PURE BIOSCIENCE, INC. Form 10-Q June 09, 2016

## **UNITED STATES**

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

# [X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

## FOR THE QUARTERLY PERIOD ENDED APRIL 30, 2016

## [ ] 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	33-0530289
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)

1725 Gillespie Way

92020

El Cajon, California (Address of principal executive offices) (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 [X] 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 [X] 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 [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [] No [X]

As of June 9, 2016, there were 64,646,645 shares of the registrant's common stock, \$0.01 par value per share, outstanding.

## **PURE Bioscience, Inc.**

Form 10-Q

for the Quarterly Period Ended April 30, 2016

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#### **PART I – Financial Information**

#### **Item 1. Financial Statements**

## **PURE Bioscience, Inc.**

#### **Condensed Consolidated Balance Sheets**

	April 30, 2016 (Unaudited)	July 31, 2015
Assets		
Current assets		
Cash and cash equivalents	\$5,405,000	\$1,321,000
Accounts receivable	68,000	189,000
Inventories, net	320,000	207,000
Restricted cash	75,000	75,000
Prepaid expenses	312,000	187,000
Total current assets	6,180,000	1,979,000
Property, plant and equipment, net	407,000	90,000
Patents, net	1,021,000	1,192,000
Total assets	\$7,608,000	\$3,261,000
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	\$522,000	\$560,000
Restructuring liability	44,000	59,000
Accrued liabilities	174,000	246,000
Derivative liability	9,802,000	4,000
Total current liabilities	10,542,000	869,000
Deferred rent	5,000	9,000
Total liabilities	10,547,000	878,000
Commitments and contingencies (See Note 6)		
Stockholders' equity (deficit)		
Preferred stock, \$0.01 par value: 5,000,000 shares authorized, no shares issued and outstanding	_	_
Common stock, \$0.01 par value: 100,000,000 shares authorized, 62,161,956 shares		
issued and outstanding at April 30, 2016, and 41,859,297 shares issued and outstanding at July 31, 2015	622,000	420,000

Additional paid-in capital	98,979,000	90,811,000
Accumulated deficit	(102,540,000)	(88,848,000)
Total stockholders' equity (deficit)	(2,939,000)	2,383,000
Total liabilities and stockholders' equity (deficit)	\$7,608,000	\$3,261,000

See accompanying notes.

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## **PURE Bioscience, Inc.**

## **Condensed Consolidated Statements of Operations**

## (Unaudited)

	Nine Months I April 30,		Three Months April 30,	
Not may have also	2016	2015 ¢ 400.000	2016	2015
Net product sales	\$765,000	\$499,000	\$403,000	\$109,000
Operating costs and expenses				
Cost of goods sold	218,000	221,000	116,000	65,000
Selling, general and administrative	3,857,000	3,731,000	1,385,000	1,207,000
Research and development	679,000	562,000	205,000	171,000
Share-based compensation	1,621,000	1,751,000	186,000	766,000
Total operating costs and expenses	6,375,000	6,265,000	1,892,000	2,209,000
Loss from operations	(5,610,000)	) (5,766,000)	(1,489,000)	(2,100,000)
Other income (expense)				
Fair value of derivative liabilities in excess of proceeds	(1,867,000)	) —		
Change in derivative liability	(6,241,000)	5,000	1,506,000	1,000
Interest expense, net	(8,000)	) (7,000 )	) (3,000 )	(2,000)
Other income (expense), net	34,000	7,000	16,000	10,000
Total other income (expense)	(8,082,000)	5,000	1,519,000	9,000
Net income (loss)	\$(13,692,000)	\$(5,761,000)	\$30,000	\$(2,091,000)
Net income (loss) per common share-basic	\$(0.25)	) \$(0.15)	\$0.00	\$(0.05)
Net income (loss) per common share-diluted	\$(0.25)	) \$(0.15)	\$(0.02)	\$(0.05)
Weighted average shares-basic	54,329,594	39,221,585	61,445,913	40,836,625
Weighted average shares-diluted	54,329,594	39,221,585	71,308,771	40,836,625

See accompanying notes.

## **PURE Bioscience, Inc.**

## **Condensed Consolidated Statements of Cash Flows**

## (Unaudited)

	Nine Months Ended April 30,	
	2016	2015
Operating activities		
Net loss	\$(13,692,000)	\$(5,761,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,621,000	1,751,000
Amortization of stock issued for services	163,000	66,000
Fair value of derivative liabilities in excess of proceeds	1,867,000	
Depreciation and amortization	154,000	154,000
Impairment of patents	48,000	
Change in fair value of derivative liability	6,241,000	(5,000)
Changes in operating assets and liabilities:		
Accounts receivable	121,000	(39,000)
Inventories	(113,000)	42,000
Prepaid expenses		(4,000)
Accounts payable and accrued liabilities	(125,000)	(1,061,000)
Deferred rent	(4,000)	(3,000)
Net cash used in operating activities	(3,719,000)	(4,860,000)
Investing activities		
Investment in patents	(11,000)	(16,000)
Purchases of property, plant and equipment	(337,000)	(81,000)
Net cash used in investing activities	(348,000)	(97,000)
Financing activities		
Net proceeds from the sale of common stock	8,000,000	7,401,000
Net proceeds from the exercise of warrants	151,000	
Net cash provided by financing activities	8,151,000	7,401,000
Net increase in cash and cash equivalents	4,084,000	2,444,000
Cash and cash equivalents at beginning of period	1,321,000	86,000
Cash and cash equivalents at end of period	\$5,405,000	\$2,530,000
Supplemental disclosure of cash flow information		
Cash paid for taxes	\$2,000	\$1,600
Warrant liability removed due to settlements	\$6,310,000	\$—
Common stock issued for prepaid services	\$288,000	\$—

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 and nine months ended April 30, 2016 are not necessarily indicative of the results that may be expected for other quarters or the year ending July 31, 2016. The July 31, 2015 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, 2015 included in our Annual Report on Form 10-K covering such period filed with the Securities and Exchange Commission, or SEC, on October 28, 2015.

