PURE BIOSCIENCE, INC. Form 10-Q December 11, 2012

#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-O

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

FOR THE QUARTERLY PERIOD ENDED OCTOBER 31, 2012

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

Commission File Number 0-21019

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 ý No o

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 ý No o

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 o Accelerated filer o Non-accelerated filer o Smaller reporting company ý

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No  $\circ$ 

As of December 7, 2012, there were 10,986,170 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 October 31, 2012

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#### Item 1. Financial Statements

#### Pure Bioscience, Inc. Consolidated Balance Sheets

| Assets   | October 31,<br>2012<br>(Unaudited) | July 31,<br>2012 |
|--|------------------------------------|------------------|
| Current assets   |                                    |                  |
| Cash and cash equivalents                                  | \$2,450,000                        | \$877,000        |
| Accounts receivable, net                                   | 64,000                             | 373,000          |
| Inventories, net   | 864,000                            | 654,000          |
| Prepaid expenses   | 80,000                             | 347,000          |
| Total current assets                                       | 3,458,000                          | 2,251,000        |
|  |                                    |                  |
| Property, plant and equipment, net                         | 226,000                            | 257,000          |
| Patents, net   | 1,988,000                          | 1,950,000        |
|  |                                    |                  |
| Total assets   | \$5,672,000                        | \$4,458,000      |
|  |                                    |                  |
| Liabilities and stockholders' equity                       |                                    |                  |
| Current liabilities  |                                    |                  |
| Accounts payable   | \$2,094,000                        | \$1,946,000      |
| Loan payable, net  | -                                  | 962,000          |
| Deferred revenue   | -                                  | 66,000           |
| Accrued liabilities  | 405,000                            | 344,000          |
| Derivative liability                                       | 91,000                             | 319,000          |
| Total current liabilities                                  | 2,590,000                          | 3,637,000        |
|  |                                    |                  |
| Deferred rent  | 3,000                              | 3,000            |
| Total liabilities  | 2,593,000                          | 3,640,000        |
| Commitments and contingencies                              |                                    |                  |
| 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                              |                                    |                  |
| 10,986,170 issued and outstanding at October 31, 2012, and |                                    |                  |
| 6,644,555 issued and outstanding at July 31, 2012.         | 110,000                            | 67,000           |
| Additional paid-in capital                                 | 67,623,000                         | 63,251,000       |
| Accumulated deficit  | (64,654,000)                       | (62,500,000)     |
| Total stockholders' equity                                 | 3,079,000                          | 818,000          |
|  | - , ,                              | ,                |
| Total liabilities and stockholders' equity                 | \$5,672,000                        | \$4,458,000      |

See accompanying notes.

# Pure Bioscience, Inc. Consolidated Statements of Operations (Unaudited)

|   |              | nonths ended<br>ober 31,<br>2011 |
|---|--------------|----------------------------------|
| Net product sales   | \$110,000    | \$257,000                        |
| Operating costs and expenses                                  |              |                                  |
| Cost of goods sold  | 31,000       | 129,000                          |
| Selling, general and administrative                           | 1,476,000    | 1,997,000                        |
| Research and development                                      | 395,000      | 493,000                          |
| Total operating costs and expenses                            | 1,902,000    | 2,619,000                        |
| Loss from operations  | (1,792,000   | ) (2,362,000 )                   |
| Other income (expense)  |              |                                  |
| Change in derivative liability                                | 228,000      | -                                |
| Interest expense  | (588,000     | ) -                              |
| Interest income   | -            | 1,000                            |
| Other (expense) income, net                                   | (2,000       | ) -                              |
| Total other (expense) income                                  | (362,000     | ) 1,000                          |
| Net loss  | \$(2,154,000 | ) \$(2,361,000 )                 |
| Basic and diluted net loss per share                          | \$(0.25      | ) \$(0.47)                       |
|   |              |                                  |
| Shares used in computing basic and diluted net loss per share | 8,720,980    | 5,044,950                        |
| See accompanying notes.                                       |              |                                  |
| 4   |              |                                  |

## Pure Bioscience, Inc. Consolidated Statements of Cash Flows (Unaudited)

2012 2011 Operating activities Net loss \$(2,154,000) \$(2,361,000) Adjustments to reconcile net loss to net cash used in operating activities: Share-based compensation 188,000 377,000 Amortization of stock issued for services 24,000 Depreciation and amortization 73,000 117,000 Amortization of deferred financing costs 215,000 Change in fair value of derivative liability (228,000 Amortization of debt discount 371,000 Changes in operating assets and liabilities: Accounts receivable 36,000 (69,000 **Inventories** (3.000)11,000 28,000 Prepaid expenses 8.000 Accounts payable and accrued liabilities 209,000 438,000 Deferred rent (4,000)Net cash used in operating activities (1,241,000)(1,483,000 Investing activities Investment in patents (77,000)(39,000 Purchases of property, plant and equipment (3.000)Net cash used in investing activities (80,000 (39,000 ) Financing activities Net proceeds from the sale of common stock 4,227,000 720,000 Payment of Bridge Loan (1.333,000)Net cash provided by financing activities 2,894,000 720,000 Net increase (decrease) in cash and cash equivalents 1,573,000 (802,000 Cash and cash equivalents at beginning of period 877,000 1,794,000 \$2,450,000 \$992,000 Cash and cash equivalents at end of period

See accompanying notes.

