

PURE BIOSCIENCE, INC.
Form 10-Q
December 15, 2011

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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED OCTOBER 31, 2011

☐ 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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☐ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of December 13, 2011, there were 41,521,750 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, 2011

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Item 1. Financial Statements

Pure Bioscience, Inc.
Consolidated Balance Sheets

	October 31, 2011 (Unaudited)	July 31, 2011
Assets		
Current assets		
Cash and cash equivalents	\$ 992,000	\$ 1,794,000
Accounts receivable, net	119,000	50,000
Inventories, net	850,000	861,000
Prepaid expenses	189,000	100,000
Total current assets	2,150,000	2,805,000
Property, plant and equipment, net	357,000	426,000
Patents, net	1,908,000	1,917,000
Total assets	\$ 4,415,000	\$ 5,148,000
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 1,025,000	\$ 677,000
Accrued liabilities	348,000	258,000
Total current liabilities	1,373,000	935,000
Deferred rent	2,000	6,000
Total liabilities	1,375,000	941,000
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		
41,148,206 issued and outstanding at October 31, 2011, and		
40,034,659 issued and outstanding at July 31, 2011	411,000	400,000
Additional paid-in capital	58,600,000	57,417,000
Accumulated deficit	(55,971,000)	(53,610,000)
Total stockholders' equity	3,040,000	4,207,000
Total liabilities and stockholders' equity	\$ 4,415,000	\$ 5,148,000

See accompanying notes.

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

	Three months ended October 31,	
	2011	2010
Net product sales	\$ 257,000	\$ 23,000
Operating costs and expenses		
Cost of goods sold	129,000	10,000
Selling, general and administrative	1,997,000	1,535,000
Research and development	493,000	502,000
Total operating costs and expenses	2,619,000	2,047,000
Loss from operations	(2,362,000)	(2,024,000)
Other income (expense)		
Interest income	1,000	2,000
Total other income (expense)	1,000	2,000
Net loss	\$ (2,361,000)	\$ (2,022,000)
Basic and diluted net loss per share	\$ (0.06)	\$ (0.06)
Shares used in computing basic and diluted net loss per share	40,370,592	35,671,933

See accompanying notes.

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

	Three months ended October 31,	
	2011	2010
Operating activities		
Net loss	\$ (2,361,000)	\$ (2,022,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	377,000	308,000
Depreciation and amortization	117,000	118,000
Changes in operating assets and liabilities:		
Accounts receivable	(69,000)	(110,000)
Inventories	11,000	(122,000)
Prepaid expenses	8,000	70,000
Accounts payable and accrued liabilities	438,000	190,000
Deferred revenue	-	345,000
Deferred rent	(4,000)	(2,000)
Net cash used in operating activities	(1,483,000)	(1,225,000)
Investing activities		
Investment in patents	(39,000)	(40,000)
Net cash used in investing activities	(39,000)	(40,000)
Financing activities		
Net proceeds from the sale of common stock	720,000	2,367,000
Net proceeds from exercise of stock options and warrants	-	385,000
Net cash provided by financing activities	720,000	2,752,000
Net increase (decrease) in cash and cash equivalents	(802,000)	1,487,000
Cash and cash equivalents at beginning of period	1,794,000	2,193,000
Cash and cash equivalents at end of period	\$ 992,000	\$ 3,680,000
Supplemental disclosure of cash flow information		
Cash paid for taxes	\$ 1,000	\$ -
Supplemental disclosure of non-cash investing and financing activities		
Common stock issued for prepaid services	\$ 97,000	\$ -

See accompanying notes.

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 has no business and no material assets or liabilities and there have been no significant transactions related to ETIH2O 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, 2011 are not necessarily indicative of the results that may be expected for other quarters or the year ending July 31, 2012. The July 31, 2011 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, 2011 included in our Annual Report on Form 10-K covering such period filed with the Securities and Exchange Commission, or SEC.

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.

Certain reclassifications have been made to prior period amounts to conform to current period presentation. These reclassifications did not have an impact on our results of operations or financial condition for the periods presented.

2. Liquidity

Since our inception, we have financed our operations through public and private offerings of securities, revenue from product sales and license agreements, proceeds from the sale of a division and interest income from invested cash balances. We have a history of recurring losses, and we have incurred a cumulative net loss of \$55,971,000.

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 will need to increase our liquidity and capital resources in the near term by one or more measures. These measures may include, but are not limited to, the following: reducing operating expenses; obtaining financing through the issuance of equity, debt, or convertible securities; entering into partnerships, licenses, or other arrangements with third

parties; and reducing the exercise price of outstanding warrants. 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 will be able to obtain capital on terms acceptable to us, or at all.

If we are unable to obtain sufficient capital in the near term, 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 delay, scale back or eliminate some or all of our research and development programs, to license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, or to reduce or cease operations. If adequate funds are not available when needed, we may be required to significantly modify our business model and operations to reduce spending to a sustainable level.

We believe our current efforts to raise capital, including our recent agreements with Lincoln Park (summarized in Note 10 below), our current efforts to market and sell our products, and our ability to significantly reduce expenses, will provide sufficient cash resources to satisfy our needs over the next 12 months. However, we do not yet have, and we may never have, significant cash inflows from product sales or from other sources of revenue to offset our ongoing and planned investments in corporate infrastructure, research and development projects, regulatory submissions, business development activities, and sales and marketing, among other investments. Some or all of our ongoing or planned investments may not be successful. In addition, irrespective of our cash resources, we may be contractually or legally obligated to make certain investments which cannot be postponed.