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 financing, and revenue from product sales and license agreements. We have a history of recurring losses, and as of April 30, 2016, we have incurred a cumulative net loss of \$102,540,000.

As of April 30, 2016, we had \$5,405,000 in cash and cash equivalents, and \$522,000 of accounts payable. As of April 30, 2016, we have 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.

We believe our available cash on-hand, 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. Income (Loss) Per Common Share

Basic earnings (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income attributable to common stockholders by the sum of the weighted-average number of common shares outstanding during the period and the weighted-average number of dilutive common share equivalents outstanding during the period, using the treasury stock method. Dilutive common share equivalents are comprised of in-the-money stock options, warrants and restricted stock units, based on the average stock price for each period using the treasury stock method. For the three months ended April 30, 2016 and 2015, the incremental dilutive common share sisuable 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 18,946,821 and 9,298,956, respectively.

#### 4. Comprehensive Income (Loss)

Comprehensive income or 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 and nine months ended April 30, 2016 and 2015, our comprehensive income (loss) consisted only of net income (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:

	April 30,	July 31,
	2016	2015
Raw materials	\$149,000	\$96,000
Finished goods	171,000	111,000
	\$320,000	\$207,000

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## 6. Commitments and Contingencies

#### Severance Agreement

On August 13, 2013, the Company entered into a Severance and Release Agreement with Dennis Brovarone, a former Board member. 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 \$44,000 remains payable under the agreement and is included in the accrued restructuring liability section of the condensed consolidated balance sheet as of April 30, 2016.

## 7. 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 and nine months ended April 30, 2016 we incurred \$48,000 of expense relating to the impairment of long-lived assets. No impairment expense was recorded during the three and nine months ended April 30, 2015.

#### 8. Fair Value of Financial Instruments

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 October and November 2015 Private Placements and a prior Bridge Loan, we issued warrants with derivative features. These instruments are accounted for as derivative liabilities (See Note 9).

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. Various factors are considered in the pricing models we use to value the warrants, including the Company's current stock price, the remaining life of the warrants, the volatility of the Company's stock price, and the risk free interest rate. Future changes in these factors will have a significant impact on the computed fair value of the warrant liability. As such, we expect future changes in the fair value of the warrants to vary significantly from quarter to quarter.

The following table provides a reconciliation of the beginning and ending balances of the derivative liabilities for the nine months ended April 30, 2016:

	Warrant
	Liability
Balance at July 31, 2015	\$4,000
Issuances	9,867,000
Settlement of warrant liability	(6,310,000)
Adjustments to estimated fair value	6,241,000
Balance at April 30, 2016	\$9,802,000

## 9. Derivative Liability

On October 23, 2015 (the "October Closing Date"), we completed a first closing of a private placement financing (the "Private Placement Financing"), where we issued an aggregate of 13,333,333 shares of our common stock (the "Common Stock"), a warrant to purchase up to an aggregate of 6,666,666 shares of common stock with a term of five years and a warrant to purchase up to an aggregate of 8,666,666 shares of common stock with a term of six months (See Note 10).

On November 23, 2015, we completed a second closing of the Private Placement Financing, where we issued 4,444,439 shares of Common Stock, warrants to purchase up to an aggregate of 2,222,217 shares of common stock with a term of five years and a warrant to purchase up to an aggregate of 2,820,670 shares of common stock with a term of six months (See Note 10).

We accounted for the combined 20,376,219 warrants issued in connection with the Private Placement Financing 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.

The estimated fair value of the five year warrants issued on the October Closing Date, as of the October Closing Date, and at April 30, 2016, was \$4,034,000 and \$6,083,000, respectively. The following assumptions were used as inputs to the Monte Carlo option pricing model at April 30, 2016 for the five year warrants: stock price of \$1.12 and a warrant exercise price of \$0.45; our historical stock price volatility of 90%; risk free interest rate on U.S. treasury notes of 1.2%; and warrant expiration of 4.5 years.

The six month warrants issued on the October Closing Date expired unexercised on April 23, 2016. The estimated fair value of the six month warrants issued on the October Closing Date, as of the October Closing Date, and at April 23, 2016, was \$2,974,000 and \$6,067,000, respectively. The fair value on expiration was returned to additional paid in capital and is reflected in the Settlement of warrant liability section on the table above.

The estimated fair value of the derivative warrants issued on the November Closing Date, as of the November Closing Date, and at April 30, 2016, was \$2,859,000 and \$3,710,000, respectively. The following assumptions were used as inputs to the Monte Carlo option pricing model at April 30, 2016: for the five year warrant, stock price of \$1.12 and a warrant exercise price of \$0.45; our historical stock price volatility of 90%; risk free interest rate on U.S. treasury notes of 1.2%; warrant expiration of 4.6 years; for the six month warrant, stock price of \$1.12 and a warrant exercise price of \$0.45; our historical stock price volatility of 90%; risk free interest rate on U.S. treasury notes of 0.2%; warrant expiration of 0.1 years.

