It is possible that, despite our efforts, competitors or others will create and use products, adopt service names similar to our service names or otherwise violate or misappropriate our proprietary rights. The infringement of such rights could have a material negative impact on our business and on our results of operations.

Litigation may be necessary to enforce our intellectual property and other proprietary rights, which would be expensive and could consume time and other resources. The result of any such litigation may be the court's ruling that our patents or other intellectual property rights are invalid and/or should not be enforced. Additionally, even if the validity of such rights is upheld, the court could refuse to stop a third party's infringing activity on the ground that such activities do not infringe our rights. The U.S. Supreme Court has recently revised certain tests regarding granting patents and assessing the validity of patents to make it more difficult to obtain patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a reexamination proceeding, or during litigation, under the revised criteria.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.***

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO, to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.***

We may rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

As is common in the biotechnology, food, chemical and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology, food, chemical or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

## **Risks Related to our Common Stock**

***We failed to meet applicable NASDAQ Stock Market requirements and as a result we delisted our stock from The NASDAQ Capital Market, which could adversely affect the market liquidity of our common stock and harm our business.***

On May 15, 2013, we received a letter indicating that the NASDAQ Listing Qualifications Panel (the Panel ) determined to delist our common stock from The NASDAQ Stock Market LLC. Trading in our securities on NASDAQ was suspended effective with the open of business on Friday, May 17, 2013. The suspension was the result of our determination that we would be unable to evidence compliance with the \$2.5 million stockholders' equity requirement for continued listing on The NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5550(b), by June 18, 2013, as required by the Panel's decision in this matter. On May 17, 2013, our common stock began trading on the OTC Markets' OTCQB marketplace under the ticker symbol PURE . We continue to file periodic reports with the Securities and Exchange Commission in accordance with the requirements of Section 12(g) of the Securities Exchange Act of 1934, as amended.

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Our delisting from The NASDAQ Capital Market and commencement of trading on the OTCQB Marketplace has resulted and may continue to result in a reduction in some or all of the following, each of which could have a material adverse effect on our stockholders:

the liquidity of our common stock;

the market price of shares of our common stock;

our ability to obtain financing for the continuation of our operations;

the number of institutional and other investors that will consider investing in shares of our common stock;

the number of market makers in shares of our common stock;

the availability of information concerning the trading prices and volume of shares of our common stock; and

the number of broker-dealers willing to execute trades in shares of our common stock.

***Following the delisting of our common stock from The NASDAQ Capital Market, our common stock is deemed to be penny stock, which may make it more difficult for investors to sell their shares due to suitability requirements.***

As a result of the delisting of our common stock from the NASDAQ, shares of our common stock are subject to the so-called penny stock rules as that term is defined in Rule 3a51-1 promulgated under the Securities Exchange Act of 1934. These requirements may reduce the potential market for our common stock by reducing the number of potential investors. This may make it more difficult for investors in our common stock to sell shares to third parties or to otherwise dispose of them. This could cause our stock price to decline.

Broker-dealers dealing in penny stocks are required to provide potential investors with a document disclosing the risks of penny stock. Moreover, broker-dealers are required to determine whether an investment in a penny stock is a suitable investment for a prospective investor. Such requirements may discourage broker-dealers from effecting transactions in our common stock, which could limit the market price and liquidity of our common stock.

***The price of our common stock may be volatile, which may cause investment losses for our stockholders.***

The price and trading volume of our common stock have historically been volatile. For example, in the twelve months through October 31, 2014, the closing market price of our common stock ranged from \$0.98 per share to \$1.49 per share, and the monthly trading volume varied from approximately 573,000 shares to 2,194,000 shares. The market price of our common stock may continue to be volatile and could fluctuate substantially due to many factors, including, among others, the following:

actual or anticipated fluctuations in our results of operations;

the determination that our shares of common stock are penny stock which will require brokers trading in our shares of common stock to adhere to more stringent rules, likely resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;

the sale by us of our common or preferred stock or other securities, or the anticipation of sales of such securities;

the trading volume of our common stock, particularly if such volume is light;

the trading market of our common stock;

the introduction of new products or services, or product or service enhancements by us or our competitors;

developments with respect to our or our competitors' intellectual property rights or regulatory approvals or denials;

announcements of significant acquisitions or other agreements by us or our competitors;

sales or anticipated sales of our common stock by our insiders (management and directors);

conditions and trends in our industry;

changes in our pricing policies or the pricing policies of our competitors;

changes in the estimation of the future size and growth of our markets; and

general economic conditions.

In addition, the stock market in general, the OTCQB, and the market for shares of novel technology and biotechnology companies in particular, have experienced extreme price and volume fluctuations that in some cases may be unrelated or disproportionate to the operating performance of those companies. Further, the market prices of bioscience companies' stock have been unusually volatile in recent periods, and such volatility may continue for the foreseeable future. These broad market and industry factors may materially harm the market price of our common stock, regardless of our operating performance. In addition, this volatility could adversely affect an investor's ability to sell shares of our common stock, and/or the available price for such shares, at any given time.