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Supplemental disclosure of cash flow information

Common stock issued for prepaid services

Supplemental disclosure of non-cash investing and financing activities

Cash paid for taxes

\$1,000

\$97,000

Three months ended October 31.

## Pure Bioscience, Inc. Notes to Consolidated Financial Statements (Unaudited)

#### 1. Basis of Presentation

The accompanying unaudited 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 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 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, 2012 are not necessarily indicative of the results that may be expected for other quarters or the year ending July 31, 2013. The July 31, 2012 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, 2012 included in our Annual Report on Form 10-K covering such period filed with the Securities and Exchange Commission, or SEC, on October 29, 2012.

Effective on August 14, 2012 and commencing with the opening of trading on August 15, 2012, we effected a reverse stock split of our issued and outstanding common stock, \$0.01 par value per share, at a ratio of one-for-eight, with each eight (8) issued and outstanding shares of our common stock automatically combined and converted into one (1) issued and outstanding share of our common stock. The reverse stock split was approved by stockholders holding a majority of our outstanding voting power at our annual meeting of stockholders held on July 31, 2012. All information in our consolidated financial statements and the notes thereto regarding share amounts of our common stock and prices per share of our common stock has been adjusted to reflect the application of the reverse stock split, unless otherwise noted.

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, revenue from product sales and license agreements, and proceeds from the sale of a division. We have a history of recurring losses, and we have incurred a cumulative net loss of \$64,654,000.

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 do not have, and may never have, significant cash inflows from product sales or from other sources of revenue to fund our operations. Accordingly, 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; reducing the exercise price of outstanding warrants; and entering into partnerships, licenses, or other arrangements with third parties, which may include licensing to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves. 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 will 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 significantly modify our business model and operations to reduce spending to a sustainable level, which may include delaying, scaling back or eliminating some or all of 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. If adequate funds are not available when needed, we may be required to reduce or cease operations altogether.

We believe our recent 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, our estimates of our operating expenses and working capital requirements could be incorrect, and we may use our cash resources faster than we presently anticipate. Further, 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.

#### 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 and warrants would have an anti-dilutive effect. As of October 31, 2012 and 2011, the number of shares issuable upon the exercise of stock options and warrants, none of which are included in the computation of basic net loss per common share, was 784,871 and 549,606, 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, 2012 and 2011, 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:

|                | October 31, | July 31,  |
|----------------|-------------|-----------|
|                | 2012        | 2012      |
| Raw materials  | \$472,000   | \$476,000 |
| Finished goods | 392,000     | 178,000   |
|                | \$864,000   | \$654,000 |

As of October 31, 2012, we increased our inventory balance by \$207,000 to reflect product held by a third party warehouse on behalf of one of our customers. The customer has authorized us to retake possession of this inventory,

and as such, we have reduced our accounts receivable by \$273,000 and reduced deferred revenue by \$66,000.

#### 6. 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, 2012 and 2011, no impairment of long-lived assets was indicated or recorded.

#### 7. Secured Convertible Note

Pursuant to a securities purchase agreement entered into on June 26, 2012, on 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 (Note 10), and accordingly all such amounts have been repaid.

Due to the repayment of the Bridge Loan, debt discounts related to the Bridge Loan, including imputed interest, an original issue discount, the embedded conversion feature of the Notes, and the detachable warrants issued to the lenders in connection with the transaction, have been fully amortized, resulting in \$371,000 of interest expense during the three months ended October 31, 2012. Additionally, deferred financing fees associated with the Bridge Loan have been fully amortized, resulting in \$215,000 of interest expense during the three months ended October 31, 2012.

While outstanding, the Notes were secured by a lien on all of our assets and shares of our common stock pursuant to a security agreement, as amended, entered in connection with the Bridge Loan. The shares were issued as additional collateral for the timely repayment of the Notes. Due to the full repayment of the Bridge Loan, the lien on our assets was terminated on October 11, 2012 and the escrow shares will be cancelled.

#### 8. Derivative Liability

We accounted for the warrants issued in connection with the Bridge Loan, and the embedded conversion feature of the Notes, 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 and the conversion feature of the Notes 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 fair value of the warrants at October 31, 2012 and July 31, 2012 was \$91,000 and \$286,000, respectively. The fair value decrease of \$195,000 was recorded as a change in derivative liability in the consolidated statement of operations.

Based on our assessment of the Notes, we determined that the conversion feature represented an embedded derivative liability. Under the terms of the Notes, if we sold shares of our common stock to the public in a registered public offering at a price per share less than \$3.28 during the 60-day period commencing on June 26, 2012, then the conversion price of the Notes would have been reduced to equal the price per share at which shares were sold to the public in such registered public offering. Accordingly, we bifurcated the embedded conversion feature and accounted for it separately as a derivative liability. The fair value of the conversion feature at July 31, 2012 was \$33,000. Due to the repayment of the Bridge Loan in September 2012, the derivative liability related to the conversion feature was settled during the three months ended October 31, 2012 and, as such, there is no related liability as of October 31, 2012. The change in fair value of \$33,000 was recorded as a change in derivative liability in the consolidated statement of operations.

