PURE BIOSCIENCE Form 10-Q December 15, 2010 UNITED STATES

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

#### FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED OCTOBER 31, 2010

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

Commission File Number 0-21019

PURE Bioscience (Exact name of registrant as specified in its charter)

California
(State or other jurisdiction of incorporation or organization)

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

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

92020 (Zip Code)

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

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

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

#### Yes o No o

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

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

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

As of December 13, 2010, there were 37,016,682 shares of the registrant's common stock, no par value, outstanding.

# PURE Bioscience

# FORM 10-Q

for the Quarterly Period Ended October 31, 2010

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## **SIGNATURES**

# PURE Bioscience CONSOLIDATED BALANCE SHEETS

		(Unaudited) October 31, 2010		July 31, 2010
ASSETS				
Current Assets				
Cash and cash equivalents	\$	3,679,485	\$	2,192,543
Accounts receivable, net of allowance for doubtful accounts				
of \$0 at October 31, 2010 and \$0 at July 31, 2010		442,912		332,493
Inventories, net		874,105		752,438
Prepaid expenses		76,496		146,307
Total current assets		5,072,998		3,423,781
Property, plant and equipment, net		625,330		696,974
<b>5</b>		1.067.622		1 072 002
Patents		1,867,622		1,872,882
T . 1	ф	7.565.050	ф	5 002 627
Total assets	\$	7,565,950	\$	5,993,637
LIADII ITIES AND STOCKHOLDEDS' EQUITY				
LIABILITIES AND STOCKHOLDERS' EQUITY Current Liabilities				
	\$	450 152	\$	329,281
Accounts payable Accrued liabilities	Ф	450,152	Ф	
		313,155		241,498
Deferred revenue		354,896		10,000
Taxes payable		-		2,400
Total current liabilities		1 110 202		502 170
Total current naomities		1,118,203		583,179
Deferred Rent		14,493		16,045
Deterred Rent		14,493		10,043
Total liabilities		1,132,696		599,224
Total habilities		1,132,090		399,224
Stockholders' Equity				
Preferred stock, no par value:				
5,000,000 shares authorized, no shares issued		_		_
Common stock, no par value:		<del>-</del>		_
50,000,000 shares authorized				
36,916,682 issued and outstanding at October 31, 2010, and				
35,488,317 issued and outstanding at July 31, 2010		44,474,077		41,679,129
Additional paid-in capital		6,430,743		6,041,143
Warrants:		0,430,743		0,041,143
1,766,298 issued and outstanding at October 31, 2010, and				
1,889,663 issued and outstanding at July 31,2010		2,809,856		2,934,600
Accumulated deficit		(47,281,422	)	(45,260,459)
Accumulated deficit		(77,201,422	,	(43,200,439 )
Total stockholders' equity		6,433,254		5,394,413
Total stockholders equity		0,733,434		J,J/ <del>T,†</del> 1J

Total liabilities and stockholders' equity

\$ 7,565,950

\$

5,993,637

The accompanying notes are an integral part of the consolidated financial statements

# PURE Bioscience CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

For the Three Months
Ended
October 31,
2010
2009

# REVENUES FROM PRODUCT SALES

Net revenues	\$23,085	\$221,871
Cost of sales	9,868	80,157
Gross profit	13,217	141,714
0.11	202.466	210.020
Selling expenses	302,466	219,938
General and administrative expenses	1,232,200	1,184,579
Research and development	501,664	457,868
Total operating expenses	2,036,330	1,862,385
Total operating expenses	2,030,330	1,002,303
Loss from operations	(2,023,113)	(1,720,671)
1		
Other income:		
Interest income	2,250	9,476
Other	-	-
Total other income	2,250	9,476
	(2.020.062.)	(1.711.105)
Net loss before income taxes	(2,020,863)	(1,711,195)
Income tax provision	(100)	-
Net loss	\$(2,020,963.)	\$(1,711,195)
1401 1055	ψ(2,020,703)	ψ(1,711,175)
Net loss per common share, basic and diluted	\$(0.06)	\$(0.05)
	·	Í
Weighted average common shares used in		
computing basic and diluted net loss per common share	35,671,933	33,454,211

The accompanying notes are an integral part of the consolidated financial statements

# PURE Bioscience CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

For the Three Months Ended October 31,

2010 2009

# Cash flows from operating activities

Net loss	\$(2,020,963)	\$(1,711,195)
Adjustments to reconcile net loss to net cash		
used in operating activities:		
Amortization and depreciation	117,091	115,245
Stock-based compensation	307,648	257,433
Changes in assets and liabilities:	307,040	237,733
Accounts receivable	(110,419 )	(2,193)
Prepaid expense	69,811	39,497
Inventories	(121,667)	/o == /
Deferred rent	(1,552)	
Deferred revenue	344,896	9,400
Accounts payable and accrued liabilities	192,528	2,370
	(2,400)	(2,400)
Income tax payable	(2,400 )	(2,400 )
Net cash used in operating activities	(1,225,027)	(1,300,024)
Cash flows from investing activities		
C		
Investment in patents	(40,187)	(58,940)
Purchase of property, plant and equipment	-	(37,720 )
Net cash used in investing activities	(40,187)	(96,660)
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Cash flows from financing activities		
Net proceeds from the sale of common stock	2,367,089	2,783,233
Proceeds from exercise of stock options and warrants	385,067	-
•		
Net cash provided by financing activities	2,752,156	2,783,233
Net increase in cash and cash equivalents	1,486,942	1,386,549
Cash and cash equivalents at beginning of period	2,192,543	4,213,744
Cash and cash equivalents at end of period	\$3,679,485	\$5,600,293
Supplemental disclosures of cash flow information		
Cash paid for taxes	\$-	\$-
Cash paid for taxes	φ-	φ-

Cash paid for interest \$-

The accompanying notes are an integral part of the consolidated financial statements

Notes to Consolidated Financial Statements (Unaudited)

#### Note 1. Basis of Presentation

PURE Bioscience (sometimes referred to herein as the "Company", "we", "us", or "our") was incorporated in the state of California on August 24, 1992. The accompanying unaudited financial statements include the consolidated accounts of PURE Bioscience and its subsidiary, ETIH2O Corporation, a Nevada corporation. All inter-company balances and transactions have been eliminated.

The financial statements included herein have been prepared by PURE Bioscience without audit, in accordance with the instructions to Securities and Exchange Commission ("SEC") Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), have been condensed or omitted as allowed by such rules and regulations, however we believe that the accompanying unaudited financial statements contain all adjustments (including normal recurring adjustments) necessary to present fairly the financial condition, results of operations and cash flows for the periods presented. The unaudited consolidated financial statements presented herein should be read in conjunction with our audited financial statements for our most recently completed fiscal year ended July 31, 2010 ("Fiscal 2010"), and their accompanying notes, as filed with the SEC in our 10-K on October 28, 2010.

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect the amounts reported in the statements and accompanying notes, and actual results could differ materially from those estimates. The results of operations for the three month period ended October 31, 2010 (the "First Quarter") are not necessarily indicative of the results of operations for the full year, or any future periods.

Note 2. Nature of Business and Summary of Significant Accounting Policies

#### Concentration of Credit Risk

As of October 31, 2010 and July 31, 2010, all cash deposits were invested in either U.S. FDIC insured bank accounts or institutional money market mutual funds investing in A-1 (S&P) or Prime-1 (Moody's).

At October 31, 2010, \$3,558,500 of our cash and cash equivalents were maintained at three separate major financial institutions in the United States in accounts that are insured by the Federal Deposit Insurance Corporation ("FDIC"). Such insurance is limited to \$250,000 through December 31, 2013.

Also at October 31, 2010, \$120,100 of our cash and cash equivalents were held in an account maintained at a major financial institution in the United States that is provided with protection by the Securities Investor Protection Corporation ("SIPC") should such a firm close due to bankruptcy or other financial difficulties and customer assets are missing. Cash and cash equivalent claims, such as for money market funds and certificates of deposit, are limited to \$100,000, however other investments are protected with up to \$500,000 of insurance by the SIPC.

As of October 31, 2010 and July 31, 2010, we had no short-term investments.

We have not experienced any losses in our cash, cash equivalents and short-term investments and believe we are not exposed to any significant credit risk. At times, deposits held may exceed the amount of insurance provided by the FDIC or SIPC. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear low risk.

Other financial instruments that potentially subject us to concentrations of credit risk consist of accounts receivable. We extend credit to certain of our U.S. domestic customers based on credit evaluations and past payment performance, but do not obtain collateral to secure our accounts receivable.

#### Fair Value of Financial Instruments

The carrying amounts for receivables and payables are the approximate fair value because of their short maturity, generally less than three months. Whenever shares are issued for services, we use market prices of our common stock to estimate the fair value of the shares issued. Whenever options or warrants are issued for services, we use the Black Scholes Option Pricing Model to estimate the fair value of the equity instrument, using historical market prices of our common stock and prevailing risk-free interest rates.