3. Net Loss Per Share

Basic loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period. Diluted loss per share is calculated by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. For the purposes of this calculation, stock options and warrants are considered to be common share equivalents, and are determined using the treasury stock method. Common share equivalents are only included in the calculation of diluted loss per share when their effect is dilutive. Because we have incurred a net loss for all the periods presented, the effect of common share equivalents is anti-dilutive, and there is no difference between basic loss per share and diluted loss per share. As of October 31, 2011 and 2010, the number of stock options and warrants not included in the computation totaled 4,396,850 and 7,409,100, 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 quarters ended October 31, 2011 and 2010, 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, 2011	July 31, 2011
Raw materials	\$ 556,000	\$ 498,000
Finished goods	294,000	363,000
	\$ 850,000	\$ 861,000

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 quarters ended October 31, 2011 and 2010, no impairment of long-lived assets was indicated or recorded.

7. Common Stock

On October 24, 2011, we entered into a one year service agreement for investor relations services. We issued 150,000 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.

In April 2011, we entered into a sales agreement with an investment banking firm. On December 14, 2011, we terminated such sales agreement, as permitted by the terms thereof. See Note 10 below. Under the terms of the sales agreement, we were permitted to offer and sell shares of our common stock having an aggregate offering price of up to \$7,000,000. The sales were made, from time to time, through the investment bank in “at the market” offerings, as defined by the SEC, and were made pursuant to our effective shelf registration statement previously filed with the SEC. During the quarter ended October 31, 2011, we sold 963,547 shares of our common stock pursuant to these offerings, for net proceeds of \$720,000. As of October 31, 2011, we had \$2,913,458 remaining on our shelf registration statement, which expires in May 2012.

8. Share-Based Compensation

The following table summarizes share-based compensation expense related to stock options and restricted stock awards for the three months ended October 31, 2011 and 2010:

	For the three months ended October 31,	
	2011	2010
Share-based compensation for employees and directors:		
Selling, general and administrative	\$ 322,000	\$ 246,000
Research and development	63,000	37,000
	385,000	283,000
Share-based compensation for consultants:		
Selling, general and administrative	(8,000)	33,000
Research and development	-	(8,000)
	(8,000)	25,000
Total share-based compensation expense	\$ 377,000	\$ 308,000

As of October 31, 2011, there was \$1,760,000 of unrecognized non-cash compensation cost related to unvested options, which will be recognized over a weighted average period of 1.78 years. Also, as of October 31, 2011, there was \$19,000 of unrecognized non-cash compensation cost related to unvested restricted shares, which will be recognized over a weighted average period 0.22 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,	
	2011	2010
Volatility	81.55% - 81.56 %	82.18% - 89.91 %
Risk-free interest rate	0.97 % - 1.32 %	0.48 % - 2.00 %
Dividend yield	0.0 %	0.0 %
Expected life	5.05 years	3.24 years

9. Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board, or FASB, issued ASU No. 2011-04, "Fair Value Measurement" to amend the accounting and disclosure requirements on fair value measurements. This ASU limits the highest-and-best-use measure to nonfinancial assets, permits certain financial assets and liabilities with offsetting positions in market or counterparty credit risks to be measured at a net basis, and provides guidance on the applicability of premiums and discounts. Additionally, this update expands the disclosure on Level 3 inputs by requiring quantitative disclosure of the unobservable inputs and assumptions, as well as description of the valuation processes and the sensitivity of the fair value to changes in unobservable inputs. ASU No. 2011-04 is to be applied prospectively and is effective during interim and annual periods beginning after December 15, 2011 (our quarter beginning February 1, 2012). We do not expect the adoption of this guidance to have a material effect on our consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05, "Presentation of Comprehensive Income". This ASU presents an entity with the option to present the total of comprehensive income, the components of net income, and the component of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. This update eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity/deficit. The amendments in this update do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. ASU No. 2011-05 should be applied retrospectively and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 (our quarter beginning February 1, 2012). As ASU No. 2011-05 relates only to the presentation of Comprehensive Income, we do not expect the adoption of this guidance to have a material effect on our consolidated financial statements.

10. Subsequent Events

At the Market Offerings and Termination of Sales Agreement

From November 1, 2011 through December 13, 2011, we sold 373,544 shares of our common stock in at the market offerings pursuant to our sales agreement with an investment banking firm as detailed further in Note 7 above. Net proceeds from the sale of these shares were \$228,000. Effective as of December 14, 2011, we terminated the sales agreement pursuant to which such at the market offerings were made. As a result of such termination, there will be no future sales of our common stock under the sales agreement. As of December 13, 2011, we had \$2,674,340 remaining on our shelf registration statement.