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Following periods of volatility in the market price of a company's securities, stockholder derivative lawsuits and securities class action litigation are common. Such litigation, if instituted against us or our officers and directors, could result in substantial costs and a diversion of management's attention and resources.

***Potential future sales or issuances of our common stock to raise capital, or the perception that such sales could occur, could cause dilution to our current stockholders and the price of our common stock to fall.***

Although we are pursuing various sources of potential funding, we have historically supported our operations through the issuance of equity and expect to continue to do so in the future. Although we may not be successful in obtaining financing through equity sales on terms that are favorable to us, if at all, any such sales that do occur could result in substantial dilution to the interests of existing holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock or other equity securities to any new investors, or the anticipation of such sales, could cause the trading price of our common stock to fall.

***We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.***

The continued operation and expansion of our business will require substantial funding. Investors seeking cash dividends in the foreseeable future should not purchase our common stock. We have paid no cash dividends on any of our capital stock to date and we currently intend to retain our available cash to fund the development and growth of our business. Any determination to pay dividends in the future will be at the discretion of our Board and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board deems relevant. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

***Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control and could also limit the market price of our stock.***

Certain provisions of our charter and bylaws may delay or frustrate the removal of incumbent directors and may prevent or delay a merger, tender offer, or proxy contest involving us that is not approved by our Board, even if such events may be beneficial to the interests of stockholders. For example, our Board, without stockholder approval, has the authority and power to authorize the issuance of up to 5,000,000 shares of preferred stock and such preferred stock could have voting or conversion rights that could adversely affect the voting power of the holders of our common stock. Further, the one-for-eight reverse stock split of our outstanding common stock that we effected on August 14, 2012 has increased the proportion of unissued and authorized common shares to issued and outstanding common shares, which could allow our Board to issue large numbers of additional shares of our common stock that could significantly reduce the voting power of our current stockholders. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our charter documents may make it more difficult for stockholders or potential acquirers to initiate actions that are opposed by our then-current board of directors, including delaying or impeding a merger, tender offer, or proxy contest or other change of control transaction involving the Company. Any delay or prevention of a change of control transaction could cause stockholders to lose a substantial premium over the then-current market price of their shares.

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

None

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

None.

**Item 5. Other Information**

None.

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**Item 6. Exhibits**

The following Exhibits are filed as part of this report pursuant to Item 601 of Regulation S-K:

- 3.1 Certificate of Incorporation of Pure Bioscience, Inc. (incorporated by reference to Exhibit 3.1 of the Annual Report on Form 10-K filed with the SEC on October 29, 2012)
- 3.1.1 Certificate of Amendment to Certificate of Incorporation of Pure Bioscience, Inc. (incorporated by reference to Exhibit 3.1.1 of the Annual Report on Form 10-K filed with the SEC on October 29, 2012)
- 3.2 Bylaws of Pure Bioscience, Inc. (incorporated by reference to Exhibit 3.2 to the Annual Report on Form 10-K, filed with the SEC on October 29, 2012)
- 3.2.1 Amendment to the Bylaws of Pure Bioscience, Inc. (incorporated by reference to Exhibit 3.2.1 to the Annual Report on Form 10-K, filed with the SEC on October 29, 2012)
- 4.1 Form of Investor Warrant (incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K, filed with the SEC on September 2, 2009)
- 4.2 Wharton Capital Markets LLC Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC on March 16, 2012)
- 4.3 Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC on September 13, 2012)
- 4.4 Morrison & Foerster LLP Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC on January 31, 2013)
- 4.5 Form of Investor Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC April 23, 2013)
- 4.6 Form of Investor Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC August 27, 2014)
- 10.1 Securities Purchase Agreement, dated August 22, 2014 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on August 27, 2014)
- 10.2 Registration Rights Agreement, dated August 22, 2014 (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on August 27, 2014)
- 10.3 Amendment to Services Agreement, dated October 2, 2014, between Pure Bioscience, Inc. and Pillar Marketing Group, Inc. (incorporated by reference to Exhibit 10.48 of the Registration Statement on Form S-1 filed with the SEC on October 10, 2014)
- 31.1 \* Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 \* Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 \* Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 \* Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101 \* The following materials from the Company's Quarterly Report on Form 10-Q for the quarterly period ended October 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets at October 31, 2014 and July 31, 2014; (ii) Consolidated Statements of Operations for the three months ended October 31, 2014 and 2013; (iii) Consolidated Statements of Cash Flows for the three

months ended October 31, 2014 and 2013; and (iv) Notes to Consolidated Financial Statements.

\* Filed herewith.

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**Signatures**

Pursuant to the requirement 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.

**PURE BIOSCIENCE, INC.**

Date: December 11, 2014

By: /s/ HENRY R. LAMBERT  
Henry R. Lambert, Chief Executive Officer  
(Principal Executive Officer)

Date: December 11, 2014

By: /s/ PETER C. WULFF  
Peter C. Wulff, Chief Financial Officer / Chief  
Operating Officer  
(Principal Financial and Accounting Officer)