During the three months ended April 30, 2016, 335,981 of the six month warrants issued on the November Closing Date were exercised. The fair value on exercise of \$243,000 was returned to additional paid in capital and is reflected in the Settlement of warrant liability section on the table above.

Given that the fair value of the derivative warrants issued on the October Closing Date exceeded the total proceeds of the private placement of \$6,000,000, as of the October Closing Date, no net amounts were allocated to the common stock. The \$1,008,000 amount by which the recorded liabilities exceeded the proceeds was charged to other expense at the October Closing Date. Given that the fair value of the derivative liabilities issued on the November Closing Date exceeded the total proceeds of the private placement of \$2,000,000, as of the November Closing Date, no net amounts were allocated to the common stock. The \$859,000 amount by which the recorded liabilities exceeded the proceeds was charged to other expense at the November Closing Date. We have revalued the derivative liability as of April 30, 2016, and will continue to do so on each subsequent balance sheet date until the securities to which the derivative liabilities relate are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense.

As of April 30, 2016, we had a warrant liability of \$9,000 related to 132,420 warrants issued pursuant to a Bridge Loan financing that occurred during the fourth quarter of 2012. Currently there are 9,709 warrants outstanding that were issued in connection with the Bridge Loan. The following assumptions were used as inputs to the model at April 30, 2016: stock price of \$1.12 and a warrant exercise price of \$0.20 as of the valuation date; our historical stock price volatility of 76.65%; risk free interest rate on U.S. treasury notes of 0.2%; warrant expiration of 0.65 years.

On April 30, 2016, the total value of the derivative liabilities was \$9,802,000. The change in fair value of the warrant liability for the three and nine months ended April 30, 2016, was a decrease of \$1,506,000 and an increase of \$6,241,000, respectively, which was recorded as a change in derivative liability in the consolidated statement of operations.

## 10. Stockholders' Equity

## Private Placements

On October 23, 2015, we completed the initial closing of the Private Placement Financing pursuant to a securities purchase agreement (the "Securities Purchase Agreement"), providing for the issuance and sale by us to Franchise Brands, LLC (the "Investor") of (i) an aggregate of 13,333,333 shares (collectively, the "Purchase Shares") of our common stock (the "Common Stock") at a purchase price of \$0.45 per share, (ii) a warrant to purchase up to an aggregate of 6,666,666 shares of Common Stock with a term of five years (the "Five-Year Warrant") and (iii) a warrant to purchase up to an aggregate of 8,666,666 shares of Common Stock with a term of six months and only exercisable for cash (the "Six-Month Warrant"), for aggregate gross proceeds to us of \$6.0 million. The six month warrants issued on October 23, 2015 expired unexercised.

On November 23, 2015, we completed the second and final closing of the Private Placement Financing. We raised \$2.0 million in this closing providing for the issuance to various investors (i) an aggregate of 4,444,439 Purchase Shares at a purchase price of \$0.45 per share, (ii) Five-Year Warrants to purchase up to an aggregate of 2,222,217 shares of Common Stock (iii) Six-Month Warrants to purchase up to an aggregate of 2,820,670 shares of Common Stock (the "Six-Month Warrants," together with the Five-Year Warrants, the "Warrants" and the shares issuable upon exercise of the Warrants, collectively, the "Warrant Shares"). We did not engage a placement agent or investment banker to facilitate the Private Placement Financing. We intend to use the aggregate net proceeds of the Private Placement Financing primarily for working capital and general corporate purposes.

During the three months ended April 30, 2016, 335,981 of the six month warrants issued on the November Closing Date were exercised and, subsequent to April 30, 2016, 2,484,689 of the six month warrants issued on the November Closing Date were exercised.

We offered the securities in the Private Placement Financing to the Company's existing investors who previously purchased securities in our private placement financings in August and September of 2014 (the "Prior Financings"). Tom Lee, a member of our board of directors and a participant in the Prior Financings, together with certain of his affiliates, invested approximately \$472,000 in the final closing of the Private Placement Financing on the same terms offered to the other Investors.

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The Warrants issued in connection with the Private Placement Financing have an exercise price of \$0.45 per share, are exercisable immediately after their issuance and have a term of exercise equal to the earlier of (i) five years or six months, for the Five-Year Warrants and Six-Month Warrants, respectively, after their issuance date or (ii) the consummation of an Acquisition Event (as defined in the Warrants). The Warrants are subject to a broad-based anti-dilution adjustment in the event the Company issues shares of Common Stock without consideration or for consideration per share less than the exercise price in effect immediately prior to such issuance; provided however, that such adjustment does not apply to an Excluded Issuance (as such term is defined in the Warrants). Additionally, the number of Warrant Shares issuable upon exercise of the Warrants and the applicable exercise price therefore are subject to adjustment in the event of a stock dividend, stock split or combination as set forth in the Warrants.

We also entered into a registration rights agreement with the Investors who participated in the Private Placement Financing (the "Registration Rights Agreement"), pursuant to which we will be obligated, upon request of Investors holding 75% of the Issuable Shares (as defined therein) and subject to certain conditions, to file with the Securities and Exchange Commission (the "Commission") as soon as practicable, but in any event within 60 days after receiving such applicable request, a registration statement on Form S-1 (the "Resale Registration Statement") to register the Purchase Shares and the Warrant Shares for resale under the Securities Act and other securities issued or issuable with respect to or in exchange for the Purchase Shares or Warrant Shares. We are obligated to use our commercially reasonable efforts to cause the Resale Registration Statement to be declared effective by the SEC as promptly as reasonably practicable after the filing of the Resale Registration Statement, but no monetary penalty or liquidated damages will be imposed upon the Company if the Registration Statement is not declared effective by the SEC.