Agreements with Lincoln Park; Engagement Letter with Wharton Capital Markets

On December 14, 2011, we entered into a purchase agreement, or the \$7.5M Purchase Agreement, and a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to \$7,500,000 in shares of our common stock from time to time over the 36-month period commencing on the date of the effectiveness of a registration statement for the resale of such shares that we must file with the SEC pursuant to the Registration Rights Agreement. We do not have the right to commence any sales to Lincoln Park under the \$7.5M Purchase Agreement until the SEC has declared effective the resale registration statement, but after such registration statement is declared effective, we may direct Lincoln Park, from time to time and at our sole discretion (subject to the terms and conditions thereof), to purchase shares of our common stock at a purchase price per share based on the prevailing market prices of our common stock immediately preceding each notice of sale to Lincoln Park. There is no upper limit on the price per share that Lincoln Park could be obligated to pay for our common stock under the \$7.5M Purchase Agreement, but in no event will such shares be sold to Lincoln Park at a price of less than \$0.25 per share. As consideration for its commitment to purchase shares of our common stock pursuant to the \$7.5M Purchase Agreement, we have issued to Lincoln Park 470,711 shares of our common stock at no cost to Lincoln Park. Such shares will be registered for resale pursuant to the registration statement that we must file pursuant to the \$7.5M Purchase Agreement and the Registration Rights Agreement.

On December 15, 2011, we entered into an additional purchase agreement, or the \$2.5M Purchase Agreement, with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to \$2,500,000 in shares of our common stock. Under the terms of the \$2.5M Purchase Agreement, Lincoln Park will initially purchase 1,347,709 shares of our common stock at a price per share of \$0.371 for an aggregate amount of \$500,000. Thereafter, we may, from time to time and at our sole discretion (subject to the terms and conditions thereof) over a 36-month period, direct Lincoln Park, to purchase shares of our common stock at a purchase price per share based on the prevailing market prices of our common stock immediately preceding each notice of sale to Lincoln Park. The shares sold to Lincoln Park pursuant to the \$2.5M Purchase Agreement will be made pursuant to our effective shelf registration statement previously filed with the SEC, as supplemented by our registration statement on Form S-3MEF. As with the

\$7.5M Purchase Agreement, there is no upper limit on the price per share that Lincoln Park could be obligated to pay for our common stock under the \$2.5M Purchase Agreement, but in no event will such shares be sold to Lincoln Park at a price of less than \$0.25 per share. As consideration for its commitment to purchase shares of our common stock under to the \$2.5M Purchase Agreement, we have issued to Lincoln Park an additional 156,904 shares of our common stock at no cost to Lincoln Park.

In connection with the sale of our common stock to Lincoln Park pursuant to the \$2.5M Purchase Agreement and the \$7.5M Purchase Agreement, subject to our receipt of written confirmation that the Corporate Finance Department of the Financial Industry Regulatory Authority, Inc., or FINRA, has determined not to raise any objection with respect to the fairness or reasonableness of the compensation terms of our arrangement with Wharton, we have agreed to pay a cash fee to Wharton Capital Markets LLC, or Wharton, pursuant to an engagement letter with Wharton dated December 8, 2011, or the Engagement Letter, in an amount equal to 6% of the aggregate gross proceeds to us from the issuance and sale of shares to be offered pursuant to our agreements with Lincoln Park. Such amounts will become due and payable to Wharton at the time that we actually receive funds from Lincoln Park pursuant to such agreements, provided that we have received such written confirmation of no objections from FINRA. Additionally, only upon our receipt of such written confirmation of no objections from FINRA, we have agreed to issue to Wharton or its designee a warrant to purchase 200,000 shares of our common stock with an exercise price of 110% of the closing sale price of our common stock on the date of the issuance of such warrant. Neither the warrant to be issued to Wharton nor the shares to be issued thereunder are to be registered for sale or resale under the Securities Act and will be issued in reliance on an exemption from registration under the Securities Act pursuant to Section 4(2) thereof.

The matters described in this Note 10 are described in more detail in our Current Report on Form 8-K, which we filed with the SEC on December 15, 2011. In addition, the \$2.5M Purchase Agreement, the \$7.5M Purchase Agreement, the Registration Rights Agreement and the Engagement Letter are each filed as exhibits to this Quarterly Report on Form 10-Q.

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

All references to "PURE," "we," "our," "us" and the "Company" refer to Pure Bioscience, Inc. and our wholly owned subsidiaries.

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," "show" 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 statements included elsewhere in this Quarterly Report on Form 10-Q.

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, and as a raw material for manufacturing use. Our current products are as follows:

Product Name	Product Use	EPA Registration
PURE® Hard Surface	Disinfectant and sanitizer	SDC3A
Axen™ 30	Disinfectant	Axen30
Silvérion®	Raw material	Not applicable
Axenohl™	Raw material	Axenohl

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.

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, Ag+ainst24 and IV-7. In prior years, we sold this product to other distributors that resold Axen30 under a variety of other private label brands.

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.

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.

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

Recent Developments

Termination of Sales Agreement

Effective as of December 14, 2011, we terminated our sales agreement with an investment banking firm pursuant to which we previously sold shares of our common stock in at the market offerings. As a result of such termination, there will be no future sales of our common stock under the sales agreement.