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

|                         | October 31, 2 | 012 | July 31, 20 | )12 |
|-------------------------|---------------|-----|-------------|-----|
| Volatility              | 85.0          | %   | 85.0        | %   |
| Risk-free interest rate | 0.72          | %   | 0.53        | %   |
| Dividend yield          | 0.0           | %   | 0.0         | %   |
|                         |               |     | 0.42 - 4    | .4  |
| Expected life           | 4.2 year      | S   | yea         | rs  |

In addition, as of the valuation dates, management assessed the probabilities of future financings assumptions in the Monte Carlo valuation models.

#### 9. 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 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 by a third party 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, 2012:

|  |           | Conversion | 1         |   |
|--|-----------|------------|-----------|---|
|  | Warrant   | Feature    |           |   |
|  | Liability | Liability  | Total     |   |
| Beginning balance July 31, 2012            | \$286,000 | \$33,000   | \$319,000 |   |
| Issuances                                  | -         | -          | -         |   |
| Settlement of conversion feature liability | -         | (33,000    | ) (33,000 | ) |
| Adjustments to estimated fair value        | (195,000  | ) -        | (195,000  | ) |
| Ending balance October 31, 2012            | \$91,000  | \$-        | \$91,000  |   |

#### 10. Common Stock

#### Reverse Stock Split

On August 13, 2012, we filed a Certificate of Amendment to our Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a reverse stock split of our issued and outstanding common stock, \$0.01 par value per share, at a ratio of one-for-eight. The reverse stock split was approved by stockholders holding a majority of

our outstanding voting power at our annual meeting of stockholders held on July 31, 2012. The reverse stock split became effective as of the close of trading on August 14, 2012 and commenced trading on a post-reverse split basis as of the opening of trading on August 15, 2012, with each eight (8) issued and outstanding shares of our common stock automatically combined and converted into one (1) issued and outstanding share of our common stock. The reverse stock split affected all issued and outstanding shares of our common stock, as well as common stock underlying stock options, warrants, and convertible notes outstanding immediately prior to the effectiveness of the reverse stock split, but did not affect the number of authorized shares of our common stock. As a result of the reverse stock split, the number of outstanding shares of our common stock was reduced from approximately 57.8 million immediately prior to the effectiveness of the reverse stock split to approximately 7.2 million immediately thereafter.

#### Common Stock

On October 24, 2011, we entered into a one year service agreement for investor relations services. We issued 18,750 shares of our common stock, with a value of \$97,000, for these services. The value was capitalized to prepaid expenses and is being amortized over the term of the agreement. During the three months ended October 31, 2012 and 2011, we recognized \$24,000 and zero, respectively, of expense related to these services.

On September 17, 2012, we closed an underwritten public offering of an aggregate of 4,341,615 shares of our common stock, including shares issued pursuant to the exercise of the underwriter's overallotment option, at a price to the public of \$1.10 per share. The offering was made pursuant to our registration statement on Form S-3 (Registration No. 333-182475), which became effective on July 31, 2012, and a preliminary and final prospectus supplement filed with the SEC on September 4, 2012 and September 13, 2012, respectively. The shares were sold pursuant to an underwriting agreement between us and Aegis Capital Corp., which is filed as an exhibit to our Current Report on Form 8-K filed with the SEC on September 13, 2012. The gross proceeds from the offering were approximately \$4,776,000 and, after deducting \$549,000 for transaction costs, including discounts, commissions, and other offering expenses, such as legal and accounting fees, the net proceeds to us from the offering were approximately \$4,227,000. We used \$1,333,000 of the net proceeds from the offering to pay the full amount of the indebtedness we incurred in connection with the Bridge Loan, described in further detail under Note 7 above. We intend to use the remaining proceeds from the offering for working capital and general corporate purposes.

#### 11. Share-Based Compensation

The following table summarizes share-based compensation expense related to employee and director stock options, consultant stock options, and restricted stock awards for the three months ended October 31, 2012 and 2011:

|   | For the three months ended October 31, |           |   |
|---|--|-----------|---|
|   | 2012                                   | 2011      |   |
| Share-based compensation for employees and directors: |  |           |   |
| Selling, general and administrative                   | \$141,000                              | \$322,000 |   |
| Research and development                              | 46,000                                 | 63,000    |   |
|   | 187,000                                | 385,000   |   |
|   |  |           |   |
| Share-based compensation for consultants:             |  |           |   |
| Selling, general and administrative                   | -                                      | (8,000    | ) |
| Research and development                              | 1,000                                  | -         |   |
|   | 1,000                                  | (8,000    | ) |
|   |  |           |   |
| Total share-based compensation expense                | \$188,000                              | \$377,000 |   |

As of October 31, 2012, there was \$862,000 of unrecognized non-cash compensation cost related to unvested options, which will be recognized over a weighted average period of 1.14 years. Also, as of October 31, 2012, there was \$14,000 of unrecognized non-cash compensation cost related to unvested restricted shares, which will be recognized over a weighted average period of 0.75 years.