#### Revenue Recognition

During the periods presented herein, our product revenue was derived from the sale of silver dihydrogen citrate ("SDC") concentrate, our ready to use disinfectant, and finished packaged products containing SDC. We recognize revenue from sales of these products under the provisions of the applicable authoritative guidance governing revenue recognition, which is generally when we ship the products free on board from either our facility or from third party packagers, we have transferred title to the goods, the price is fixed or determinable and we have eliminated our risk of loss. Where payment is not reasonably assured at the time of shipment, we will either decline a purchase or defer the revenue until payment is assured. In the First Quarter we recorded deferred revenue of \$344,900 for a transaction where payment on agreed terms was not reasonably assured at the time of shipment of the product, as discussed further in Note 8 below.

Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue in the consolidated balance sheets. We recorded deferred revenue of \$10,000 at July 31 and October 31, 2010, related to an amount that we received from FTA Bioscience, LLC, our development partner for SDC-based products for human use, in connection with a request for us to issue a license for a new indication. We are reviewing pre-clinical data submitted by FTA and have not yet issued a license. As a result, the license payment is not deemed to have been earned.

## Cost of Goods Sold

Cost of goods sold for product sales includes direct and indirect costs to manufacture products, including materials consumed, manufacturing overheads, shipping costs, salaries, benefits and related expenses of operations.

#### Intangible Assets / Long-Lived Assets

Our intangible assets primarily consist of the worldwide patent portfolio of our silver ion technologies. Outside legal costs and filing fees related to obtaining patents are capitalized as incurred. The total amounts capitalized for pending patents were \$40,200 and \$58,900 in the First Quarter and the three month period ended October 31, 2009, respectively. Patents are stated net of accumulated amortization of \$1,476,200 and \$1,430,700 at October 31, 2010 and July 31, 2010, respectively. The cumulative cost of acquiring patents is amortized on a straight-line basis over the estimated remaining useful lives of the patents, generally between 17 and 20 years from the date of issuance. At October 31, 2010, the weighted average remaining amortization period for all patents was approximately 10.1 years. Amortization expense for the First Quarter and the three month period ended October 31, 2009 was \$45,400 and \$44,300, respectively.

#### Accounting for Stock-Based Compensation

We utilize the fair value method of accounting for stock-based compensation arrangements. Accordingly, the compensation cost of share-based awards issued in connection with employee and director services is measured at the grant date based on the estimated fair value of the award, and is recognized as expense over the applicable service period. We do not have, and have not had during the First Quarter or the three month period ended October 31, 2009, any stock option awards with market or performance conditions.

#### Stock Options to Non-Employees

Charges for stock options granted to non-employees have been determined using the estimated fair value of the stock options issued, based on the Black-Scholes Option Pricing Model. Such options are revalued quarterly until fully vested, with any change in fair value expensed. During the First Quarter, we recorded \$37,500 in selling expense, and recorded a reduction in both general and administrative expense and research and development expense of \$4,500 and \$8,200, respectively. During the three month period ended October 31, 2009, we recorded \$10,500 in selling expense, \$2,800 in general and administrative expense, and \$4,100 in research and development expense for stock options granted to non-employees.

#### Cash, Cash Equivalents, Short-term Investments and Liquidity

We consider all liquid investments with maturities of ninety days or less when purchased to be cash equivalents. Our short-term investments have maturities of greater than ninety days from the date of purchase. We classify securities as "available for sale" in accordance with authoritative guidance, and carry these investments at fair value with any unrealized gains and losses reported as a component of shareholders' equity on the consolidated balance sheets and in the statements of shareholders' equity. At October 31, 2010 and July 31, 2010 we had no short-term investments.

On October 25, 2010 we consummated a financing whereby we entered into common stock purchase agreements with a total of eleven non-affiliated accredited investors for the sale of 1,080,000 shares of our common stock at a price of \$2.20 per share, for a total purchase price of \$2.376 million. We did not engage any underwriter or placement agent to assist with the financing, and therefore no underwriter discounts or commissions were paid. The shares sold in the financing represented approximately 3% of our outstanding common stock prior to the sale. We relied on an exemption from registration under Regulation D and Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"). No advertising or general solicitation was employed in offering the shares, which were offered solely to a limited number of non-affiliated accredited investors (as defined in Rule 501(a) of the Securities Act) and transfer of the shares is restricted by the Company in accordance with the requirements of the Securities Act. After expenses, the net proceeds of the financing to us were \$2.367 million, which will be used for working capital.

On September 3, 2009, we closed a registered direct offering whereby we sold \$3 million of our common stock and warrants to institutional investors. After fees and expenses, the aggregate net proceeds of the offering to us were approximately \$2.8 million.

We currently believe that our current cash resources are sufficient to meet our anticipated needs during the next twelve months, however, we expect that we will need to increase our liquidity and capital resources in future periods by one or more measures, which may include reducing operating expenses, raising additional financing in future periods through the issuance of debt, equity, or convertible securities, entering into partnerships, licenses, or other arrangements with third parties, reducing the exercise price of outstanding warrants, or through other means, any one of which could reduce the value to us, perhaps substantially, of our technologies and their commercial potential. Such funds may not be available on favorable terms, or at all. Insufficient funds would result in a material adverse effect on our business and operations and could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to competitive pressures or customer requirements, and further may require us to delay, scale back or eliminate some or all of our research and product development programs, license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, or to reduce or cease operations. If adequate funds are not available when needed, we may be required to significantly modify our business model and operations to reduce spending to a sustainable level. Such modification of our business model and operations could also result in an impairment of assets, which cannot be determined at this time. Furthermore, if we issue equity or convertible debt securities to raise additional funds, our existing shareholders may experience dilution, and in addition the new equity or debt securities may have rights, preferences and privileges that are superior to those of our existing shareholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization.

#### Comprehensive Income

We display comprehensive income or loss and its components as part of our consolidated financial statements. Our comprehensive loss includes our net loss and certain changes in equity that are excluded from our net loss, including unrealized holding gains and losses on available for sale securities. Such changes in shareholders' equity are included in accumulated other comprehensive income or loss. For the First Quarter and the three month period ended October 31, 2009, we did not record any realized or unrealized gains on available for sale securities and our comprehensive loss was \$2,021,000 and \$1,712,000, respectively, which was unchanged from our net loss.

#### Net Loss Per Common Share

We compute basic loss per share by dividing the applicable net loss by the weighted average number of common shares outstanding during the respective period. Diluted per share amounts assume the conversion, exercise or issuance of all potential common stock equivalents, which include stock options, common stock warrants and unvested restricted stock, unless the effect is to reduce a loss or increase the income per common share from continuing operations. As we incurred losses in the First Quarter and the three month period ended October 31, 2009, we did not include common stock equivalent shares in the computation of net loss per share as the effect would have been anti-dilutive. Therefore, both the basic and diluted loss per common share for the First Quarter and the three month period ended October 31, 2009 are based on the weighted average number of shares of our common stock outstanding during these periods. As of October 31, 2010, anti-dilutive instruments excluded from the computation of net loss per share were made up of 5,581,600 stock options, 1,766,300 warrants, and 61,200 shares of unvested restricted stock; a total of 7,409,100 potential common stock equivalents.

#### **Recent Accounting Pronouncements**

In June 2009, the FASB issued authoritative guidance for the consolidation of variable interest entities, to require an issuer to perform an analysis to determine whether the issuer's variable interest or interests give it a controlling financial interest in a variable interest entity, if any. This analysis identifies the primary beneficiary of a variable interest entity as one with the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance and the obligation to absorb losses of the entity that could potentially be significant to the variable interest. The guidance became effective for us on August 1, 2010, however it did not have a material impact on our consolidated financial statements.

In October 2009, the FASB issued authoritative guidance that amends existing revenue recognition accounting pronouncements related to multiple-deliverable revenue arrangements. The new guidance provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and how the consideration should be allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The guidance became effective for us on August 1, 2010, however it did not have a material impact on our consolidated financial statements.

In December 2009, the FASB issued authoritative guidance that changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The new guidance also requires a reporting entity to provide additional disclosures about its involvement with variable interest entities and any significant changes in risk exposure due to that involvement. The guidance became effective for us on August 1, 2010, however it did not have a material impact on our consolidated financial statements.

In January 2010, the FASB issued authoritative guidance that requires new disclosures and clarifies certain existing disclosure requirements about fair value measurements. The new guidance requires a reporting entity to disclose significant transfers in and out of Level 1 and Level 2 fair value measurements, to describe the reasons for the transfers and to present separately information about purchases, sales, issuances and settlements for fair value measurements using significant unobservable inputs. We adopted the guidance in the third quarter of Fiscal 2010, except for the disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements, which is effective for interim and annual reporting periods beginning after December 15, 2010 (our fiscal quarter ending April 30, 2011). The adoption of the guidance did not have a material impact on our consolidated financial statements, and we do not currently expect the adoption of this guidance to have a material impact on our consolidated financial statements in future periods.