Agreements with Lincoln Park; Engagement Letter with Wharton Capital Markets

On December 14, 2011, we entered into a purchase agreement, or the \$7.5M Purchase Agreement, and a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park Capital Fund LLC, or Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to \$7,500,000 in shares of our common stock from time to time over the 36-month period commencing on the date of the effectiveness of a registration statement for the resale of such shares that we must file with the SEC pursuant to the Registration Rights Agreement. We do not have the right to commence any sales to Lincoln Park under the \$7.5M Purchase Agreement until the SEC has declared effective the resale registration statement, but after such registration statement is declared effective, we may direct Lincoln Park, from time to time and at our sole discretion (subject to the terms and conditions thereof), to purchase shares of our common stock at a purchase price per share based on the prevailing market prices of our common stock immediately preceding each notice of sale to Lincoln Park. There is no upper limit on the price per share that Lincoln Park could be obligated to pay for our common stock under the \$7.5M Purchase Agreement, but in no event will such shares be sold to Lincoln Park at a price of less than \$0.25 per share. As consideration for its commitment to purchase shares of our common stock pursuant to the \$7.5M Purchase Agreement, we have issued to Lincoln Park 470,711 shares of our common stock at no cost to Lincoln Park. Such shares will be registered for resale pursuant to the registration statement that we must file pursuant to the \$7.5M Purchase Agreement and the Registration Rights Agreement.

On December 15, 2011, we entered into an additional purchase agreement, or the \$2.5M Purchase Agreement, with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to \$2,500,000 in shares of our common stock. Under the terms of the \$2.5M Purchase Agreement, Lincoln Park will initially purchase 1,347,709 shares of our common stock at a price per share of \$0.371 for an aggregate amount of \$500,000. Thereafter, we may, from time to time and at our sole discretion (subject to the terms and conditions thereof) over a 36-month period, direct Lincoln Park, to purchase shares of our common stock at a purchase price per share based on the prevailing market prices of our common stock immediately preceding each notice of sale to Lincoln Park. The shares sold to Lincoln Park pursuant to the \$2.5M Purchase Agreement will be made pursuant to our effective shelf registration statement previously filed with the SEC, as supplemented by our registration statement on Form S-3MEF. As with the \$7.5M Purchase Agreement, there is no upper limit on the price per share that Lincoln Park could be obligated to pay for our common stock under the \$2.5M Purchase Agreement, but in no event will such shares be sold to Lincoln Park at a price of less than \$0.25 per share. As consideration for its commitment to purchase shares of our common stock under to the \$2.5M Purchase Agreement, we have issued to Lincoln Park an additional 156,904 shares of our common stock at no cost to Lincoln Park.

In connection with the sale of our common stock to Lincoln Park pursuant to the \$2.5M Purchase Agreement and the \$7.5M Purchase Agreement, subject to our receipt of written confirmation that the Corporate Finance Department of

the Financial Industry Regulatory Authority, Inc., or FINRA, has determined not to raise any objection with respect to the fairness or reasonableness of the compensation terms of our arrangement with Wharton, we have agreed to pay a cash fee to Wharton Capital Markets LLC, or Wharton, pursuant to an engagement letter with Wharton dated December 8, 2011, or the Engagement Letter, in an amount equal to 6% of the aggregate gross proceeds to us from the issuance and sale of shares to be offered pursuant to our agreements with Lincoln Park. Such amounts will become due and payable to Wharton at the time that we actually receive funds from Lincoln Park pursuant to such agreements, provided that we have received such written confirmation of no objections from FINRA. Additionally, only upon our receipt of such written confirmation of no objections from FINRA, we have agreed to issue to Wharton or its designee a warrant to purchase 200,000 shares of our common stock with an exercise price of 110% of the closing sale price of our common stock on the date of the issuance of such warrant. Neither the warrant to be issued to Wharton nor the shares to be issued thereunder are to be registered for sale or resale under the Securities Act and will be issued in reliance on an exemption from registration under the Securities Act pursuant to Section 4(2) thereof.

Richmont Corporation Proxy Fight

We have received a notice from Richmont Corporation, or Richmont, announcing its intended nomination of six individuals for election to our Board of Directors at our 2012 annual meeting. In the notice, Richmont confirmed its ownership of shares of our common stock, which represents less than one half of one percent of our outstanding common stock. If a proxy contest results from these actions by Richmont, our business could be adversely affected. Responding to proxy contests and other actions by insurgent stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees. Perceived uncertainties as to our future direction may impact our existing and potential collaborations or strategic relationships and may make it more difficult to attract and retain qualified personnel. If individuals are elected to our Board of Directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan.

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)

Other income (expense) consists of interest income and interest expense, as well as other non-operating transactions.

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 quarterly and annual 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 good indication of our future performance.

Comparison of the Three Months Ended October 31, 2011 and 2010

Net Product Sales

Net product sales were \$257,000 and \$23,000 for the three months ended October 31, 2011 and 2010, respectively. The increase of \$234,000 was primarily attributable to sales to a new customer, as well as increased sales to a few existing customers. The new customer accounted for \$153,000 of net product sales for the three months ended October 31, 2011.

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.

For the three months ended October 31, 2010, three individual customers each accounted for 10% or more of our net product sales. One customer accounted for 55%, another for 17%, and the third for 15%. No other individual customer accounted for 10% or more of our net product sales. The geographic breakdown of net product sales is as follows: 100% U.S. and 0% foreign.