During the nine months ended January 31, 2015, we issued a total of 10,086,025 shares of common stock and warrants to purchase 4,652,312 shares of common stock for gross proceeds of \$7,493,000. After deducting fees of \$92,000, the net proceeds to us were \$7,401,000. The warrants issued during the six months ended January 31, 2015 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 \$4,397,000 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.

#### <u>Warrants</u>

During the three months ended April 30, 2016, we received \$151,000 from the exercise of warrants issued in November 2015 to purchase 335,981 shares of our common stock.

During the nine months ended April 30, 2016, there was a net exercise on 28,000 warrants which resulted in the issuance of 13,906 shares of our common stock. As these warrants were net exercised, as permitted under the respective warrant agreement, we did not receive any cash proceeds. The warrants were issued in connection with a prior year private placement and were considered equity instruments.

Other Activity

During the three months ended April 30, 2016, we entered into a two-year service agreement for general financial advisory services. In accordance with the agreement we issued 250,000 shares of common stock, with a value of \$288,000. The value was capitalized to prepaid expense and is being amortized over the term of the agreement. During the three months ended April 30, 2016, we recognized \$7,000 of expense related to these services.

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## **11. Share-Based Compensation**

## Restricted Stock Units

During the nine months ended April 30, 2016, the Compensation Committee of the Board of Directors issued 200,000 restricted stock units ("RSUs") to Henry R. Lambert, our Chief Executive Officer. The RSUs vest based on performance conditions and expire July 31, 2018. If the performance conditions are not met, or expected to be met, no compensation cost will be recognized on the underlying RSUs. If the performance condition is expected to be met, the expense will be allocated over the performance period. The RSUs granted to Mr. Lambert were not granted pursuant to any compensatory, bonus, or similar plan maintained or otherwise sponsored by the Company.

In addition, during the nine months ended April 30, 2016, we issued 612,500 RSUs to key employees. The RSUs vest based on performance and service conditions. If the performance conditions are not met, or expected to be met, no compensation cost will be recognized on the underlying RSUs. If the performance condition is expected to be met, the expense will be allocated over the performance period.

During the three and nine months ended April 30, 2016, 1,400,000 and 1,925,000 RSUs vested based on service conditions that were satisfied during the period, resulting in the issuance of 1,400,000 and 1,925,000 shares of common stock, respectively. Of the 1,285,000 RSUs outstanding, we currently expect 400,000 to vest. As of April 30, 2016, there was \$196,000 of unrecognized non-cash compensation cost related to RSUs we expect to vest, which will be recognized over a weighted average period of 1.12 years. During the nine months ended April 30, 2016, 812,500 RSUs were forfeited.

For the three months ended April 30, 2016 and 2015, share-based compensation expense for outstanding RSUs was \$136,000 and \$750,000, respectively. For the nine months ended April 30, 2016 and 2015, share-based compensation expense was \$1,495,000 and \$1,703,000, respectively.

Stock Option Plans

In February 2016, we amended and restated our 2007 Equity Incentive Plan, or the Plan, to, among other changes, increase the number of shares of common stock issuable under the Plan by 4,000,000 shares and extend the term of the Plan until February 4, 2026. The Plan provides for the grant of incentive and non-qualified stock options, as well as other share-based payment awards, to our employees, directors, consultants and advisors. These awards have up to a 10-year contractual life and are subject to various vesting periods, as determined by the Compensation Committee or the Board of Directors. Our 2007 Equity Incentive Plan is the only active plan pursuant to which options to acquire common stock or restricted stock awards can be granted and are currently outstanding. As of April 30, 2016, there were approximately 3.0 million shares available for issuance under the Plan

A summary of our stock option activity for the nine months ended April 30, 2016 is as follows:

	Shares	Weighted- Average Exercise Price	Aggregate Intrinsic Value
Outstanding at July 31, 2015	434,218	\$ 4.07	
Granted	850,000	\$ 1.07	
Cancelled	(3,125)	\$ 19.76	
Outstanding at April 30, 2016	1,281,093	\$ 2.04	\$ 84,000

The weighted-average remaining contractual term of options outstanding at April 30, 2016 was 2.43 years.

At April 30, 2016, 528,593 options were exercisable. These options had a weighted-average exercise price of \$3.31, an aggregate intrinsic value of \$72,000, and a weighted average remaining contractual term of 3.19 years.

We use the Black-Scholes valuation model to calculate the fair value of stock options. Stock-based compensation expense is recognized over the vesting period using the straight-line method. The fair value of stock options was estimated at the grant date using the following weighted average assumptions:

	For the nine		
	months ended April		
	30,		
	2016		2015
Volatility	84.20	%	-
Risk-free interest rate	0.70	%	-
Dividend yield	0.0	%	-
Expected life	1.73 years		-

Volatility is the measure by which our stock price is expected to fluctuate during the expected term of an option. Volatility is derived from the historical daily change in the market price of our common stock, as we believe that historical volatility is the best indicator of future volatility.

The risk-free interest rates used in the Black-Scholes calculations are based on the prevailing U.S. Treasury yield as determined by the U.S. Federal Reserve.

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. Accordingly, we have assumed no dividend yield for purposes of estimating the fair value of our share-based compensation.