In April 2010, the FASB issued guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. The guidance became effective for us on a prospective basis for milestones achieved beginning with the First Quarter; however it did not have a material impact on our consolidated financial statements. We will continue to evaluate this guidance, however we do not expect it to have a material impact on our consolidated financial statements for futures periods.

## Note 3. Accounts Receivable

Trade accounts receivable are recorded net of allowances for doubtful accounts. Estimates for allowances for doubtful accounts are determined based on payment history and individual customer circumstances. The allowance for doubtful accounts was zero at October 31, 2010 and at July 31, 2010.

Included in accounts receivable at October 31, 2010 is \$359,620 billed to a customer for product shipped, where payment on agreed terms was not reasonably assured at the time of shipment. We recognized this amount, less our

costs associated with the shipment, as deferred revenue on the consolidated balance sheets at October 31, 2010.

#### Note 4. Private Placement

On October 25, 2010 we consummated a financing whereby we entered into common stock purchase agreements with a total of eleven non-affiliated accredited investors for the sale of 1,080,000 shares of our common stock at a price of \$2.20 per share, for a total purchase price of \$2.376 million. We did not engage any underwriter or placement agent to assist with the financing, and therefore no underwriter discounts or commissions were paid. The shares sold in the financing represented approximately 3% of our outstanding common stock prior to the sale. We relied on an exemption from registration under Regulation D and Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"). No advertising or general solicitation was employed in offering the shares, which were offered solely to a limited number of non-affiliated accredited investors (as defined in Rule 501(a) of the Securities Act) and transfer of the shares is restricted by the Company in accordance with the requirements of the Securities Act. After expenses, the net proceeds of the offering to us were \$2.367 million, which will be used for working capital.

#### Note 5. Other Equity and Common Stock Transactions

We paid no dividends during any of the periods presented, and have never paid dividends.

During the First Quarter, we issued options to purchase 75,000 shares of our common stock in exchange for business development services, at an exercise price of \$2.43, valued at \$104,100 (based on the Black-Scholes Option Pricing Model assuming no dividend yield, volatility of 90.70% and a risk-free interest rate of 0.54%). Two-thirds of the options vest in annual increments over two years with one third vesting on grant date. Additionally during the First Quarter, we issued options to purchase 25,000 shares of our common stock in exchange for intellectual property management services, at an exercise price of \$2.43, valued at \$33,900 (based on the Black-Scholes Option Pricing Model assuming no dividend yield, volatility of 89.90% and a risk-free interest rate of 0.52%). The options vest in bi-annual increments over one year. Each award will be revalued quarterly until fully vested, with any change in fair value expensed.

Also during the First Quarter, we received \$259,100 from the exercise of warrants to purchase 123,365 shares of our common stock, at an average exercise price \$2.10; received \$20,000 from the exercise of options to purchase 25,000 shares of our common stock issued under employee stock option plans; and received an aggregate of \$106,000 from the exercise of options to purchase 200,000 shares of our common stock by two of our directors. In addition, we recorded \$264,900 of expense for options issued to employees, officers, directors, and consultants.

At October 31, 2010, we had outstanding warrants to purchase 1,766,298 shares of our common stock, with exercise prices ranging from \$2.06 to \$8.60. These warrants expire at various times between March 2011 and March 2015.

#### Note 6. Stock-Based Compensation

We have the following active equity incentive plans (the "Plans") pursuant to which options to acquire common stock or restricted stock awards have been granted and are currently outstanding: the 2001 Directors and Officers Stock Option Plan; the 2001 Consultants and Advisors Stock Option Plan; the 2002 Non-Qualified Stock Option Plan; the 2002 Employee Incentive Stock Option Plan; the 2004 Consultants and Advisors Stock Option Plan; and the 2007 Equity Incentive Plan. The Plans are administered by the Compensation Committee of the Board of Directors (the "Compensation Committee"), except that the full Board of Directors makes decisions regarding equity grants to our executive officers, although officers who are also members of our Board do not vote on matters related to their own compensation or equity awards. The exercise price for stock options, or the value of other incentive grants granted under the Plans, are set by the Compensation Committee or Board of Directors but may not be for less than the fair market value of the shares on the date the award is granted. The term of option grants and their vesting provisions are set by the Compensation Committee or Board of Directors.

We recognize compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period are defined pursuant to the terms of the consulting agreement. Share-based compensation expense for awards granted subsequent to July 31, 2006 is based on the grant date fair value estimated using the Black-Scholes Option Pricing Model. The following assumptions were used to calculate the fair value of share based compensation for the First Quarter and the three month period ended October 31, 2009:

	For the three month periods ended			
	October	r 31,		
	2010	2009		
	82.18% -	99.87% -		
Expected price volatility	89.91%	99.92%		
	0.48% -	0.42% -		
Risk-free interest rate	2.00%	0.43%		
Expected rate of forfeiture	0.0%	0.0%		
Expected dividend yield	0.0%	0.0%		
Weighted average expected term	3.24 years	1.0 years		

Expected price volatility is the measure by which our stock price is expected to fluctuate during the expected term of an option. Expected volatility is derived from the historical daily change in the market price of our common stock, as we believe that historical volatility is the best indicator of future volatility. For stock options granted subsequent to July 31, 2006, we have excluded the period prior to November 1, 2005 from our historical price volatility, as during this period our market price reflected significant uncertainty associated with both our arbitration proceedings against Falken Industries and our ability to close the sale of the assets of the Water Treatment Division. We believe that the volatility of the market price of our common stock during periods prior to November 1, 2005 is not reflective of future expected volatility.

Following the guidance of Staff Accounting Bulletin No. 107 ("SAB 107"), we have been following the "Simplified Method" to determine the expected term of "Plain Vanilla" options issued to employees and directors. All of our outstanding options granted to employees and directors are Plain Vanilla options. Under the Simplified Method, the expected term is presumed to be the mid-point between the vesting date and the end of the contractual term. In SAB 107, the Staff stated that it would not expect a company to use the Simplified Method for share option grants after December 31, 2007, however on December 21, 2007 the SEC published Staff Accounting Bulletin No. 110 ("SAB 110"), which expressed the views of the Staff regarding the continued use of the Simplified Method in certain circumstances where a company is unable to rely on historical data. We are unable to rely on our historical exercise data as there have been only a limited number of option exercises in recent periods; our common stock was traded until April 2008 on the illiquid Bulletin Board but our common stock is now listed on the NASDAQ Capital Market; we have had over recent years significant trading blackout periods for employees and directors; there has been minimal employee and director turnover; we have periodically changed the terms of employee stock option grants to amend the standard term of such grants; there are no comparable companies in terms of size, location and industry (particularly as we are developing a platform technology and operate in multiple industries); and we have had significant structural changes in our business including the sale of the Water Treatment Division and abandonment of our Triglycylboride technology, and expect to continue to change in the foreseeable future. We are therefore, under the guidance of SAB 110, continuing to use the Simplified Method to determine the expected term of options issued to employees and directors, but will continually evaluate our historical data as a basis for determining the expected terms of such options.

Our estimation of the expected term for stock options granted to parties other than employees or directors is the contractual term of the option award. For the purposes of estimating the fair value of stock option awards, the risk-free interest rate used in the Black-Scholes calculation is based on the prevailing U.S. Treasury yield as determined by the U.S. Federal Reserve. We have never paid any dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future.

Stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. Authoritative guidance requires forfeitures to be estimated at the time of grant, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Historically, we have not had significant forfeitures of stock options granted to employees and directors. A significant number of our historical stock option grants were fully vested at issuance or were issued with short vesting provisions. Therefore, we have estimated the forfeiture rate of our outstanding stock options as zero, but will continually evaluate our historical data as a basis for determining expected forfeitures.

The following table sets forth the share-based compensation expense recorded in our consolidated statements of operations for the First Quarter and the three month period ended October 31, 2009 resulting from share-based compensation awarded to our employees, directors and third party service providers:

Share-based compensation for employees and directors:	Three Months Ended October 31, 2010			e Months Ended ober 31, 2009
Selling expense	\$	29,400	\$	19,600
General and administrative expenses		216,600		195,600
Research and development		36,800		24,800
Total share-based compensation for employees and directors		282,800		240,000
Share-based compensation for third party service providers:				
Selling expense	\$	37,500	\$	10,500
General and administrative expenses		(4,500	)	2,800
Research and development		(8,200	)	4,100
Total share-based compensation for third party service providers		24,800		17,400
• • •				
Total share-based compensation expense	\$	307,600	\$	257,400

A summary of stock option activity is as follows:

		Weighted-Average	Aggregate Intrinsic Value
	Number of Shares	Exercise Price	(\$000's)
Balance at July 31, 2010	5,736,050	\$ 2.12	\$ 4,628
Granted	110,000	\$ 2.38	
Exercised	(225,000)	\$ 0.56	
Forfeited / Cancelled	(39,500)	\$ 4.17	
Balance at October 31, 2010	5,581,550	\$ 2.17	\$ 3,391

		Outstanding			Exercisable	
		Weighted Average Remaining	Weighted		Weighted Average Remaining	Weighted
Range of	Number of	Contractual	Average	Number of	Contractual	Average
Exercise	Shares	Life (in	Exercise	Shares	Life (in	Exercise
Prices	Outstanding	years)	Price	Exercisable	years)	Price
\$0.50 to						
\$0.75	360,000	0.19	\$0.53	360,000	0.19	\$0.53
\$0.80 to \$1.20	495,000	0.15	\$0.80	495,000	0.15	\$0.80
\$1.40 to \$7.50	4,726,550	2.78	\$2.44	3,305,713	1.22	\$2.35
	5,581,550	2.38	\$2.17	4,160,713	1.00	\$2.01

Cash received from options and warrants exercised in the First Quarter and the three month period ended October 31, 2009 was \$385,100 and zero, respectively. The intrinsic value of all stock options exercised during the First Quarter and the three month period ended October 31, 2009 was \$400,600 and \$505,800, respectively, and the weighted-average grant date fair value of stock options granted during the First Quarter and the three month period ended October 31, 2009 was \$2.60 and \$0.63, respectively.