Cost of Goods Sold

Cost of goods sold was \$129,000 and \$10,000 for the three months ended October 31, 2011 and 2010, respectively. The increase of \$119,000 was attributable to increased net product sales, as well as an inventory charge. 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 50% and 57% for the three months ended October 31, 2011 and 2010, respectively. The decrease in gross margin percentage was attributable to the inventory charge noted above. Gross margin percentage, excluding the inventory charge, was 75% and 57% for the three months ended October 31, 2011 and 2010, respectively. This increase in gross margin percentage was primarily attributable to the sale of higher margin formulations and packaging configurations of our products during the quarter ended October 31, 2011 as compared to prior year.

Selling, General and Administrative Expense

Selling, general and administrative expense was \$1,997,000 and \$1,535,000 for the three months ended October 31, 2011 and 2010, respectively. The increase of \$462,000 was primarily attributable to increases in professional fees, sales and marketing activities, personnel and related costs, and share-based compensation.

Research and Development Expense

Research and development expense was generally unchanged at \$493,000 and \$502,000 for the three months ended October 31, 2011 and 2010, respectively.

Liquidity and Capital Resources

Since our inception, we have financed our operations through public and private offerings of securities, revenue from product sales and license agreements, proceeds from the sale of a division and interest income from invested cash balances. We have a history of recurring losses, and we have incurred a cumulative net loss of \$55,971,000.

In April 2011, we entered into a sales agreement with an investment banking firm. Under the terms of the sales agreement, we were permitted to offer and sell shares of our common stock having an aggregate offering price of up to \$7,000,000. The sales were made, from time to time, through the investment bank in an “at the market” offering program, or ATM Program, as defined by the Securities and Exchange Commission, or SEC, and were made pursuant to our effective shelf registration statement previously filed with the SEC. During the three months ended October 31, 2011, we sold 963,547 shares of our common stock pursuant to the ATM Program, for net proceeds of \$720,000. As of October 31, 2011, we had \$2,913,458 remaining on our shelf registration, which expires in May 2012.

Effective as of December 14, 2011, we terminated the sales agreement in order to make available under our shelf registration statement additional funds for the consummation of the transactions contemplated by our agreements with Lincoln Park, as are further detailed above under the heading “Recent Developments”. As a result of such termination, there will be no future sales of our common stock under the sales agreement.

On December 14, 2011 and December 15, 2011, we entered into certain purchase agreements with Lincoln Park for future sales of our common stock. Other than an initial purchase of 1,347,709 shares of our common stock at a price per share of \$0.371 for an aggregate amount of \$500,000, future sales of our common stock under such agreements are not guaranteed. Although sales of our common stock to Lincoln Park are at our sole discretion, such sales are subject to our satisfaction of certain conditions and the market price of our common stock remaining at or above \$0.25 per share. We believe we will, if desirable, be able to raise sufficient capital under our agreements with Lincoln Park to provide us with adequate liquidity to fund our business plans. Sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us.

During the three months ended October 31, 2010, we received \$2,367,000 from the sale of common stock. We also received \$385,000 from the issuance of common stock upon the exercise of stock options and warrants.

As of October 31, 2011, we had \$992,000 in cash and cash equivalents, and \$119,000 in accounts receivable, compared to \$1,794,000 in cash and cash equivalents, and \$50,000 in accounts receivable as of July 31, 2011. The net decrease in cash and cash equivalents was primarily attributable to the use of cash to fund our operations, partially offset by proceeds from the issuance of common stock through securities offerings. The increase in accounts receivable was attributable to higher sales for the three months ended October 31, 2011.

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 will need to increase our liquidity and capital resources by one or more measures in the near term. These measures may include, but are not limited to, the following: reducing operating expenses; obtaining financing through the issuance of equity, debt, or convertible securities; entering into partnerships, licenses, or other arrangements with third parties; and reducing the exercise price of outstanding warrants. 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 will be able to obtain capital on terms acceptable to us, or at all.

If we are unable to obtain sufficient capital in the near term, 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 delay, scale back or eliminate some or all of our research and development programs, to license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, or to reduce or cease operations. If adequate funds are not available when needed, we may be required to significantly modify our business model and operations to reduce spending to a sustainable level.

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

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our audited 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. Upfront product and technology license fees under multiple-element arrangements are deferred and recognized over the period of such services or performance, if such arrangements require on-going 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. 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 an asset;
- 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 that 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 technologies. 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.

Recent Accounting Pronouncements

See Note 9 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 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 in 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 our fiscal quarter ended October 31, 2011 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

We filed suit against Richmond Sciences, LLC on June 29, 2011 in San Diego County Superior Court, Case No. 37-2011-00068549-CU-CO-EC asserting various causes of action to collect on outstanding invoices. Richmond Sciences, LLC and Richmond Holdings, LLC filed a cross-complaint for damages against us asserting contract, tort and statutory (trade secret) claims arising out of business dealings with us. We then filed a cross-complaint for compensatory and punitive damages against both Richmond entities asserting contract and fraud claims. We intend to vigorously pursue our claims and defend against the cross-claims. We are unable to determine to the likelihood or the amount of any adverse judgment in this litigation.

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. The impact and outcome of litigation, if any, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. Other than our ongoing litigation with Richmond, 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 affect 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. 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 \$1.5 million in the three months ended October 31, 2011, and \$6.4 million in the year ended July 31, 2011. Cash outflows may be greater in future periods.