The weighted average expected life of options was estimated using the average of the contractual term and the weighted average vesting term of the options. Certain options granted to consultants are subject to variable accounting treatment and are required to be revalued until vested.

Stock-based compensation expense is based on awards ultimately expected to vest, and therefore is reduced by expected forfeitures. We have not had significant forfeitures of stock options granted to employees and directors as a significant number of our historical stock option grants were fully vested at issuance or were issued with short vesting provisions. Therefore, we have estimated the forfeiture rate of our outstanding stock options as zero.

The total unrecognized compensation cost related to unvested stock option grants as of April 30, 2016 was approximately \$216,000 and the weighted average period over which these grants are expected to vest is 0.89 years.

For the three months ended April 30, 2016 and 2015, share-based compensation expense for outstanding stock options was \$50,000 and \$16,000, respectively. For the nine months ended April 30, 2016 and 2015, share-based compensation expense was \$126,000 and \$48,000, respectively.

#### 12. Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2014-15, Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. The ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We do not intend to early adopt this standard. We are still evaluating what effect the adoption of this standard will have on the financial condition of the Company.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires lessees to recognize "right of use" assets and liabilities for all leases with lease terms of more than 12 months. The ASU requires additional quantitative and qualitative financial statement footnote disclosures about the leases, significant judgments made in accounting for those leases and amounts recognized in the financial statements about those leases. The effective date will be the first quarter of fiscal year 2019. We are currently evaluating the impact of the adoption of this accounting standard update on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606), which requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The amendments in this Update do not change the core principle of the guidance. The amendments clarify the implementation guidance on principal versus agent considerations. ASU No. 2016-08 was amended by ASU No. 2016-10 to identify performance obligations and licensing. These amendments should be adopted concurrent with adoption of ASU 2014-09. We have not yet determined the effect of the standard on our ongoing financial reporting.

In March 2016, the FASB issued ASU No. 2016-09, "Improvements to Employee Share-Based Payment Accounting", which is designed to simplify several aspects of accounting for share-based payment award transactions, including income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. ASU No. 2016-09 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016, with early adoption permitted. We are currently evaluating the impact of ASU No. 2016-09 on our consolidated financial statements.

## **13. Subsequent Events**

Subsequent to April 30, 2016, we received \$1,118,110 from the exercise of warrants to purchase 2,484,689 shares of our common stock. The warrants were issued in connection with the November 23, 2015 Private Placement Financing.

#### 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., a Delaware corporation, 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," "shou 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 proprietary antimicrobial products that provide safe and cost-effective 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, we believe 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.

Our SDC-based technology platform has potential application in a number of industries. Our near-term focus is to offer products that address food safety risks across the food industry supply chain. In 2011, the Centers for Disease Control and Prevention (CDC) reported that foodborne illnesses affect more than 48 million people annually in the U.S., causing 128,000 hospitalizations and 3,000 fatalities. The CDC estimated that more than 9 million of these foodborne illnesses were attributed to major pathogens. The CDC reported that contaminated produce was responsible for approximately 46% of the foodborne illnesses caused by pathogens and 23% of the foodborne illness-related deaths in the US between 1998 and 2008. Among the top pathogens contributing to foodborne illness in the U.S. are Norovirus, *Salmonella, Campylobacter, Staphylococcus*, Shiga toxin–producing *Escherichia coli* and *Listeria. Salmonella* is the leading cause of hospitalization, followed by Norovirus, and is the leading cause of deaths related to foodborne illness.

Based on these statistics, we believe there is a significant market opportunity for our safe, non-toxic and effective SDC-based solutions. We currently offer PURE<sup>®</sup> Hard Surface as a food contact surface sanitizer and disinfectant to restaurant chains and food processors. One of our customers is SUBWAY<sup>®</sup> Restaurants, which has approved PURE Hard Surface for use system-wide (27,000 U.S. stores). We also intend to offer PURE Control<sup>®</sup> as a direct food contact processing aid, which requires certain FDA and USDA approvals. We received the required FDA approvals to market PURE Control as a direct food contact processing aid for raw poultry and fresh produce in December 2015 and January 2016, respectively, and are preparing to launch PURE Control as a direct food contact processing aid for fresh produce. We intend to offer PURE Control as a direct food contact processing aid for raw poultry upon receipt of the required USDA approvals, which we expect as early as the third calendar quarter of 2016. We are currently testing and continuing development of PURE Control to allow us to seek regulatory approval to also utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork. In addition to our direct sales efforts with PURE Hard Surface and PURE Control, we market and sell our SDC-based products indirectly through third-party distributors.

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#### **Business Strategy**

Our goal is to become a sustainable company by commercializing the SDC-based products we have developed with our proprietary technology platform. We are focused on delivering leading antimicrobial products that address food safety risks across the food industry supply chain. Key aspects of our business strategy include:

Expanding sales and distribution for our products into the food industry with a focus on a dual track of food safety market opportunities:

*Hard Surface Disinfectant* - commercializing the current EPA registered PURE Hard Surface disinfectant and sanitizer for use in foodservice operations and food manufacturing.

*Direct Food Contact* - commercializing FDA approved PURE Control as a direct food contact processing aid for fresh produce; commercialize, subject to USDA approval, the use of SDC as a food processing and intervention aid for food processors treating raw poultry; commercialize, subject to both FDA and USDA approval, the use of SDC as a food processing and intervention aid for food processors treating raw beef and pork.

• Establishing strategic alliances to maximize the commercial potential of our technology platform;

Developing additional proprietary products and applications; and

Protecting and enhancing our intellectual property.