As of October 31, 2010, there was \$2,901,500 of unrecognized non-cash compensation cost related to unvested options, which will be recognized over a weighted average period of 2.93 years.

A summary of restricted stock activity is as follows:

	Number of Shares
Unvested at July 31, 2010	61,200
Granted	-
Exercised	-
Forfeited / Cancelled	-
Unvested at October 31, 2010	61,200

During the First Quarter and the three month period ended October 31, 2009, we recognized stock based compensation expense for restricted stock of \$42,800 and \$27,500 respectively. As of October 31, 2010, there was \$96,300 of unrecognized non-cash compensation cost related to unvested restricted shares, which will be recognized over a period of 0.51 years.

#### Note 7. Inventory

Inventories are stated at the lower of cost or net realizable value using the average cost method. Inventories at October 31, 2010 and July 31, 2010 consisted of:

	O	October 31,		July 31,
		2010		2010
Raw Materials	\$	126,800	\$	448,300
Work in Progress		-		-
Finished Goods		747,300		304,100
	\$	874,100	\$	752,400

Included in our inventory of finished goods as of July 31, 2010 was approximately 3,700 gallons of SDC concentrate out of 12,000 gallons that we purchased in prior periods from an unrelated third party in a lien sale, for \$27,500. None of the product purchased in the lien sale remained in inventory at October 31, 2010.

#### Note 8. Business Segment and Sales Concentrations

Operating segments are defined as components for which separate financial information is available and evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. We believe that based upon the end use of our products, the value added contributions made by us, the regulatory requirements, our customers and partners, and the strategy required to successfully market finished products, we are operating in a single segment.

In Fiscal 2010 we commenced selling our EPA-approved hard surface disinfectant under our own label, IV-7 Ultimate Germ Defense<sup>TM</sup> ("IV-7") through an alliance with a Dallas-based sales and marketing organization, Richmont Sciences, LLC ("Richmont"), to U.S. commercial distributors and commercial customers. Under this agreement with Richmont, we recognize revenues for products sold to third parties, and pay marketing fees to Richmont based upon those revenues. We recognized revenue from the first sales of IV-7 under this agreement during the three month period ended January 31, 2010.

In the second quarter of calendar 2010, IV-7 was launched direct to consumers via a direct sales channel, by a newly formed company called IV-7 Direct, an affiliate of Richmont. PURE Bioscience does not have an equity interest in either IV-7 Direct or Richmont. Under this arrangement, we sell finished products at contracted unit prices to Richmont, and we also expect to receive additional revenues based on IV-7 Direct's sales, which are made through a network of independent sales associates using a multi-level sales model. We recognized revenue from the first sales of IV-7 under this agreement during the three month period ended April 30, 2010.

In October 2010, Richmont established distribution of SDC-based products in the Middle East region. Richmont is initially purchasing IV-7 products for resale into the Middle East, where the IV-7 water treatment and disinfection products have been registered by the United Arab Emirates-Dubai Municipality. Richmont is focusing first on distribution of IV-7 Water Treatment<sup>TM</sup>. We made the first shipments of IV-7 Water Treatment<sup>TM</sup>, a concentrated product, during the First Quarter, and recorded deferred revenue of \$344,900 on the consolidated balance sheets at October 31, 2010, as collection was not reasonably assured at the time of shipment.

During the First Quarter, product sales were made to five customers. 100% of product revenue for the First Quarter was derived from sales made to U.S. domestic customers. We categorize revenue between U.S. domestic and international based on the country of domicile of our customer.

During the First Quarter, 100% of our revenue was derived from bulk ready to use disinfectant or finished packaged products containing our ready to use disinfectant. Our deferred revenue as reported on the consolidated balance sheets at October 31, 2010 was derived from concentrate sales. During the same period of the prior year, 98% of our product sales were of bulk ready to use disinfectant or finished packaged products containing our ready to use disinfectant, and 2% of our product sales were of SDC concentrate.

All of our tangible assets are located in the United States.

## Note 9. Subsequent Events

Subsequent to October 31, 2010, we received \$21,200 from the exercise of options on 40,000 shares of common stock by a Director of the Company; we received \$15,900 from the exercise of options on 30,000 shares of common stock by an Officer of the Company; and we received \$24,000 from the exercise of options on 30,000 shares of common stock by employees.

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

This report contains forward-looking statements. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of such terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we, nor any other person, assume responsibility for the accuracy and completeness of the forward-looking statements. We are under no obligation to update any of the forward-looking statements after the filing of this Quarterly Report on Form 10-Q to conform such statements to actual results or to changes in our expectations.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes and other financial information appearing elsewhere in this Quarterly Report. Readers are also urged to carefully review and consider the various disclosures made by us which attempt to advise interested parties of the factors which affect our business, including without limitation the disclosures made in Item 1A of Part II of this Quarterly Report under the Caption "Risk Factors" and in our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the fiscal year ended July 31, 2010 ("Fiscal 2010"), previously filed with the Securities and Exchange Commission ("SEC").

Risk factors that could cause actual results to differ from those contained in the forward-looking statements include but are not limited to: our limited operating history; our history of losses; our future capital needs; our ability to manage growth; the rapidly changing technologies and market demands related to our products; the failure of our products to achieve broad acceptance; our failure to successfully compete; our dependence on a single core technology; our reliance on third parties; our lack of product distribution experience; our exposure to pricing and supply issues; our failure to comply with government regulation; the loss of a key member of our management team; our ability to recruit additional key employees; our failure to protect our intellectual property; our exposure to intellectual property and product liability claims; changes in government policies and other risks identified in Part II, Item 1A of this Quarterly Report on Form 10-Q.

The financial statements presented herein, and discussed below, have been prepared in accordance with U.S. Generally Accepted Accounting Principles.

#### Overview

PURE Bioscience (sometimes referred to herein as the "Company," "we", "us" or "our") was incorporated in the state of California on August 24, 1992 as Innovative Medical Services. In September 2003, we changed our name from Innovative Medical Services to PURE Bioscience. We began as a provider of pharmaceutical water purification products for the pharmacy market; however we divested all assets associated with this business in the sale, in May 2005, of our Water Treatment Division. In 2000, we commenced investments in the development of novel bioscience technologies, and subsequent to May 2005 we have been exclusively focused on the development and commercialization of our current and future bioscience products.

We are expanding into markets that we believe have broad potential by developing new, proprietary bioscience products based upon our patented silver ion antimicrobial technologies. We are developing technology-based products, including our silver dihydrogen citrate-based antimicrobials, which we believe can provide novel, non-toxic solutions to numerous global health challenges and represent innovative advances in diverse markets. We believe that our technologies are in a position to contribute significantly to today's global trend toward industrial and consumer use of environmentally friendly products, while providing competitive advantages in efficacy and safety.

#### Bioscience Technologies

Our flagship bioscience technology is a patented, aqueous antimicrobial called silver dihydrogen citrate ("SDC"). A novel molecular entity, SDC is an electrolytically generated source of stabilized ionic silver that can serve as the basis for a broad range of products in diverse markets. SDC liquid is colorless, odorless, tasteless, non-caustic and formulates well with other compounds. We believe that our SDC-based antimicrobial is distinguished from competitors in the marketplace because of its superior efficacy combined with reduced toxicity. We are producing pre-formulated, ready-to-use products for both our own brands and for private label distribution, as well as varying strengths of SDC concentrate as an additive or raw material for inclusion in other companies' products. We are also producing SDC as an Active Pharmaceutical Ingredient ("API"), currently in clinical trials for multiple indications. In addition to SDC, we have obtained patent protection for ionic silver-based molecular entities utilizing 14 organic acids other than citric acid.

#### Sources of Revenue

Our principal sources of revenue are comprised of sales of SDC concentrate as well as both bulk and individually bottled SDC-based hard surface disinfectants. We sell SDC in a variety of concentrations and formulations to certain partners and distributors who in turn (i) resell the concentrate as an active ingredient or preservative in other companies' products; (ii) blend the product into hard surface disinfectant products for sale to retail, commercial and institutional customers; and/or (iii) develop novel formulations under a license granted by us. In addition, we sell both bulk and individually bottled hard surface disinfectant products, both directly and through distributors, to retail, commercial and institutional customers.