We estimate the fair value of each option grant on the grant date using the Black-Scholes option valuation model with the following weighted-average assumptions:

For the three months ended October 31.

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|                         | 2012 |   | 2011        |     |
|-------------------------|------|---|-------------|-----|
|                         |      |   | 81.55% -    |     |
| Volatility              | 0.00 | % | 81.56       | %   |
| Risk-free interest rate | 0.00 | % | 0.97% - 1.3 | 32% |
| Dividend yield          | 0.0  | % | 0.0         | %   |
| Expected life           | 0    |   | 5.05 year   | rs  |

No options were granted during the three months ended October 31, 2012.

#### 12. 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.

#### 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," "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.

Unless otherwise noted, all information in this Item 2 regarding share amounts of our common stock and prices per share of our common stock has been adjusted to reflect the application of the one-for-eight reverse stock split of our common stock that we effected on August 14, 2012, as further described below.

#### Overview

#### Company Overview

We are focused on the discovery, development and commercialization of bioscience products that provide solutions to global health challenges. Our technology platform is based on stabilized ionic silver, and our initial products contain silver dihydrogen citrate, or SDC. SDC is a broad-spectrum, non-toxic antimicrobial. We manufacture and sell SDC-based disinfecting and sanitizing products, which are registered by the Environmental Protection Agency, or EPA, to distributors and end users. We also manufacture and sell various SDC-based formulations to manufacturers for use as a raw material in the production of personal care and other products. We believe our technology platform has potential application in a number of industries, and we have ongoing research and development projects in food processing, agriculture, water treatment, pharmaceuticals, and oil and gas.

Our goal is to become a sustainable company by using our proprietary technology platform to deliver leading antimicrobial products to multiple industries. We manufacture and sell SDC-based products for end use, products preserved with SDC and SDC as a raw material for manufacturing use. Our current products are as follows:

| Product Name                           | Product Use                | EPA Registration |
|--|----------------------------|------------------|
| PURE Complete System:                  |                            |                  |
| PURE® Hard Surface                     | Disinfectant and sanitizer | SDC3A            |
| PURE Multi-Purpose Cleaner Concentrate | Cleaner                    | Not applicable   |
| PURE Floor Cleaner Concentrate         | Cleaner                    | Not applicable   |

| Axen® 30   | Disinfectant | Axen30         |
|------------|--------------|----------------|
| Axenohl®   | Raw material | Axenohl        |
| Silvérion® | Raw material | Not applicable |

#### **PURE Complete System**

Our PURE Complete System is comprised of PURE® Hard Surface and our two new cleaning products that were launched as companion products to PURE Hard Surface, PURE Multi-Purpose Cleaner and PURE Floor Cleaner. The PURE Complete System offers a comprehensive, cost-effective and user-friendly product line to end-users, janitorial service providers and the distributors that supply them.

#### PURE® Hard Surface

PURE® Hard Surface is our patented and EPA-registered 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 and Floor Cleaner Concentrates

Our recently launched cleaning products, PURE Floor Cleaner and PURE Multi-Purpose Cleaner, are environmentally responsible cleaning products that are protected by SDC, a natural, non-toxic antimicrobial. SDC ensures the quality and safety of PURE Floor Cleaner and PURE Multi-Purpose Cleaner without human or environmental exposure to toxic chemical preservatives. PURE Floor Cleaner and PURE Multi-Purpose Cleaner are non-toxic and non-flammable and contain no EDTA, phosphates, ammonia or bleach as well as no VOCs or NPEs. PURE Floor Cleaner and PURE Multi-Purpose Cleaner provide professional strength cleaning in a concentrate formula that yields a 1:128 use dilution that is safe for use on all resilient surfaces.

#### Axen® 30

Axen®30 is our patented and EPA-registered hard surface disinfectant and is a predecessor product to PURE Hard Surface. Axen30 is sold by distributors under the private label brands SpectraSan24, PureGreen24, Critical Care, Mother Nature's Choice and Ag+ainst24. In prior years, we sold this product to other distributors that resold Axen30 under a variety of other private label brands.

#### Axenohl®

Axenohl® is our patented and EPA-registered antimicrobial formulation for use as a raw material 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®

Silvérion® is our patented antimicrobial formulation for use as a raw material 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.

We are a Delaware corporation and operate in one business segment.

#### Recent Developments

#### Reverse Stock Split

On August 13, 2012, we filed a Certificate of Amendment to our Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a reverse stock split of our issued and outstanding common stock, \$0.01 par value per share, at a ratio of one-for-eight. The reverse stock split was approved by stockholders holding a majority of our outstanding voting power at our annual meeting of stockholders held on July 31, 2012. The reverse stock split became effective as of the close of trading on August 14, 2012 and shares of our common stock commenced trading on a post-reverse split basis as of the opening of trading on August 15, 2012, with each eight (8) issued and outstanding shares of our common stock automatically combined and converted into one (1) issued and outstanding

share of our common stock. The reverse stock split affected all issued and outstanding shares of our common stock, as well as common stock underlying stock options, warrants, and convertible notes outstanding immediately prior to the effectiveness of the reverse stock split and the number of shares reserved for issuance under our equity incentive plan, but did not affect the number of authorized shares of our common stock. As a result of the reverse stock split, the number of outstanding shares of our common stock was reduced from approximately 57.8 million immediately prior to the effectiveness of the reverse stock split to approximately 7.2 million immediately thereafter.