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

- 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 of the collection of receivables, among other factors affecting our working capital;

the exercise of outstanding options or warrants to acquire our common stock;
the number and timing of acquisitions and other strategic transactions, if any; and
the costs associated with the continued operation, and any future growth, of our business.

We will need to increase our liquidity and capital resources. We have entered into agreements with Lincoln Park Capital Fund, LLC, or Lincoln Park, to raise capital through the issuance of our common stock, on which we expect to rely in the near term. However, pursuant to the terms of such agreements, we would be unable to sell shares to Lincoln Park if and when the market price of our common stock is below \$0.25 per share. Additionally, we anticipate that we may 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 (whether through our agreements with Lincoln Park or otherwise), or convertible securities, entering into partnerships, licenses, or other arrangements with third parties, reducing the exercise price of outstanding warrants, or through other means, any one of which could reduce the value to us, perhaps substantially, of our technology and its commercial potential. There is no guarantee that we will be able to obtain capital on terms acceptable to us, or at all. Insufficient funds would result in a material adverse effect on our business and operations and could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to competitive pressures or customer requirements, and further may require us to delay, scale back or eliminate some or all of our research and product development programs, license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, to reduce or cease operations, or otherwise significantly modify our business model or cease operations altogether. Modification of our business model and operations could result in an impairment of assets, which cannot be determined at this time. Furthermore, if we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience dilution, and in addition the new equity or debt securities may have rights, preferences and privileges that are superior to those of our existing stockholders. If we incur debt, it may increase our leverage relative to our earnings or to our equity capitalization.

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

We had a loss of \$2.4 million for the three months ended October 31, 2011, and a loss of \$8.3 million for the year ended July 31, 2011. As of October 31, 2011, we had an accumulated deficit of approximately \$56.0 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 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, or other issuances of our securities, 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 the year ending July 31, 2012 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 (including pursuant to our recent agreements with Lincoln Park or otherwise), debt financings or corporate collaborations and licensing arrangements. The extent to which we rely on Lincoln Park as a source of funding will depend on a number of factors including, without limitation, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. To the extent that we raise additional capital by issuing equity securities, our stockholders' ownership will be diluted. 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 additional 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.

Our authorized common stock is 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, or other transactions and corporate purposes that our Board of Directors, or Board, deems are in the Company's 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, the Board could sell shares of common stock in a private transaction to purchasers who would 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, the Board could also issue 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 13, 2011, in addition to 41,521,750 shares of common stock issued and outstanding, we currently have 2,887,750 shares reserved for issuance under equity compensation plans for vested and unvested stock options. We also have 1,509,100 shares reserved for issuance on the exercise warrants and we have agreed to issue, subject to certain conditions, an additional warrant exercisable for 200,000 shares to Wharton Capital Markets LLC for its assistance in arranging our agreements with Lincoln Park. 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 outstanding options and warrants granted under our stock option plans, and 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; our financial results may fluctuate and these fluctuations 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;
- we or our partners and/or distributors may not establish or maintain effective marketing programs and 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 issues.

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. Although we believe SDC has applications in multiple industries, we expect that sales of SDC 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, 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 new antimicrobial silver ion technology to industrial and consumer markets. These products 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 us, have a greater number of products on the market and have 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 that large chemical and pharmaceutical companies are consolidating 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 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 and have previously relied primarily on product distribution arrangements and/or sales and marketing services provided by third parties.

We recently developed and obtained EPA registration of our proprietary new brand, PURE™ Hard Surface disinfectant and food contact surface sanitizer, to resume direct control of our sales of this product through a restructuring of our sales strategy and operations. We intend to market and sell our PURE Hard Surface product into consumer, commercial and institutional markets, including the food processing industry, though both alternative and traditional distribution channels. We have recently resumed direct control of our sales and marketing of this product, which requires that we enact various operational changes in our business, including making significant investments in our own sales and marketing organization, and we expect in some cases to pay sales commissions to sales representatives. We may not be able to establish such sales, marketing, and distribution capabilities. If we are not able to successfully sell, market and distribute this product 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 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 applications of our SDC technology as a broad-spectrum antimicrobial for use in human and veterinary healthcare products. Any product developed 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. There can be no assurance that we will have sufficient resources to do. There also can be no assurance that if we continue to invest in additional infrastructure, we will be effective in expanding our operations or that our systems, procedures or controls will be adequate to support such expansion. In addition, we would need to provide additional sales and support services to our partners, potentially in multiple markets. 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 on 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 all 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, and regulatory review may 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.

Our SDC is a platform technology rather than a single use applied technology. As such, products developed from the platform 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 by other government agencies prior to marketing or sale in the U.S. or in foreign markets, such as the 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 of product approvals.