In prior years, customers purchasing our EPA approved disinfectants were primarily distributors who sell such products under their own labels as a sub-registrant of our EPA master label, however in Fiscal 2010 we commenced selling our EPA-approved hard surface disinfectant under our own label, IV-7 Ultimate Germ Defense<sup>TM</sup> ("IV-7") through an agreement with a Dallas-based sales and marketing organization, Richmont Sciences, LLC ("Richmont"), to U.S. commercial distributors and commercial customers. Under this agreement with Richmont, we recognize revenues for products sold to third parties, and pay marketing fees to Richmont based upon those revenues. We recognized revenue from the first sales of IV-7 under this agreement during the three month period ended January 31, 2010.

In the second quarter of calendar 2010, IV-7 was launched direct to consumers via a direct sales channel, by a newly formed company called IV-7 Direct, an affiliate of Richmont. PURE Bioscience does not have an equity interest in either IV-7 Direct or Richmont. Under this arrangement, we sell finished products at contracted unit prices to Richmont, and we also expect to receive additional revenues based on IV-7 Direct's sales, which are made through a network of independent sales associates using a multi-level sales model. We recognized revenue from the first sales of IV-7 under this agreement during the three month period ended April 30, 2010.

Richmont is also commencing the marketing of our sanitizer for surfaces touched by food in restaurants, hotels, food processing plants, and other environments. In August 2009, as a result of our 6-year petition process, the U.S. Environmental Protection Agency ("EPA") published an amendment to the Federal Register establishing a concentration limit for silver in end use solutions eligible for tolerance exemption, specifically in the form of silver dihydrogen citrate (SDC), of 50 parts per million ("ppm"). Concurrently with the new regulation, the EPA registered our 50 ppm indirect food contact surface sanitizer product. We subsequently submitted a registration to the EPA to add the food contact surface sanitizer claims to our previously-registered 30 ppm hard surface disinfectant formula. The EPA registered the disinfectant/sanitizer formula in April 2010, and we immediately filed a federal sub-registration and subsequent state registrations for the disinfectant/sanitizer product to be sold as IV-7 Ultimate Germ Defense for Food Contact Surfaces<sup>TM</sup>. The final state approval was received in November 2010, and we are now able to market, through Richmont, IV-7 Ultimate Germ Defense for Food Contact Surfaces<sup>TM</sup> throughout the U.S.

In October 2010, Richmont established distribution of SDC-based products in the Middle East region. Richmont is initially purchasing IV-7 products for resale into the Middle East, where the IV-7 water treatment and disinfection products have been registered by the United Arab Emirates-Dubai Municipality. Richmont is initially focusing on distribution of IV-7 Water Treatment<sup>TM</sup>. We made the first shipments of IV-7 Water Treatment<sup>TM</sup>, a concentrated product, during the First Quarter, and recorded deferred revenue of \$344,900 on the consolidated balance sheets at October 31, 2010, as collection was not reasonably assured at the time of shipment.

During Fiscal 2010 and in prior years, we sold SDC concentrate to BASF under an agreement whereby BASF resold the concentrate under its own brand names within the global personal care, household and institutional markets. We have chosen to terminate the agreement and are currently evaluating alternatives for distribution in these markets. We believe we can secure better positioning for SDC with companies that do not carry proprietary competing products.

In July 2008, we entered into a development and licensing agreement for SDC-based products for human use with FTA Bioscience, LLC ("FTA"). Under our agreement with FTA, FTA is funding and directing all development activities and FDA regulatory filings. In July 2010, based on preclinical data developed by FTA, we granted two product-specific licenses to FTA for the development of an SDC-based treatment for tinea unguium, also referred to as onychomycosis (nail fungus), as well as for tinea pedis (athlete's foot); and concurrently recognized the first milestone payments under this agreement with FTA.

Our revenues have historically fluctuated from period to period. In future periods, we expect our revenues to continue to fluctuate, however we are not currently able to accurately predict such revenues. Our IV-7 brand hard surface disinfectant products have recently launched, and the prospects for sales of additional products, such as our sanitizer for surfaces touched by food, our IV-7 Water Treatment<sup>TM</sup>, and products sold by our distributors and strategic partners are uncertain, and may be dependent on approvals from U.S. or overseas regulatory agencies, which we may not obtain.

#### Cost of Revenues and Operating Expenses

Costs of Revenue. Costs of product revenue includes direct and indirect costs to manufacture products, including materials consumed, manufacturing overheads, shipping costs, salaries, benefits, and related expenses of our operations; and, during Fiscal 2010, costs incurred to have products bottled and labeled by a third party. In addition, included in our inventory of finished goods as of July 31, 2010 were approximately 3,700 gallons of SDC concentrate

that we purchased from an unrelated third party in a lien sale. None of the product purchased in the lien sale remained in inventory at October 31, 2010 (see Note 7 to the consolidated financial statements for further information regarding this transaction).

Gross profit on product sales represents net revenue less the costs of revenue. Our gross profit percentage is highly dependent on pricing, contractual agreements, product mix, customer mix, and other factors. We do not believe that historical gross profit margins on product sales are a reliable indicator of future gross profit margins.

Selling and Marketing. Selling and marketing expenses consist primarily of salaries and benefits, and amounts paid to third party providers for marketing, sales, public relations and advertising, along with promotional and trade show costs and travel expenses. Sales and marketing expenses also include share-based compensation allocable to employees and third party advisors performing services related to sales and marketing. Under our agreement with Richmont, we pay marketing fees to Richmont and record such fees as selling expense in the consolidated statements of operations.

General and Administrative. General and administrative expenses include employee salaries and benefits, and amounts paid to third party providers for finance and accounting, legal, human resources, insurance, information technology, and other administrative activities. General and administrative expenses also include share-based compensation allocable to employees and third party advisors performing general and administrative services.

Research and Development. Research and development costs include in-house research costs, expenditures for third party testing, patent amortization, outside legal costs for maintaining issued patents, and product registration expenditures. We do not currently expect our research and development expense to grow significantly in future periods, however if opportunities arise, particularly in the development and testing of new formulations, we will evaluate the need for additional research expenditures based on potential market sizes and our estimation of the likelihood of our technology achieving successful results. Research and development expenses also include share-based compensation allocable to employees and third party advisors performing services related to research and development.

#### **Critical Accounting Policies**

Accounting for Long-Lived Assets / Intangible Assets

We assess the impairment of long-lived assets, consisting of property, plant, equipment and finite-lived intangible assets, whenever events or circumstances indicate that the carrying value may not be recoverable. Examples of such events or circumstances include:

- an asset'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.

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.

#### Accounting for Stock-Based Compensation

Stock-based compensation expense for all stock-based compensation awards granted after August 1, 2006 is based on the grant date fair value estimated in accordance with the provisions of applicable authoritative guidance. Specifically, we estimate the weighted-average fair value of options granted using the Black-Scholes Option Pricing Model based on evaluation assumptions regarding expected volatility, dividend yield, risk-free interest rates, the expected term of the option and the expected forfeiture rate. Each of these assumptions, while reasonable, requires a certain degree of judgment and the fair value estimates could vary if the actual results are materially different than those initially applied.

Prior to August 1, 2006, we were not required to record compensation cost in the consolidated financial statements for stock options issued to employees or directors. Subsequently, the estimated grant date fair value of such awards is expensed over the applicable service period of the award, which is generally the vesting period. We do not have any stock option awards with market or performance conditions.

The fair value of stock options granted to non-employees is expensed over the applicable service period. Such options are revalued quarterly until fully vested.

Results of Operations for the Three Months Ended October 31, 2010 vs. Three Months Ended October 31, 2009

Revenue and Gross Margin

For the First Quarter, product revenues of \$23,100 declined by \$198,800 compared with comparable revenues of \$221,900 in the same period of the prior year.

In prior years, customers purchasing our EPA approved disinfectants were primarily distributors who sell such products under their own labels as a sub-registrant of our EPA master label, however in Fiscal 2010 we commenced selling our EPA-approved hard surface disinfectant under our own label, IV-7 Ultimate Germ Defense<sup>TM</sup> ("IV-7") through our agreement with Richmont to U.S. commercial distributors and commercial customers. Under this agreement with Richmont, we recognize revenues for products sold to third parties, and pay marketing fees to Richmont based upon those revenues.

In the second quarter of calendar 2010, IV-7 was launched direct to consumers via a direct sales channel, by a newly formed company called IV-7 Direct, an affiliate of Richmont. PURE Bioscience does not have an equity interest in either IV-7 Direct or Richmont. Under this arrangement, we sell finished products at contracted unit prices to Richmont, and we also expect to receive additional revenues based on IV-7 Direct's sales, which are made through a network of independent sales associates using a multi-level sales model.