#### **Underwritten Public Offering**

On September 17, 2012, we closed an underwritten public offering of an aggregate of 4,341,615 shares of our common stock, including shares issued pursuant to the exercise of the underwriter's overallotment option, at a price to the public of \$1.10 per share. The offering was made pursuant to our registration statement on Form S-3 (Registration No. 333-182475), which became effective on July 31, 2012, and a preliminary and final prospectus supplement filed with the Securities and Exchange Commission, or SEC, on September 4, 2012 and September 13, 2012, respectively. The shares were sold pursuant to an underwriting agreement between us and Aegis Capital Corp. The gross proceeds from the offering were approximately \$4,776,000 and, after deducting \$549,000 therefrom for transaction costs, including discounts, commissions, and other offering expenses, such as legal and accounting fees, the net proceeds to us from the offering were approximately \$4,227,000.

#### Bridge Loan

Pursuant to a securities purchase agreement entered into on June 26, 2012, on 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 an aggregate of 54,878 shares of our common stock and warrants to acquire up to 128,046 shares of our common stock issued to such lenders). We refer to such transaction as the "Bridge Loan". Pursuant to the terms of the Notes and 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 have been repaid in accordance with such terms.

#### NASDAQ Deficiency

As previously disclosed in certain of our reports filed with the SEC, commencing in September 2011, we have received a series of deficiency letters from the NASDAQ Stock Market, or NASDAQ, and have undergone a lengthy appeal process with a NASDAQ Hearings Panel, or the Panel, relating to the potential delisting of our common stock from the NASDAQ Capital Market for noncompliance with several listing rules and standards. After receiving several letters from the Panel granting our continued listing contingent upon our satisfaction of certain specified conditions, on September 21, 2012, we received a final decision letter notifying us that the NASDAQ Listing Qualifications Staff had concluded that we had satisfied those conditions and regained compliance with all applicable listing requirements, and accordingly had determined to continue the listing of our securities on The NASDAQ Capital Market and to close the matter of our delisting on that date.

On October 1, 2012, we received a new deficiency letter from NASDAQ regarding our noncompliance with NASDAQ's audit committee membership requirements as a result of the death of our former director and Audit Committee member Gregory Barnhill. Consistent with applicable NASDAQ listing rules, NASDAQ has granted us the following cure period to regain compliance with NASDAQ's audit committee membership requirements: (i) until the earlier of our next annual meeting of stockholders or September 14, 2013, or (ii) if our next annual meeting of stockholders is held before March 13, 2013, until March 13, 2013. We intend to appoint an independent director who satisfies NASDAQ's requirements for membership on our Audit Committee as promptly as practicable to rectify this noncompliance.

#### 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 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, 2012 and 2011

#### **Net Product Sales**

Net product sales were \$110,000 and \$257,000 for the three months ended October 31, 2012 and 2011, respectively. The decrease of \$147,000 was primarily attributable to sales to one customer. This customer accounted for zero and \$153,000 of net product sales for the three months ended October 31, 2012 and 2011, respectively

For the three months ended October 31, 2012, two individual customers each accounted for 10% or more of our net product sales. One customer accounted for 47% 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: 53% U.S. and 47% foreign.

For the three months ended October 31, 2011, two individual customers each accounted for 10% or more of our net product sales. One customer accounted for 60% and the other for 17%. No other individual customer accounted for 10% or more of our net product sales. The geographic breakdown of net product sales is as follows: 93% U.S. and 7% foreign.

#### Cost of Goods Sold

Cost of goods sold was \$31,000 and \$129,000 for the three months ended October 31, 2012 and 2011, respectively. The decrease of \$98,000 was attributable to decreased net product sales, as well as an inventory charge in the three months ended October 31, 2011. The inventory charge represents costs incurred by us to rework certain finished goods inventory, as well as a write-off of certain packaging inventory.

Gross margin as a percentage of net product sales, or gross margin percentage, was 72% and 50% for the three months ended October 31, 2012 and 2011, respectively. The increase in gross margin percentage was attributable to the inventory charge recognized in 2011, as noted above. Gross margin percentage, excluding the inventory charge, was 72% and 75% for the three months ended October 31, 2012 and 2011, 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, 2011 as compared to current year.

#### Selling, General and Administrative Expense

Selling, general and administrative expense was \$1,476,000 and \$1,997,000 for the three months ended October 31, 2012 and 2011, respectively. The decrease of \$521,000 was primarily attributable to a decrease in stock option expense, legal fees, depreciation, amortization, and professional service costs.

#### Research and Development Expense

Research and development expense was \$395,000 and \$493,000 for the three months ended October 31, 2012 and 2011, respectively. The decrease of \$98,000 was primarily attributable to decreases in personnel costs and related expenses, third-party research and testing activities, and stock option expense.