In addition to our current products addressing food safety, we intend to continue to leverage our technology platform through licensing and distribution collaborations in order to develop new products and enter into new markets that could potentially generate multiple sources of revenue.

**Our Products** 

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Our near-term focus is on delivering leading antimicrobial products that address food safety risks across the food industry supply chain. We currently offer PURE Hard Surface as a food contact surface sanitizer and disinfectant to restaurant chains and food processors. One of our customers is SUBWAY<sup>®</sup> Restaurants, which has approved PURE Hard Surface for use system-wide (27,000 U.S. stores). We received the required FDA approvals to market PURE Control as a direct food contact processing aid for raw poultry and fresh produce in December 2015 and January 2016, respectively, and are preparing to launch PURE Control as a direct food contact process aid for raw poultry as soon as we receive the required approvals from the USDA, which we expect as early as the third calendar quarter of 2016. We are currently testing and continuing development of PURE Control to allow us to seek regulatory approval to utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork.

In addition to our direct sales efforts with PURE Hard Surface and PURE Control, we market and sell our SDC-based products indirectly through third-party distributors. In addition to PURE Hard Surface and PURE Control, we manufacture and sell (i) SDC-based products for end use, (ii) products preserved with SDC and (iii) SDC as a raw material ingredient for manufacturing use.

## 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. PURE Hard Surface combines high efficacy and low toxicity with bacterial and viral kill times as few as 30-seconds 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 Control®

We have the necessary regulatory approvals to offer PURE Control as a direct food contact processing aid for fresh produce. We are currently in the process of developing and obtaining regulatory approval to offer PURE Control as a direct food contact processing aid for poultry, beef and pork.

<u>Poultry Processing Aid.</u> In December 2015, we received the required approvals from the FDA stating that our FCN (food contact notification) for SDC as a raw poultry processing aid is complete.

Receipt of the FDA's approval enabled us to initiate the next step in the regulatory approval process: obtaining USDA approval. As part of that process, we are preparing to conduct in-plant trials with the authorization of the USDA. We anticipate receiving the required approvals to market PURE Control as a direct food contact processing aid for raw poultry as early as the third calendar quarter of 2016.

Testing data conducted by Dr. James Marsden at Kansas State University and submitted in support of our FCN showed that, SDC achieved an average reduction in *Salmonella* of 2.75  $\log_{10}$  CFU/cm<sub>2</sub> when applied as an OLR (online reprocessing) spray and 6.28  $\log_{10}$  CFU/cm<sub>2</sub> when combined with an immersion chilling process simulating current U.S. industry practices. We believe that testing by Dr. Marsden provides support to the following benefits of SDC for poultry processing:

The use of SDC antimicrobial solution in poultry processing has the potential to enable plants to achieve non-detectable *Salmonella* levels post-chill process.

A sensory evaluation of SDC showed no difference in color, appearance or odor in treated poultry.

SDC offers a highly effective alternative to hazardous and difficult to blend chemicals currently used as treatments in raw poultry processing.

SDC is a significant improvement over current processing practices. The product is:

Easier to handle and dilute;

Non-corrosive to processing equipment;

Does not create noxious fumes; and

Poultry processors will also benefit from the highly stable solution, ease of use and improved worker safety.

## Produce Processing Aid.

In January 2016, we received the required approvals from the FDA stating that our FCN for SDC as a spray or dip on processed fruits and vegetables is complete. We are not required to obtain any approvals from the USDA to use PURE Control as a produce processing aid.

Testing data conducted by Dr. James Marsden at Kansas State University and submitted in support of our FCN for produce showed that, SDC achieved average reductions up to  $2.36 \log_{10} \text{CFU/cm}_2$  when applied alone as a spray and up to  $3.10 \log_{10} \text{CFU/cm}_2$  when combined with chlorine wash, simulating current processing practices. Sensory evaluations of produce treated with SDC indicated no difference in color, appearance or odor to untreated controls; and SDC had no effect on the nutritional composition of the produce.

Currently, produce processors target achieving only a  $1 \log_{10} \text{CFU/cm}_2$  reduction per intervention treatment. Data suggests that by incorporating SDC, processors can improve their results 100-fold with only one step. This represents a significant advantage to produce processors as well as improvement to the safety of processed produce going to the consumer.

<u>Other Processing Aids Under Development.</u> We are developing the use of SDC as an intervention in the processing of beef and pork. Subject to successful pilot testing results and development, we intend to submit for both FDA and USDA approval during 2016. In addition, we may identify other food processing opportunities for SDC.

#### Additional SDC-Based Products

In addition to PURE Hard Surface and PURE Control, we manufacture and sell (i) SDC-based products for end use, (ii) products preserved with SDC and (iii) SDC as a raw material ingredient for manufacturing use. These products include:

Product Name	Product Use	EPA Registration
PURE Complete Solution:		
PURE <sup>®</sup> Multi-Purpose and Floor Cleaner Concentrate	Cleaner	Not applicable
PURE <sup>®</sup> Multi-Purpose Hi-Foam Cleaner Concentrate	Cleaner	Not applicable
Axen <sup>®</sup> 30	Disinfectant	Axen30
Axenohl®	Raw material ingredient	Axenohl
SILVÉRION®	Raw material ingredient	Not applicable

#### **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. This product line can also be targeted to hospital and medical care facilities; janitorial service providers and the distributors that supply them.