We intend to fund and manage certain of our EPA-regulated product development internally, in conjunction with our regulatory consultants and by 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 to the withdrawal of approval for us or our partners and distributors to market our products, in any or all jurisdictions, and/or our failure 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 governmental regulations and quality assurance guidelines could lead to temporary manufacturing shutdowns, product recalls or related field actions, product shortages, delays in product manufacturing, and significant cost to us. 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, declining sales, and/or 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, resulting 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 these products. Similarly, negative publicity could result in an increased number of product liability claims, whether or not these 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 they were affected by a disaster, we would be forced to set up alternative production capacity, or rely on third party manufacturers to whom 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 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, and 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 term. 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. 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. If certain of our proprietary rights cannot be, or are not sufficiently, protected by patents 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, 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 that our patents or other intellectual property rights are invalid and/or should not be enforced. Additionally, even if the validity of such rights is upheld, the court could refuse to stop a third party's infringing activity on the ground that such activities do not infringe our rights. The U.S. Supreme Court has recently revised certain tests regarding granting patents and assessing the validity of patents to make it more difficult to obtain patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a reexamination proceeding, or during litigation, under the revised criteria.

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 the 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 amounts 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.

We are currently involved in litigation, and such existing litigation, other 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. We are currently involved in litigation with Richmond Sciences, LLC and Richmond Holdings, LLC. On

June 29, 2011, we filed suit against Richmond Sciences, LLC asserting various causes of action to collect on an outstanding invoice. Richmond Sciences, LLC and Richmond Holdings, LLC filed a cross-complaint for damages against us asserting contract, tort and statutory (trade secret) claims arising out of business dealings with us. We then filed a cross-complaint for compensatory and punitive damages against both Richmond entities asserting contract and fraud claims. We intend to vigorously pursue our claims and defend against the cross-claims of the Richmond entities, which may divert management's attention and consequently have a negative impact on our business. Further, although we are unable to determine the length of the dispute or the likelihood or amount of any adverse judgment in this litigation and resources, our involvement in this litigation could be costly and adversely affect our financial condition.

Other lawsuits or actions could from time to time be filed against us and/or our executive officers and directors. For example, lawsuits 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.

We could be negatively affected as a result of a threatened proxy fight

We have received a notice from Richmond Corporation, or Richmond, and such notice, the Richmond Notice, announcing its intended nomination of six individuals for election to our Board of Directors at our 2012 annual meeting. In the Richmond Notice, Richmond confirmed its ownership of shares of our common stock, which shares represent less than one half of one percent of our outstanding common stock. If a proxy contest results from these actions by Richmond, our business could be adversely affected because:

- responding to proxy contests and other actions by insurgent stockholders can be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees;

- perceived uncertainties as to our future direction may impact our existing and potential collaborations or strategic relationships and may make it more difficult to attract and retain qualified personnel; and
- if individuals are elected to our Board of Directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan.

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. These additional regulatory costs and requirements will reduce our future profits or increase our future losses, and an increasing amount of management time and effort will be needed to meet our regulatory obligations.

We are required to evaluate our internal control systems in order to allow management to report on our internal controls as required by Section 404 of the Sarbanes-Oxley Act of 2002, and our management is required to 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 will face, 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, and we could therefore be subject to sanctions or investigation, or the delisting of our common stock, by regulatory authorities such as the SEC or the NASDAQ Capital Market. 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.

On June 9, 2011, we announced the appointment of Craig Johnson as our Chief Financial Officer, which became effective August 1, 2011. With his appointment, Mr. Johnson also serves as our Principal Financial Officer and Principal Accounting Officer. Mr. Johnson 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 planned 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 growth.

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 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, 2011, we had federal and California tax net operating loss carry-forwards of approximately \$64.7 million and \$54.6 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 complete assurance cannot be provided that the taxing authorities would not 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, 2030. In the years ending July 31, 2012 and 2013, \$3.3 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, 2030. 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, 2030. 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 13, 2011, the closing market price of our common stock ranged from \$0.37 per share to \$2.64 per share, and the monthly trading volume varied from approximately 1.8 million shares to 15.5 million shares. Our agreements with Lincoln Park to sell up to an aggregate of \$10,000,000 of our common stock to Lincoln Park could increase the volatility of the price of our common stock for the duration of such agreements. Other factors that could contribute to the continued volatility of the market price of our common stock include:

- actual or anticipated fluctuations in our results of operations;
- the introduction of new products or services, or product or service enhancements by us or our competitors;
- developments with respect to our or our competitors' intellectual property rights or regulatory approvals or denials;
 - announcements of significant acquisitions or other agreements by us or our competitors;
- the sale by us of our common or preferred stock or other securities, or the anticipation of sales of such securities;
 - sales or anticipated sales of our common stock by our insiders (management and directors);
 - the trading volume of our common stock, particularly if such volume is light;
 - 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, among other factors,
 - 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 have often been unrelated or disproportionate to the operating performance of those companies. Further, the market prices of bioscience companies have been unusually volatile in the last year, 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.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall

On December 14, 2011, we entered into a purchase agreement with Lincoln Park, or the \$7.5M Purchase Agreement, pursuant to which Lincoln Park has committed to purchase up to \$7,500,000 of our common stock and we issued 470,711 shares of our common stock at no cost to Lincoln Park as a fee for its commitment to purchase such shares. The shares to be sold pursuant to the \$7.5M Purchase Agreement are to be sold by us to Lincoln Park from time to time over a 36-month period commencing after the SEC has declared effective a registration statement for the resale

of such shares, which we must file with the SEC within 30 business days after the date of such agreement. In connection with such agreement, on December 15, 2011, we entered into an additional purchase agreement with Lincoln Park, or the \$2.5M Purchase Agreement, pursuant to which we may issue to Lincoln Park up to \$2,500,000 of our common stock (subject to certain limitations) and we issued 156,904 shares of our common stock to Lincoln Park at no cost as a fee for its commitment to purchase such shares.