#### Change in Derivative Liability

Change in derivative liability for the three months ended October 31, 2012 and 2011 was \$228,000 and zero, respectively. The increase is due to the issuance of warrants with anti-dilution provisions during the year ended July 31, 2012, offset by a decrease related to the cancellation of the conversion feature associated with the secured convertible promissory notes that we issued in July 2012 in connection with the Bridge Loan.

#### Interest Expense

Interest expense for the three months ended October 31, 2012 and 2011 was \$588,000 and zero, respectively. The increase is primarily attributable to non-cash amortization of debt discounts related to the secured convertible promissory notes that we issued in July 2012 in connection with the Bridge Loan.

#### Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through public and private offerings of securities, revenue from product sales and license agreements and proceeds from the sale of a division. We have a history of recurring losses, and as of October 31, 2012 we have incurred a cumulative net loss of \$64,654,000.

On September 17, 2012, we closed an underwritten public offering of an aggregate of 4,341,615 shares of our common stock, including shares issued pursuant to the exercise of the underwriter's overallotment option, at a price to the public of \$1.10 per share. The gross proceeds from the offering were approximately \$4,776,000 and, after deducting \$549,000 therefrom for transaction costs, including discounts, commissions, and other offering expenses, such as legal and accounting fees, the net proceeds to us from the offering were approximately \$4,227,000. We used \$1,333,000 of the net proceeds from the offering to pay the full amount of the indebtedness we incurred in connection with the Bridge Loan. We intend to use the remaining proceeds from the offering for working capital and general corporate purposes.

Pursuant to a securities purchase agreement entered into on June 26, 2012, on 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 Notes in an aggregate principal amount of \$1,333,000 and certain other consideration (including an aggregate of 54,878 shares of our common stock and warrants to acquire up to 128,046 shares of our common stock issued to such lenders) in the Bridge Loan transaction. 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 have been repaid in accordance with such terms.

During the three months ended October 31, 2012, there were no exercises of stock options or warrants.

As of October 31, 2012, we had \$2,450,000 in cash and cash equivalents compared to \$877,000 in cash and cash equivalents as of July 31, 2012. The net increase in cash and cash equivalents was primarily attributable to proceeds from our issuance of common stock in the public offering noted above, partially offset by our repayment of amounts owed under the Bridge Loan. Additionally, as of October 31, 2012, we had \$2,590,000 of current liabilities, and \$2,094,000 in accounts payable, compared to \$3,637,000 of current liabilities, and \$1,946,000 in accounts payable as of July 31, 2012. The net decrease in current liabilities was primarily attributable to repayment of the Bridge Loan, and the net increase in accounts payable was primarily attributable to timing.

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 do not have, and may never have, significant cash inflows from product sales or from other sources of revenue to fund our operations. Accordingly, 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; reducing the exercise price of outstanding warrants; and entering into partnerships, licenses, or other arrangements with third parties, which may include licensing to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves. 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 will 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 significantly modify our business model and operations to reduce spending to a sustainable level, which may include delaying, scaling back or eliminating some or all of 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. If adequate funds are not available when needed, we may be required to reduce or cease operations altogether.

We believe our recent 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, our estimates of our operating expenses and working capital requirements could be incorrect, and we may use our cash resources faster than we presently anticipate. Further, 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.

Product sales are recognized when delivery of the products has occurred, 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 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 Controls

There were no changes in our internal controls over financial reporting during the three months ended October 31, 2012 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

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, 2012 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 will need to raise additional capital in order to continue operating our business and continue to develop new products and technologies, and such additional funds may not be available on acceptable terms or at all

We have not generated, and may never generate, significant cash from operations and must raise additional funds in order to continue operating our business. Our cash outflows for operating activities and for investments in patents and fixed assets were \$1.3 in the three months ended October 31, 2012, and \$5.8 million in the year ended July 31, 2012. Cash outflows may be greater or lesser in future periods.

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

- the acceptance of, and demand for, our products;
- our success and that 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;
  - the extent to which we invest in new technology, testing and product development;
- the timing of vendor payments and 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 in which we participate, if any; and
    - the costs associated with the continued operation, and any future growth, of our business.

We will need to increase our liquidity and capital resources. We expect to rely in the near term on funds raised pursuant to an underwritten public offering closed on September 17, 2012 of an aggregate of 4,341,615 shares of our

common stock (including shares issued pursuant to the exercise of the underwriter's overallotment option), as well as funds raised pursuant to other recent private placement offerings of our common stock and other equity (although we have used certain of those funds to repay certain indebtedness as required by the repayment terms thereof). However, we anticipate that we will require additional capital in future periods to continue our operations and further develop our products and technologies. Until we can generate a sufficient amount of revenue to finance our cash requirements, which we may never do, we expect to increase our liquidity and capital resources by one or more measures, which may include reducing operating expenses; raising additional financing through the issuance of debt, equity, or convertible securities; reducing the exercise price of outstanding warrants; entering into partnerships, licenses, or other arrangements with third parties, which may include licensing to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves; 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 will be able to obtain capital on terms acceptable to us, or at all. Insufficient funds would have 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 significantly modify our business model and/or reduce our operations, which could include delaying, scaling back or eliminating some or all of 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. If funding is not available when needed and we are not able to modify our operations to sufficiently reduce spending, then we may be required to cease operations altogether. Modification of our business model and operations could result in an impairment of assets, the effects of which cannot be determined at this time. Furthermore, if we continue to issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges that are superior to those of our existing stockholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization.