PURE® Multi-Purpose and Floor Cleaner Concentrate (End-User Dilutable)

PURE Multi-Purpose and Floor Cleaner, is an environmentally responsible cleaning product that is protected by SDC. SDC ensures the quality and safety of PURE Multi-Purpose and Floor Cleaner without human or environmental exposure to toxic chemical preservatives. PURE Multi-Purpose and Floor Cleaner is non-toxic and non-flammable and contains no EDTA, phosphates, ammonia or bleach as well as no VOCs or NPEs. This efficient 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<sup>®</sup> 30 (Ready-to-Use)

Axen30 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.

## Axenohl<sup>®</sup> (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<sup>®</sup> (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 domestically and outside of the United States in various personal care products.

#### Financial Overview

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

<u>Revenue</u>

We contract 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 April 30, 2016 and 2015

#### Net Product Sales

Net product sales were \$403,000 and \$109,000 for the three months ended April 30, 2016 and 2015, respectively. The increase of \$294,000 was primarily attributable to an increase in food safety sales and fluctuations within our existing legacy customer base.

For the three months ended April 30, 2016, two individual customers accounted for 48% and 25%, of our net product sales, respectively. 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.

For the three months ended April 30, 2015, four individual customers accounted for 25%, 19%, 17%, and 10% of our net product sales, respectively. 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

# Cost of Goods Sold

Cost of goods sold was \$116,000 and \$65,000 for the three months ended April 30, 2016 and 2015, respectively. The Increase of \$51,000 was attributable to increased net product sales.

Gross margin as a percentage of net product sales, or gross margin percentage, was 71% and 40% for the three months ended April 30, 2016 and 2015, respectively. The increase in gross margin percentage was primarily attributable to the sale of higher margin formulations and packaging configurations of our products during the quarter ended April 30, 2016 as compared with the prior year.

## Selling, General and Administrative Expense

Selling, general and administrative expense was \$1,385,000 and \$1,207,000 for the three months ended April 30, 2016 and 2015, respectively. The increase of \$178,000 was primarily attributable to marketing costs, investor relations and personnel costs.

## Research and Development Expense

Research and development expense was \$205,000 and \$171,000 for the three months ended April 30, 2016 and 2015, respectively. The increase of \$34,000 was primarily attributable to third-party testing and research.

# Share-Based Compensation

Share-based compensation expense was \$186,000 and \$766,000 for the three months ended April 30, 2016 and 2015, respectively. The decrease of \$580,000 is primarily due to the vesting of stock options and restricted stock units granted to employees supporting our selling, general and administrative, and research and development functions during the prior fiscal year.

## Change in Derivative Liability

Change in derivative liability for the three months ended April 30, 2016 and 2015 was a decrease of \$1,506,000 and \$1,000, respectively. The decrease is primarily due to the expiration of 8,666,666 warrants issued in connection with the October Private Placement Financings, as well as, a decrease in the Company's common stock price and updates to the assumptions used in the fair value pricing model (See Notes 8 and 9).

# Interest Expense

Interest expense for the three months ended April 30, 2016 and 2015 was \$3,000 and \$2,000, respectively.

## Other Income (Expense)

Other income for the three months ended April 30, 2016 and 2015 was \$16,000 and \$10,000, respectively. The increase is primarily due to the sale of reserved inventory that occurred during the current quarter.

### Comparison of the Nine Months Ended April 30, 2016 and 2015

#### Net Product Sales

Net product sales were \$765,000 and \$499,000 for the nine months ended April 30, 2016 and 2015, respectively. The increase of \$266,000 was primarily attributable to an increase in food safety sales and fluctuations within our existing legacy customer base.

For the nine months ended April 30, 2016, two individual customers accounted for 45% and 13%, of our net product sales, respectively. 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.

For the nine months ended April 30, 2015, three individual customers each accounted for 10% or more of our net product sales. One customer accounted for 38% and the other two for 11%. No other individual customer accounted for 10% or more of our net product sales. The geographic breakdown of net product sales was as follows: 96% U.S. and 4% foreign, with foreign sales occurring in the United Kingdom.

## Cost of Goods Sold

Cost of goods sold was \$218,000 and \$221,000 for the nine months ended April 30, 2016 and 2015, respectively. The decrease of \$3,000 was primarily attributable to the sales of higher margin products during the current year.

Gross margin as a percentage of net product sales, or gross margin percentage, was 72% and 56% for the nine months ended April 30, 2016 and 2015, respectively. The increase in gross margin percentage was primarily attributable to the sale of higher margin formulations and packaging configurations of our products during the nine months ended April 30, 2016 as compared with the prior year.

Selling, general and administrative expense was \$3,857,000 and \$3,731,000 for the nine months ended April 30, 2016 and 2015, respectively. The increase of \$126,000 was primarily attributable to increased marketing costs offset by decreased personnel and facility costs.

### Research and Development Expense

Research and development expense was \$679,000 and \$562,000 for the nine months ended April 30, 2016 and 2015, respectively. The increase of \$117,000 was primarily attributable to third-party testing and research supporting our FDA approvals.

#### Share-Based Compensation

Share-based compensation expense was \$1,621,000 and \$1,751,000 for the nine months ended April 30, 2016 and 2015, respectively. The decrease of \$130,000 is primarily due to the vesting of stock options and restricted stock units granted to employees supporting our selling, general and administrative, and research and development functions during the prior fiscal year.

## Fair Value of Derivative Liabilities in Excess of Proceeds.

The fair value of derivative liabilities in excess of proceeds was \$1,867,000 and zero for the nine months ended April 30, 2016 and 2015, respectively (See Notes 8 and 9).