In October 2010, Richmont established distribution of SDC-based products in the Middle East region. Richmont is initially purchasing IV-7 products for resale into the Middle East, where the IV-7 water treatment and disinfection products have been registered by the United Arab Emirates-Dubai Municipality. Richmont is initially focusing on distribution of IV-7 Water Treatment<sup>TM</sup>. We made the first shipments of IV-7 Water Treatment<sup>TM</sup>, a concentrated product, during the First Quarter, and recorded deferred revenue of \$344,900 on the consolidated balance sheets at October 31, 2010, as collection was not reasonably assured at the time of shipment.

During the First Quarter, product sales were made to five customers. 100% of product revenue for the First Quarter was derived from sales made to U.S. domestic customers. 100% of our revenue was derived from bulk ready to use disinfectant or finished packaged products containing our ready to use disinfectant. Our deferred revenue as reported on the consolidated balance sheets at October 31, 2010 was derived from concentrate sales.

During the three month period ended October 31, 2009, 98% of our product sales were of bulk ready to use disinfectant or finished packaged products containing our ready to use disinfectant, and 2% of our product sales were of SDC concentrate. 92% of sales were made to two customers and 34% of sales were made to U.S. domestic customers, with 66% of sales being derived from shipments to Taiwan, for further distribution and sale by our distributor to several Asian countries.

Primarily as a result of the mix of products sold and prices, our gross margin percentage declined from 64% in the three months ended October 31, 2009, to 57% in the First Quarter. Due to the limited volume of sales in each period, historical margins should not be used as a predictor of future margins. Gross profit on product sales for the First Quarter was \$13,200, compared with comparable gross profit of \$141,700 in the same period of the prior fiscal year.

#### **Operating Costs**

Operating costs increased by \$173,900, or 9%, from \$1,862,400 in the three month period ended October 31, 2009, to \$2,036,300 in the First Quarter. Within these aggregate operating costs, selling expense increased by \$82,500 in the First Quarter compared with the same period in the prior fiscal year, primarily due to fees and non-cash stock option expense for business development consultants and trade show exhibition costs.

General and administrative expense increased by \$47,600, from \$1,184,600 in the three month period ended October 31, 2009, to \$1,232,200 in the First Quarter, primarily due to increased payroll and associated costs. Research and development costs during the First Quarter of \$501,700, including in-house costs, patent amortization, outside legal costs for maintaining approved patents, and product registration expenditures, increased by \$43,800, or 10%, compared with the comparable prior year period. This increase was primarily due to increased salary and related costs, which were partially offset by reduced third party testing costs. We do not currently expect our research and development expense to grow significantly in future periods; however, if opportunities arise, particularly in the development and testing of new formulations, we will evaluate the need for additional research expenditures based on potential market sizes and our estimation of the likelihood of our technology achieving successful results.

Our loss from operations increased by \$302,400, from a loss of \$1,720,700 for the three months ended October 31, 2009 to a loss of \$2,023,100 for the First Quarter.

#### Other Income

Other income declined year over year by \$7,200 due mainly to reduced interest rates earned on our investments.

#### Net Loss

Our net loss after income and taxes increased by \$309,800, from a net loss of \$1,711,200, or \$0.05 per share, for the three months ended October 31, 2009 to a net loss of \$2,021,000, or \$0.06 per share, for the First Quarter.

## Liquidity and Capital Resources

Since the sale of our Water Treatment Division in 2005, we have financed our operations primarily through sales of our common stock.

At October 31, 2010, we had cash and cash equivalents of \$3,679,500, an increase of \$1,486,900 from July 31, 2010. Net cash used in operations, and for investments in both intangible and fixed assets, was \$1,265,200 in the First Quarter, \$5,853,518 in Fiscal 2010, and \$6,107,400 for the fiscal year ended July 31, 2009 ("Fiscal 2009"). At October 31, 2010, we had no short-term investments and no long-term debt. Total current assets at October 31, 2010 were \$5,073,000, an increase of \$1,649,200 from July 31, 2010.

Our future capital needs and our future profits, if any, are uncertain, and will depend on many factors including, among others, the acceptance of, and demand for, our products; our success and the success of our partners and distributors 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, and developing new, products or technologies; the extent to which we invest in new technology and product development; and the costs associated with the continued

operation, and any future growth, of our business. We currently believe that our current cash resources are sufficient to meet our anticipated needs during the next twelve months, however we expect that we will need to increase our liquidity and capital resources in future periods by one or more measures, which may include reducing operating expense, by raising additional financing in future periods through the issuance of debt, equity, or convertible securities, entering into partnership, license, 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 technologies and their commercial potential. Such financing, if any, could also lead to the dilution of our existing shareholders. There can be no assurance that additional financing will be available, or if available, that such financing can be obtained on satisfactory terms. 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 unanticipated customer requirements, and further may require us to delay, scale back or eliminate some or all of our research and product development programs, license to third parties the right to commercialize products or technologies that we would otherwise commercialize ourselves, or to reduce or cease operations. If adequate funds are not available when needed, we may be required to significantly modify our business model to reduce spending to a sustainable level. Such modification of our business model could also result in an impairment of assets, which cannot be determined at this time.

Cash used in operating activities for the First Quarter was \$1,225,000, as compared to \$1,300,000 used in operating activities for the same three month period of the prior fiscal year.

During the First Quarter, cash used in investing activities was \$40,200, consisting entirely of investments in patents. At October 31, 2010, the net book value of our capitalized patents was \$1,867,622, and the net book value of our property, plant and equipment was \$625,300. In the three month period ended October 31, 2009, cash used in investing activities was \$96,700, consisting of investments in patents of \$59,000 and purchases of property, plant and equipment of \$37,700.

During the First Quarter, cash provided by financing activities was \$2,752,200. On October 25, 2010, we consummated a financing whereby we entered into common stock purchase agreements with a total of eleven non-affiliated accredited investors for the sale of 1,080,000 shares of our common stock at a price of \$2.20 per share, for a total purchase price of \$2.376 million. We did not pay any placement agent fees associated with the financing and no underwriter discounts or commissions were paid. After legal and other expenses, the net proceeds of the financing to us were \$2.367 million.

Also during the First Quarter, we received \$259,100 from the exercise of warrants to purchase 123,365 shares of our common stock, at an average exercise price of \$2.10, and we received \$126,000 from the exercise of 225,000 common stock options, at an average exercise price of \$0.56.

During the three months ended October 31, 2009, cash provided by financing activities was \$2,783,200, all of which was derived from the net proceeds of our September 2009 registered direct offering whereby we sold \$3 million of our common stock and warrants to institutional investors, for net proceeds of \$2,783,200 after fees and expenses.

At October 31, 2010, we had total liabilities of \$1,132,700, an increase of \$533,500 from July 31, 2010. Included in current liabilities is \$344,900 of deferred revenue related to amounts billed for product shipped where payment on agreed terms was not reasonably assured at the time of shipment. We recognized this amount, less our costs associated with the shipment, as deferred revenue on the consolidated balance sheets at October 31, 2010. Accounts payable and accrued liabilities also increased from July 31, 2010,by \$192,500, due primarily to the timing of accounts payable and accrued salaries and wages.

Off Balance Sheet Arrangements

We do not have any off balance sheet arrangements.

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

Our exposure to interest rate risk at October 31, 2010 is related to our investment portfolio which consists largely of debt instruments and other securities of high quality corporate issuers and the U.S. government and its agencies. From time to time our investments may be exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting only of diversified institutional money market mutual funds investing in A-1 (S&P) or Prime-1 (Moody's), U.S. Treasury Securities, or United States Government obligations issued by or backed by a federal agency of the United States Government. We do not enter into investments for trading or speculative purposes, and our cash is deposited in, and invested through, highly rated financial institutions in the United States. While our available for sale securities are subject to interest rate risk and would fall in value if market interest rates increased, we estimate that the fair value of our investment portfolio would not decline by a material amount in the event of an increase in market interest rates. We therefore would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

We have operated mainly in the United States, and the majority of our sales since inception have been made in U.S. dollars. Further, all of our sales to international markets have been to independent parties in transactions denominated in U.S. dollars. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

#### Item 4. 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 SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, who also acts as our Principal Accounting Officer, as appropriate, to allow timely decisions regarding required disclosure based closely on the definition of "disclosure controls and procedures" in Rule 13a-14(c). In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

#### **Evaluation of Disclosure Controls and Procedures**

We have carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer/Principal Accounting Officer, of the effectiveness of the design and operation of all of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer/Principal Accounting Officer concluded that our disclosure controls and procedures were effective as of October 31, 2010.

#### Changes in Internal Control Over Financial Reporting

In the First Quarter we implemented a web-based stock option and equity plan administration and accounting system. We made no other changes in our internal control over financial reporting during the First Quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II - OTHER INFORMATION

#### Item 1. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings, which arise, in the ordinary course of business. However, litigation 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. We are not currently aware of any such legal proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

#### Item 1A. Risk Factors

Except for the historical information contained herein or incorporated by reference, this quarterly report on Form 10-Q and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part I, Item 2 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this quarterly report on Form 10-Q and in any other documents incorporated by reference into this report. You should consider carefully the following risk factors, together with all of the other information included or incorporated in this quarterly report on Form 10-Q. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. 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. If any of the events described below were to occur, our financial condition, our ability to access capital resources, our results of operations and/or our future growth prospects could be materially and adversely affected and the market price of our common stock could decline. As a result you could lose some or all of any investment you may have made or may make in our common stock.