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

We had a loss of \$2.2 million for the three months ended October 31, 2012, and a loss \$8.9 million for the year ended July 31, 2012. As of October 31, 2012, we had an accumulated deficit of approximately \$64.7 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 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.

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 our current fiscal year and 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 recently effected, 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.

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 7, 2012, in addition to 10,986,170 shares of common stock issued and outstanding, we currently have 317,105 shares reserved for issuance under equity compensation plans for vested and unvested stock options. We also have 467,454 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 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.

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

We rely in part, and expect to rely in the future, on 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 these 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 inanimate surfaces, we are pursuing potential applications of our SDC technology as a broad-spectrum antimicrobial for use in human and veterinary healthcare products. Any product that may be developed in these fields may be delayed or may never achieve regulatory approval or be commercialized. 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.

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.

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. Obtaining FDA approval is a complicated and expensive process and such approvals may never be obtained for any SDC products. If FDA 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 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.

We are subject to substantial regulation related to quality standards applicable to our manufacturing and quality processes, and our 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 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.

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.

If a natural or man-made disaster strikes our manufacturing facility, we may be unable to manufacture our products for a substantial amount of time and our sales and profitability may decline

Our sole manufacturing facility and the manufacturing equipment we use to produce our products would be costly to replace and could require substantial lead-time to repair or replace. The facility may be affected by natural or man-made disasters and in the event our facility or our manufacturing equipment were affected by a disaster, we would be forced to set up alternative production capacity or rely on third party manufacturers that may not match our

quality standards or be able to meet customer requirements and to which we would have to disclose our trade secrets. Although we possess insurance for damage to our property and the disruption of our business, such insurance may not be sufficient to cover all of our potential losses, may not continue to be available to us on acceptable terms, or at all, and may not address the marketing and goodwill consequences of our potential inability to provide products to meet customers' requirements.

If we are unable to obtain, maintain or defend patent and other intellectual property ownership rights relating to our technology, we or our collaborators and distributors may not be able to develop and market 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 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 nine 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, legal standards relating to the validity, enforceability and scope of patent protection and protections of other intellectual property and proprietary rights in the U.S. are uncertain. Additionally, 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. For instance, 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 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 these 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.

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 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.

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. 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. 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.

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 or The NASDAQ Stock Market, or NASDAQ, and/or our common stock could be delisted. 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.

We are dependent on our management team, and we recently appointed a new Chief Financial Officer

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, other than Michael L. Krall, our President and Chief Executive Officer. The policy we have on Mr. Krall would likely not provide a benefit sufficient to offset the financial losses resulting from the loss of Mr. Krall's future services. 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.

Effective November 5, 2012, we appointed Peter Wulff as our Chief Financial Officer. With his appointment, Mr. Wulff also serves as our Principal Financial Officer and Principal Accounting Officer. Mr. Wulff has not previously worked with our existing executive management team. This management transition may result in some disruption of our business. If our new Chief Financial Officer is unable to work with our existing management team to implement our strategies, manage our operations and accomplish our objectives, our business, operations and financial results could be impaired.

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 continue to 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 anticipate significant changes to the composition of our Board of Directors in the near term

Effective July 9, 2012, we entered a settlement agreement in connection with the termination of certain litigation and the withdrawal of a proxy solicitation in opposition to our slate of nominees for election as directors on our Board at our 2012 annual meeting of stockholders held on July 31, 2012. Pursuant to the terms of that settlement agreement, we are obligated to make good faith efforts to replace one member of our Board with a new independent director and add to our Board an additional independent director within 12 months after the date of our 2012 annual meeting of stockholders. In addition, one of our independent directors and a member of our Audit Committee and our Compensation Committee, Gregory Barnhill, unexpectedly died on September 14, 2012. Accordingly, we anticipate significant changes to the composition of our Board and the committees thereof in the near term. We may not be able to identify, attract and retain qualified and suitable candidates for seats on our Board and certain Board committees who meet the requirements set forth in the settlement agreement and applicable SEC and NASDAQ listing rules in a timely manner, or at all. If we are unable to do so, we could be subject to litigation relating to the settlement agreement or sanctions by applicable regulatory authorities, including without limitation the potential delisting of our common stock from The NASDAQ Capital Market for failure to comply with certain board and board committee requirements. Further, even if we do identify and successfully attract new directors to serve on our Board, such transition in the composition of our Board and its committees could result in inefficiencies in Board activity, disagreements regarding our business models or other operational strategies, and disruptions to our business.

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.