#### Change in Derivative Liability

Change in derivative liability for the nine months ended April 30, 2016 and 2015 was an increase of \$6,241,000 and a decrease of \$5,000, respectively. The increase is due to the 20,376,219 warrants issued in connection with the October and November Private Placement Financings, as well as, updates to the assumptions used in the fair value pricing model (See Notes 8 and 9).

### Interest Expense

Interest expense for the nine months ended April 30, 2016 and 2015 was \$8,000 and \$7,000, respectively.

#### Other Income (Expense)

Other income for the nine months ended April 30, 2016 and 2015 was \$34,000 and \$7,000, respectively. The increase is primarily due to the sale of reserved inventory that occurred during the nine months ended April 30, 2016.

### 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 April 30, 2016 we have incurred a cumulative net loss of \$102,540,000.

During the nine months ended April 30, 2016, we issued a total of 17,777,772 shares of common stock and warrants to purchase 20,376,219 shares of common stock for gross proceeds of \$8.0 million in private placement financings 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. In addition, we received \$151,000 from the exercise of warrants to purchase 335,981 shares of our common stock.

As of April 30, 2016, we had \$5,405,000 in cash and cash equivalents compared with \$1,321,000 in cash and cash equivalents as of July 31, 2015. The net increase in cash and cash equivalents was primarily attributable to proceeds from our issuance of common stock in the private placement noted above. Additionally, as of April 30, 2016, we had \$10,542,000 of current liabilities, including \$522,000 in accounts payable, compared with \$869,000 of current liabilities, including \$560,000 in accounts payable as of July 31, 2015. The net increase in current liabilities is due to the derivative liability incurred from the issuance of warrants associated with the \$8.0 million financing discussed above.

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 April 30, 2016, no events have occurred resulting in the obligation of any such payments.

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 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 available cash on-hand, 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.

In addition, the consolidated financial statements included in this Quarterly Report have been prepared and presented on a basis assuming we will continue as a going concern. Until we can generate significant cash from operations, we expect to continue to fund our operations with the proceeds of offerings of our equity and debt securities. However, we cannot assure you that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. Further, any contracts or license

arrangements we enter into to raise funds may require us to relinquish our rights to our products or technology, and we cannot assure you that we will be able to enter into any such contracts or license arrangements on acceptable terms, or at all. Having insufficient funds may require us to delay or scale back our marketing, distribution and other commercialization activities or cease our operations altogether. Our financial statements do not include any adjustment relating to recoverability or classification of recorded assets and classification of recorded liabilities.

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.

### 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 12 to the consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

#### **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 Principal Executive Officer and Principal 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 Principal Executive Officer and our Principal 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 Internal Control Over Financial Reporting**

In connection with the evaluation required by Exchange Act Rule 13a-15(d), our management, under the supervision and with the participation of our Principal Executive Officer and our Principal Financial Officer, concluded that there were no changes in our internal controls over financial reporting during the three months ended April 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

#### **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**

In evaluating us and our common stock, we urge you to carefully consider the risks and other information in this Quarterly Report on Form 10-Q, as well as the risk factors disclosed in Item 1A. to Part I of our Annual Report on Form 10-K for the fiscal year ended July 31, 2015, which we filed with the SEC on October 28, 2015 (the "Form 10-K") and Item 1A. to Part II of our Quarterly Report on Form 10-Q for the quarter ended October 31, 2015, which we filed on December 10, 2015 (the "Previous Form 10-Q"). The risks and uncertainties described in "Item 1A — Risk Factors" of our Form 10-K and "Item 1A – Risk Factors" of our Previous Form 10-Q have not materially changed. Any of the risks discussed in this Quarterly Report on Form 10-Q or any of the risks disclosed in Item 1A. to Part I of our Previous Form 10-Q, as well as additional risks and uncertainties not currently known to us or that we currently deem immaterial, could materially and adversely affect our results of operations, financial condition or prospects.

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

During the three months ended April 30, 2016, we entered into a two-year service agreement for general financial advisory services. In accordance with the agreement, we issued 250,000 shares of common stock with a stated value of \$288,000. The shares of common stock were issued 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 law.

# Item 3. Defaults Upon Senior Securities

None.

# Item 4. Mine Safety Disclosures

Not Applicable.

## **Item 5. Other Information**

None.

### 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)
- 4.7 Form of Five-Year Warrant (incorporated by reference to Exhibit 4.11 to the Company's Annual Report on Form 10-K, filed with the SEC on October 28, 2015)
- 4.8 Form of Six-Month Warrant (incorporated by reference to Exhibit 4.11 to the Company's Annual Report on Form 10-K, filed with the SEC on October 28, 2015)

- 31.1 \* Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 \* Certification of Principal 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 Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

The following materials from the Company's Quarterly Report on Form 10-Q for the quarterly period ended April 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance

101 \* Sheets at April 30, 2016 and July 31, 2015; (ii) Consolidated Statements of Operations for the three and nine months ended April 30, 2016 and 2015; (iii) Consolidated Statements of Cash Flows for the nine months ended April 30, 2016 and 2015; and (iv) Notes to Consolidated Financial Statements.

\* Filed herewith.

### 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: June 9, 2016 By:/s/ HENRY R. LAMBERT Henry R. Lambert, Chief Executive Officer (Principal Executive Officer)

Date: June 9, 2016 By:/s/ MARK S. ELLIOTT Mark S. Elliott, Vice President, Finance (Principal Financial and Accounting Officer)