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

We had a loss of \$2.0 million after taxes for the First Quarter, a loss of \$6.8 million after taxes for Fiscal 2010, and a loss of \$7.1 million after taxes for Fiscal 2009. As of October 31, 2010, we had an accumulated deficit of approximately \$46.9 million. We expect to continue to have losses in future periods. If the penetration into the marketplace of SDC and SDC based products takes longer than anticipated or is otherwise 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 generally, 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 recent deterioration and continuing weakness in the U.S. and global economies, as well as the decreasing purchasing power of consumers and institutions, we expect that our business will continue to be adversely affected for so long as, and to the extent that, such adverse economic conditions exist.

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

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

- the acceptance of, and demand for, our products;
- the success of our strategic partners in developing and selling products derived from our technology;
  - the costs of further developing our existing, and developing new, products or technologies;
    - 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 do not yet have, and we may never have, significant cash inflows from product sales or from other sources of revenue to offset our ongoing and planned investments in corporate infrastructure, research and development projects, regulatory submissions, business development activities, and sales and marketing, among other investments. Some or all of our ongoing or planned investments may not be successful. In addition, irrespective of our cash resources, we may be contractually or legally obligated to make certain investments, which cannot be postponed.

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

We have 44,325,730 shares of common stock issued and outstanding or reserved for issuance. Shares reserved for issuance include shares under equity compensation plans, vested and unvested options, warrants, and unvested restricted stock. Our current authorized capital stock is limited to 50,000,000 shares of common stock and 5,000,000 shares of preferred stock. As set forth in our Proxy Statement for our annual meeting of shareholders to be held on January 19, 2011, our Board has proposed that we reincorporate from the state of California to the state of Delaware. As part of the proposed reincorporation, the Board has approved an increase to the number of authorized shares of common stock from 50,000,000 shares that are currently available for issuance to 100,000,000. The increase in authorizes shares is contingent on the approval by our shareholders of the reincorporation.

As is true for shares presently authorized but unissued, the future issuance of common stock authorized by the proposed increase may, among other things, decrease existing shareholders' percentage equity ownership and, depending on the price at which they are issued, could be dilutive to the voting rights of existing shareholders and have a negative effect on the market price of the common stock. However, if we were unable to increase our authorized capital stock for any reason, our ability to raise additional capital through the issuance of equity or convertible debt would be severely compromised and we may be unable to obtain equity or convertible debt capital at all.

If our efforts to achieve and maintain market acceptance of our core SDC technology are not successful, we are unlikely to attain profitability

For the past several years, we have invested most of our time and financial resources in the development and commercialization of our core SDC technology. We expect that sales of SDC concentrate and SDC-based products will constitute a substantial portion, or all, of our revenues in future periods. As a result, our success is highly dependent on a single technology. Any material decrease in the level of sales or expected sales of, or the prices for, SDC concentrate or SDC-based products, whether as a result of competition, change in customer demand, government regulatory action, or any other factor, would have a materially adverse effect on our business, financial condition and results of operations.

We are marketing SDC and SDC-based products 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. Other risks involved in introducing these new products include, but are not limited to, liability for product effectiveness and safety, and competition from existing or emerging sources.

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 a bioscience company focused on the marketing and continued development of our electrolytically generated stabilized ionic silver technology, including our flagship SDC antimicrobial. The risks, regulatory hurdles and costs of doing business in our target markets are high. Government regulation in the U.S. and in other countries is a significant factor in the development, manufacturing and marketing of our products, and in our ongoing research and development activities. We believe that all products derived from SDC, or products that may be derived from SDC 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 time consuming and expensive, and there can be no assurance that regulatory review will not involve delays or other actions adversely affecting the marketing and sale of our products. For example, regulatory review of SDC by the EPA has historically been time consuming and expensive, due in part, we believe, to the novel nature of our technology. While we cannot accurately predict the outcome of any pending or future regulatory review processes, we expect such processes to remain time consuming and expensive as we, or our partners, apply for approval to market new formulations or to make new or additional claims. We also cannot predict the extent or impact of future legislation or regulation in the U.S. or in foreign markets.

Some of our potential bioscience applications, for example those aimed at healthcare, food preparation and agriculture markets, will also require approval by government agencies prior to marketing or sale in the U.S. or in foreign markets. If or until we, or our partners, obtain approvals from the appropriate regulatory authorities, we would not be able to market or sell such products, which would limit our revenues. Even after approval, if any, we will remain subject to changing governmental policies regulating antimicrobial products.

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. We currently have EPA registration for our 2400-parts per million (ppm) technical grade SDC concentrate (trade name Axenohl), as well as for our Axen and Axen30 hard surface disinfectant products. In addition, in August 2009, the EPA published an amendment to the Federal Register establishing a concentration limit for silver in end use solutions eligible for tolerance exemption, specifically in the form of 50 ppm silver dihydrogen citrate. Concurrently with the amendment, the EPA registered our 50 ppm indirect food contact surface sanitizer product. We subsequently submitted a registration to the EPA to add the food contact surface sanitizer claims to our previously-registered 30 ppm hard surface disinfectant formula, SDC3A. The EPA registered the disinfectant/sanitizer formula in April 2010, and we immediately filed a federal sub-registration and subsequent state registrations for the disinfectant/sanitizer product to be sold as IV-7 Ultimate Germ Defense for Food Contact Surfaces<sup>TM</sup>. 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. There can be no guarantee that a particular state, or any state, will allow the continued sale of existing SDC-based products, or will allow the sale of any new applications of our products in future periods.

We are responsible for the accuracy of any claims made by us or our partners or distributors related to SDC-based products, and their consistency with claims approved by the regulatory authorities, including the EPA, any state, or any foreign regulatory authority. We have limited ability to monitor or regulate claims made by our partners and distributors, including but not limited to claims made in marketing materials, internet sites, by e-mail, or verbally. Failure by our partners or us to comply with approved label claims 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 revenue growth.

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 also 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. However, the introduction of additional regulated antimicrobial products in the U.S., or in markets outside the U.S., could take several years, or may never be achieved. Existing state, federal or international approvals may not be maintained. Additionally, doing business internationally carries a great deal of risk with regard to foreign government regulation, financial instruments and banking, currency fluctuation, and many other factors.

#### We are subject to intense competition

Our SDC-based products compete in highly competitive markets dominated by prominent chemical and pharmaceutical companies. Many of our competitors have significantly greater financial resources than we do in multiple areas that include sales, marketing, branding, product development and research. 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. Competition by existing or potential chemical and pharmaceutical manufacturers and distributors could substantially limit or eliminate our potential market share and ability to profit from our products and technologies. 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 and/or diligent in doing so.

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.

In many of our distribution and development agreements, we are unable to raise our product prices to our customers 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.

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 have an adverse effect on our business, financial condition, or results of operations

The EPA regulates the registration, manufacturing, and sales and marketing of many of our products, and those of our distributors and partners, in the United States. Significant government regulation also exists in overseas markets. Compliance with applicable regulatory requirements is subject to continual review and is monitored through periodic inspections and other review and reporting mechanisms.

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.

In addition, the FDA and comparable agencies in many foreign countries impose substantial limitations on the introduction of new products through costly and time-consuming laboratory and clinical testing and other procedures. The process of obtaining FDA and other required regulatory approvals is lengthy, expensive and uncertain. There is no guarantee that we, or our partners, will be able to obtain the resources necessary to further develop our technology or obtain regulatory approvals, or that the products will be successful in meeting the strict criteria imposed by the FDA. It may be several years before we, or any third party to whom we grant rights to use our silver ion technologies, are able to introduce any FDA regulated antimicrobial pharmaceutical or medical device products containing our technology.

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 successfully develop or commercialize new applications of our SDC technology, our operating results will suffer

In addition to its use on inanimate surfaces, we believe that our SDC technology also shows promise as a broad-spectrum antimicrobial for use in human and veterinary healthcare products. We or our partners plan to pursue additional EPA, FDA and other required regulatory approvals for other applications. We have entered into agreements with FTA Bioscience, LLC for the development and commercialization of certain FDA regulated SDC-based products. However, we do not exercise any control over FTA. FTA's resources are limited and progress to date on all indications has been slow. Any products developed may never achieve regulatory approval or be commercialized. If indications are commercialized, we may not receive a share of future revenues that provides an adequate return on our historical or future investment.

Our ability to generate increased revenue depends in part upon the ability and willingness of our current and potential strategic partners to increase awareness of our technology and its applications to their customers, and to provide implementation services.