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, 2012, we had federal and California tax net operating loss carry-forwards of approximately \$70.7 million and \$60.0 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 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, 2031. In the years ending July 31, 2013 and 2014, \$1.9 million of our federal net operating loss carry-forwards will expire, and the balance of our current federal net operating loss carry-forwards will expire between July 31, 2018 and July 31, 2031. Our California tax loss carry-forwards will begin to expire in the year ending July 31, 2014, and will completely expire in the year ending July 31, 2031. 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 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 December 7, 2012, the closing market price of our common stock ranged from \$0.77 per share to \$4.00 per share, and the monthly trading volume varied from approximately 298,000 shares to 11,042,000 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 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 and our ability to maintain the listing of our common stock on a national securities exchange;
- the introduction of new products or services, or product or service enhancements by us or our competitors; elevelopments 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 NASDAQ Capital Market, 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.

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 may not be able to maintain our NASDAQ listing

In April 2008, we obtained a listing for our common stock on The NASDAQ Capital Market. In order to maintain our listing, we must meet certain listing standards that include maintaining minimum thresholds of stockholders' equity, market value of our listed or publicly held securities, number of publicly held shares, bid price for our common stock, number of stockholders, number of market makers, and our net income. In addition, certain of our corporate governance policies are required to remain compliant with standards determined, and amended from time to time, by NASDAQ.

As previously disclosed in certain of our reports filed with the SEC, during the period between September 2011 and September 2012, we received a series of deficiency letters from NASDAQ and endured a lengthy appeal process with a NASDAQ Hearings Panel, or the Panel, relating to the potential delisting of our common stock from The NASDAQ Capital Market for noncompliance with several listing rules and standards. Although NASDAQ determined on September 21, 2012 that we had regained compliance with applicable listing standards and closed the matter of our delisting on that date, on October 1, 2012 we received an additional deficiency letter from NASDAQ notifying us of our noncompliance with NASDAQ listing rules related to audit committee membership requirements. Although NASDAQ has granted us a cure period in connection with our most recent noncompliance, we may not be able to regain or maintain our compliance with applicable NASDAQ requirements in the future and our securities could be delisted from The NASDAQ Capital Market. Such delisting could cause our common stock to be classified as "penny stock" and decrease the liquidity of our common stock, among other potentially detrimental consequences, any of which could significantly impact your ability to sell your shares of our common stock or to sell your shares at a price that you may deem to be acceptable. Further, should our securities fail to be listed on The NASDAQ Capital Market at any time in the future, our ability to attract new or certain types of investors and raise additional capital could be adversely affected, which could harm our business and financial condition.

Our recently effected one-for-eight reverse stock split has not resulted in a lasting increase in our stock price at an equivalent ratio

On August 14, 2012 and commencing with the opening of trading on August 15, 2012, we effected a one-for-eight reverse stock split of our outstanding shares of common stock. We effected the reverse stock split in large part to increase the per share price of our common stock in order to regain compliance with certain NASDAQ minimum bid price requirements. Although the trading price of our common stock increased by a corresponding ratio in the weeks immediately following the effectuation of the reverse stock split, as of December 7, 2012, the closing price of our common stock on The NASDAQ Capital Market had dropped to \$0.86. If the trading price of our common stock continues to decline, we could again be at risk for the delisting of our securities from The NASDAQ Capital Market due to our failure to satisfy NASDAQ's \$1.00 per share minimum bid price requirement or other listing standards or rules. Additionally, the decline in our stock price after the reverse stock split may materially reduce our ability to attract new investors in our securities, particularly institutional investors that are frequently subject to investment restrictions with respect to securities trading below a pre-established per share trading price. Further, the liquidity of our outstanding common stock may be adversely affected by the reverse stock split due to the one-for-eight reduction

in the number of outstanding shares and the increase in our stock price at a significantly lesser ratio, which may impact your ability to sell your shares of our common stock at a price you consider acceptable.

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 recently effected 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 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)
- 10.1 Second Addendum to Transaction Documents, dated August 20, 2012, by and between Pure Bioscience, Inc. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on September 14, 2012)
- 10.2 Third Addendum to Transaction Documents, dated August 20, 2012, by and between Pure Bioscience, Inc. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on September 14, 2012)
- 10.3 Underwriting Agreement, dated September 11, 2012, by and between Pure Bioscience, Inc. and Aegis Capital Corp. (incorporated by reference to Exhibit 1.1 of the Current Report on Form 8-K filed with the SEC on September 13, 2012)
- 10.4 Form of Underwriter Warrant (Incorporated by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the SEC on September 13, 2012)
- 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
- 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, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets at October 31, 2012 and July 31, 2012; (ii) Consolidated Statements of Operations for the three months ended October 31, 2011 and 2012; (iii) Consolidated Statements of Cash Flows for the three months ended October 31, 2011 and 2012; and (iv) Notes to Consolidated Financial Statements.

<sup>\*</sup> 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: December 11, 2012 By: /s/ MICHAEL L. KRALL

Michael L. Krall, President / Chief Executive

Officer

(Principal Executive Officer)

Date: December 11, 2012 By: /s/ PETER C. WULFF

Peter C. Wulff, Chief Financial Officer (Principal Financial and Accounting Officer)