Other than Lincoln Park's initial purchase under the \$2.5M Purchase Agreement of 1,347,709 shares of our common stock at a price per share of \$0.371 for an aggregate amount of \$500,000, or the Initial Purchase, the purchase price for the shares that we may sell to Lincoln Park under either the \$2.5M Purchase Agreement or the \$7.5M Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park if and when the market price of our common stock is below \$0.25 per share. Sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. As such, other than the Initial Purchase, Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to such agreements and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

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 will need to continue to 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 the NASDAQ Stock Market, or NASDAQ.

On September 16, 2011, we received a deficiency letter, the Notification Letter, from NASDAQ notifying us that we no longer meet NASDAQ's requirements for continued listing on the NASDAQ Capital Market under NASDAQ Listing Rule 5550(a)(2), the Bid Price Rule, because the minimum bid price of our common stock did not equal or exceed \$1.00 at least once over a period of 30 consecutive trading days. NASDAQ explained in the Notification Letter that under NASDAQ Listing Rule 5810(c)(3)(A), we will be afforded 180 calendar days, or until March 14, 2012, to regain compliance with the Bid Price Rule. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for at least 10 consecutive business days. If we do not regain compliance by March 14, 2012, NASDAQ will provide written notification to us that our common stock will be subject to delisting from the NASDAQ Capital Market. We may, however, be eligible for an additional grace period of 180 calendar days if we satisfy the continued listing requirement for market value of publicly held shares and all other initial listing standards (with the exception of the Bid Price Rule) for listing on the NASDAQ Capital Market, and submit a timely notification to NASDAQ of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary, which would need to be approved by our stockholders.

We are evaluating various actions to pursue to ensure compliance with NASDAQ's continued listing requirements, and there can be no assurance that we will be able to regain compliance with NASDAQ's continued listing requirements. If we fail to regain compliance with the Bid Price Rule or otherwise maintain the standards required now or in future by NASDAQ, our common stock could be delisted. Such delisting could cause our stock to be classified as "penny 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.

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 issue 5,000,000 shares of preferred stock and such preferred stock could have voting or conversion rights which could adversely affect the voting power of the holders of our common stock. 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 the then-current board of directors, including delaying or impeding a merger, tender offer, or proxy contest or other change of control transaction involving our company. Any delay or prevention of a change of control transaction could cause stockholders to lose a substantial premium over the then-current market price of their shares.

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

On October 24, 2011, we entered into a one year agreement with a consultant for investor relations services and, on October 27, 2011 and pursuant to such agreement, we issued 150,000 shares of our common stock, with a value of \$97,000, in exchange for these services. Such shares were sold pursuant to an exemption from registration under Section 4(2) of the Securities Act, based on the offering of such shares to only one investor and the lack of any general solicitation or advertising in connection with the sale of such shares; the representation of the investor to the Company that it was an accredited investor (as that term is defined in Rule 501 of Regulation D) and that it was purchasing the shares for its own account and without a view to distribute them; and our issuance of the shares restricted securities.

Item 4. (Removed and Reserved)

Item 6. Exhibits

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

- 10.1 Employment Agreement by and between Pure Bioscience, Inc. and Craig Johnson, dated October 26, 2011 (Incorporated by reference to Exhibit 10.8 of the Company's Annual Report on Form 10-K filed with the SEC on October 31, 2011)
- 10.2 Form of Indemnification Agreement (Incorporated by reference to Exhibit 10.9 of the Company's Annual Report on Form 10-K filed with the SEC on October 31, 2011)
- 10.3 Amendment to Amended and Restated Employment Agreement by and between Pure Bioscience, Inc. and Michael L. Krall, dated October 26, 2011 (Incorporated by reference to Exhibit 10.10 of the Company's Annual Report on Form 10-K filed with the SEC on October 31, 2011)
- 10.4 Amendment to Employment Agreement by and between Pure Bioscience, Inc. and Donna Singer, dated October 26, 2011 (Incorporated by reference to Exhibit 10.11 of the Company's Annual Report on Form 10-K filed with the SEC on October 31, 2011)
- 10.5 Purchase Agreement, dated December 14, 2011, by and between Pure Bioscience, Inc. and Lincoln Park Capital Fund, LLC (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 15, 2011)
- 10.6 Purchase Agreement, dated December 15, 2011, by and between Pure Bioscience, Inc. and Lincoln Park Capital Fund, LLC (Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on December 15, 2011)
- 10.7 Registration Rights Agreement, dated December 15, 2011, by and between Pure Bioscience, Inc. and Lincoln Park Capital Fund, LLC (Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on December 15, 2011)
- 10.8 Engagement Letter, dated December 8, 2011, by and between Pure Bioscience, Inc. and Wharton Capital Markets LLC (Incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on December 15, 2011)
- 31.1 * Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 * Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 * Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 * Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* 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.

By: /s/ MICHAEL L. KRALL
Michael L. Krall, President /
Chief Executive Officer
(Principal Executive Officer)

By: /s/ CRAIG A. JOHNSON
Craig A. Johnson, Chief
Financial Officer
(Principal Financial and
Accounting Officer)