During the three months ended April 30, 2010, we commenced selling our EPA-approved hard surface disinfectant under our own label, IV-7 Ultimate Germ Defense<sup>TM</sup> ("IV-7") through an alliance with a Dallas-based sales and marketing organization, Richmont Sciences, LLC, to commercial distributors and commercial customers. Additionally, beginning in May 2010, IV-7 was sold for the first time to consumers through a separate newly established direct sales channel, by a newly formed company called IV-7 Direct, an affiliate of Richmont. Sales to date have not been significant, and if Richmont or our other our strategic partners fail to generate sales of, or increase awareness of, our products or technology for any reason, or to assist us in getting access to decision-makers, we may need to increase our marketing expenses, change our marketing strategy or enter into marketing relationships with different parties, any of which could impair our ability to generate increased revenue or to generate profits from our technology.

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 expand our customer base;
- we may not succeed in maintaining or expanding our current sales and in penetrating other markets and applications of 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; and
      - we may not be able to adequately protect our intellectual property.

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 customer base is 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 not meet market expectations and that also 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 have no product distribution experience, and we expect to rely on third parties who may not successfully sell our products

We have no product distribution experience and currently rely and plan to rely primarily on product distribution arrangements and/or sales and marketing services provided by third parties. We have licensed or plan to license our technology to certain third parties for commercialization of multiple applications. We expect to enter into additional distribution agreements and licensing agreements in the future, and we may not be able to enter into these additional agreements on terms that are favorable to us, if at all. Our future revenues from sales of our products, if any, will depend on the success of the efforts of these third parties, however we may have limited or no control over the distribution activities of these third parties, who could sell competing products and/or may devote insufficient sales efforts to our products.

During Fiscal 2010 and in prior years, we sold SDC concentrate to BASF under an agreement whereby BASF resold the concentrate under their own brand names within the global personal care, household and institutional markets. We have chosen to terminate this agreement, and we are currently evaluating alternatives for distribution in these markets. We may not be successful in finding such alternatives on terms that are acceptable to us.

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 on third parties to whom we license rights to our technology to develop products containing SDC for many of the applications for which we believe SDC-based products have, or may have, market opportunities. Generally, under our contractual relationships with these third parties, we 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, 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 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. These legal protections afford only limited protection for our intellectual property and trade secrets. Despite efforts to protect our proprietary rights, unauthorized parties may attempt to copy aspects of our proprietary technology or otherwise obtain and use information that we regard as proprietary. We may not have sufficient resources to defend or litigate our proprietary rights, and we cannot assure you that our means of protecting such rights will be adequate. The infringement of such rights could have a material negative impact on our business and on our results of operations.

We own seven U.S. patents related to our SDC technology. The lives of these patents are not finite, and the value to us of some or all of the patents may be limited by their term.

In addition to U.S. patents and trademarks, we have filed for foreign patent applications and trademark registrations. We may not be successful in obtaining any of these patents and trademarks, whether in the U.S. or overseas, and we may be unable to obtain additional patent and trademark protection in the future. Furthermore, legal standards relating to the validity, enforceability and scope of protection of intellectual property rights are uncertain. It is possible that, despite our efforts, competitors or others will create and use products in violation of our patents and/or adopt service names similar to our service names or otherwise misappropriate our intellectual property. Such patent infringement or misappropriation could have a material adverse effect on our business. Any unauthorized production of our SDC-based products, whether in the U.S. or overseas, may reduce our own sales of SDC-based products,

thereby reducing, perhaps significantly, our actual or potential profits. Adopting similar names and trademarks by competitors could lead to customer confusion. Any claims or customer confusion related to our trademarks could negatively affect our business.

Litigation may be necessary to enforce our intellectual property rights and protect our trade secrets. If third parties prepare and file applications in the U.S. or other countries that claim trademarks used or registered by us, we may oppose those applications and may be required to participate in proceedings before the regulatory agencies who determine priority of rights to such trademarks. We may not have sufficient resources to defend our trademarks and any litigation or adverse priority proceeding could seriously harm our business and operating results.

If we are found to have violated the trademark, trade secret, copyright, patent or other intellectual property 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. It could also be necessary for us to pay a substantial amount in the future if the rights holders are willing to permit us to continue to use the intellectual property rights. Either having to cease use or pay such amounts could make us much less competitive and could have a material adverse impact on our business, operating results and financial condition.

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 United States. Many countries have a "first-to-file" trademark registration system. As a result, we may be prevented 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. Our means of protecting our proprietary rights may not be adequate, and our competitors, or potential competitors, could independently develop similar technology.

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. Any such claim of liability, whether meritorious or not, could be time-consuming and/or result in costly litigation. 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, and you may lose some or all of any investment you have made, or may make, in our common stock.

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

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

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

Our common stock is registered under the Securities Exchange Act of 1934, as amended (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, 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 of 2002 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 the loss of any key member of this team may prevent us from achieving our objectives in a timely manner

Our success depends largely upon the continued services of our executive officers and other key personnel. Pursuant to the employment laws of the State of California, 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.

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.

Anti-takeover provisions under our charter documents and California 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 by-laws 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 of Directors (the "Board"), even if such events may be beneficial to the interests of shareholders. For example, our Board, subject to certain limitations, has the authority and power to issue all authorized and unissued shares of common stock, which have not otherwise been reserved for issuance, on such terms as the Board determines. The Board could also issue 5,000,000 shares of preferred stock on terms determined by the Board, 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, California law contains provisions that have the effect of making it more difficult for others to gain control of the Company.

The price of our common stock may be volatile, which may cause investment losses for our shareholders

The price and trading volume of our common stock have historically been volatile. For example, in the twelve months through December 13, 2010, the closing market price of our common stock ranged from \$1.22 per share to \$3.74 per share, and the monthly trading volume varied from 1.1 million shares to 34.7 million shares. In the future, the market price of our common stock may continue to be volatile and could fluctuate substantially due to many factors, including:

- 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, shareholder 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.

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 shareholders' equity, market value of our listed or publicly held securities, number of publicly held shares, bid price for our common stock, number of shareholders, 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. If we fail to maintain the standards required now or in future by the NASDAQ Stock Market, 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 or to sell your shares at a price that you may deem to be acceptable.

If outstanding options and warrants to purchase shares of our common stock are exercised, or if other shares of our common stock or preferred stock are issued, the interests of our shareholders could be diluted

In addition to 37,016,682 shares of common stock issued and outstanding, we currently have 7,309,048 shares of common stock reserved for issuance, which includes shares under equity compensation plans, vested and unvested options, warrants, and unvested restricted stock. The outstanding stock options and warrants have a weighted-average exercise price of approximately \$2.64. In addition, 5,674,270 authorized shares of our common stock remain available for future issuance under equity compensation plans or otherwise. 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.

Of our authorized capital stock of 50,000,000 shares of common stock, 5,674,270 remain available for issuance. Such common stock may be issued under equity compensation plans; or our Board, subject to certain limitations, has the authority and power to issue any or all authorized and unissued shares of common stock which have not otherwise been reserved for issuance, on such terms as the Board determines. Additionally, 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.

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, 2010, we had federal and California tax net operating loss carry-forwards of approximately \$56.3 million and \$46.2 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 shareholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future 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 will begin expiring in the year ending July 31, 2011 unless previously utilized, and will completely expire in the fiscal year ending July 31, 2029. In the two fiscal years ending July 31, 2011 and 2012, \$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, 2029. Our California tax loss carry-forwards will begin to expire in the year ending July 31, 2014, and will completely expire in the fiscal year ending July 31, 2029. 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.

We may never pay dividends

We have never paid any dividends and do not anticipate paying dividends in the foreseeable future. The future payment of dividends, if any, is dependent on the discretion of our Board, our earnings, our financial condition and other business and economic factors that our Board may consider relevant.

#### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

As previously reported in our Annual Report on Form 10-K for the fiscal year ended July 31, 2010, on October 25, 2010 we consummated a financing whereby we entered into common stock purchase agreements with a total of eleven non-affiliated accredited investors for the sale of 1,080,000 shares of our common stock at a price of \$2.20 per share,

for a total purchase price of \$2.376 million. We did not engage any underwriter or placement agent to assist with the financing, and therefore no underwriter discounts or commissions were paid. The shares sold in the financing represented approximately 3% of our outstanding common stock prior to the sale. We relied on an exemption from registration under Regulation D and Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"). No advertising or general solicitation was employed in offering the shares, which were offered solely to a limited number of non-affiliated accredited investors (as defined in Rule 501(a) of the Securities Act) and transfer of the shares is restricted by the Company in accordance with the requirements of the Securities Act. After expenses, the net proceeds of the offering to us were \$2.367 million, which will be used for working capital.

ITEM 4. (REMOVED AND RESERVED)

### ITEM 6. EXHIBITS

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

- 10.1 -- Form of Common Stock Purchase Agreement (1)
- 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\*
- (1) Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 26, 2010.
- \* 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** 

By: /s/ Michael L. Krall

Michael L. Krall

President / Chief Executive Officer (Principal Executive Officer)

December 15, 2010

By: /s/ Andrew J. Buckland

Andrew J. Buckland

Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) December 15, 2010