

PURE BIOSCIENCE, INC.  
Form 10-K  
October 25, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

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

**For the fiscal year ended July 31, 2018**

**or**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file No. 001-14468**

**PURE Bioscience, Inc.**

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

**Delaware**

**33-0530289**

**(State or other jurisdiction of (IRS Employer  
incorporation or organization) Identification No.)**

**1725 Gillespie Way**

**El Cajon, California 92020**

**(Address of principal executive office, including zip code)**

**(619) 596-8600**

**(Registrant's telephone number, including area code)**

**Securities registered pursuant to Section 12(b) of the Act:**

**None**

**Securities registered pursuant to Section 12(g) of the Act:**

**Common Stock, \$0.01 par value**

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes  No

Edgar Filing: PURE BIOSCIENCE, INC. - Form 10-K

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company [X]

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The aggregate market value of the registrant's voting stock held by non-affiliates, as of the last day of the registrant's second quarter, was approximately \$39,000,000 (computed on the basis of the closing price of the common stock on the OTCQB Bulletin Board on January 31, 2018). For purposes of this computation only, all executive officers, directors and 10% or greater stockholders have been deemed affiliates.

As of October 25, 2018, there were 71,582,122 shares of the registrant's common stock, \$0.01 par value per share, outstanding.

### Other Information

As used in this Annual Report on Form 10-K, the terms "we," "us," "our," "PURE" and the "Company" refer to PURE Bioscience, Inc., a Delaware corporation, and its subsidiary, on a consolidated basis, unless otherwise stated.



## TABLE OF CONTENTS

	<b>Page</b>
<b><u>Part I</u></b>	
Item 1. <u>Business</u>	4
Item 1A. <u>Risk Factors</u>	17
Item 1B. <u>Unresolved Staff Comments</u>	33
Item 2. <u>Properties</u>	33
Item 3. <u>Legal Proceedings</u>	34
Item 4. <u>Mine Safety Disclosures</u>	34
<b><u>Part II</u></b>	
Item 5. <u>Market for the Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	34
Item 6. <u>Selected Financial Data</u>	35
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	35
Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	44
Item 8. <u>Consolidated Financial Statements and Supplementary Data</u>	44
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	44
Item 9A. <u>Controls and Procedures</u>	44
Item 9B. <u>Other Information</u>	45
<b><u>Part III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	45
Item 11. <u>Executive Compensation</u>	50
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	56
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	58
Item 14. <u>Principal Accounting Fees and Services</u>	60
<b><u>Part IV</u></b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	61
<u>Signatures</u>	65

## CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K may constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Forward-looking statements are based upon our current assumptions, expectations and beliefs concerning future developments and their potential effect on our business. In some cases, you can identify forward-looking statements by words such as “if,” “shall,” “may,” “might,” “will likely result,” “should,” “expect,” “anticipate,” “believe,” “estimate,” “project,” “intend,” “goal,” “objective,” “predict,” “potential” or “continue,” or the negative terms and other comparable terminology, although the absence of these words does not necessarily mean that a statement is not forward-looking. Additionally, statements concerning future matters such as our business strategy, development of new products, regulatory approvals, sales levels, expense levels, cash flows, future commercial and financing matters, future partnering opportunities and other statements regarding matters that are not historical are forward-looking statements.

Although the forward-looking statements in this Annual Report reflect our good faith judgment, based on currently available information, they involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed in the “Risk Factors” contained in Part I, Item 1A of this Annual Report. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate, and you are cautioned not to place undue reliance on any forward-looking statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date we file this Annual Report with the Securities and Exchange Commission, or to conform these statements to actual results or to changes in our expectations. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission after the date we file this Annual Report. Readers are urged to carefully review and consider the various disclosures made in this Annual Report.

## PART I

### Item 1. Business

#### Overview

We are focused on developing and commercializing proprietary antimicrobial products that provide safe and cost-effective solutions to the health and environmental challenges of pathogen and hygienic control. Our technology platform is based on patented stabilized ionic silver, and our initial products contain silver dihydrogen citrate, or SDC. SDC is a broad-spectrum, non-toxic antimicrobial agent, which offers 24-hour residual protection and formulates well with other compounds. As a platform technology, we believe SDC is distinguished from existing products in the marketplace because of its superior efficacy, reduced toxicity, non-causticity and the inability of bacteria to form a resistance to it.

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

Based on these statistics, we believe there is a significant market opportunity for our safe, non-toxic, non-caustic and effective SDC-based solutions. We currently offer PURE<sup>®</sup> Hard Surface as a food contact surface sanitizer and disinfectant to restaurant chains, food processors and food transportation companies. We also offer PURE Control<sup>®</sup> as a direct food contact processing aid. We received the required FDA approvals to market PURE Control as a direct food contact processing aid for raw poultry and fresh produce in December 2015 and January 2016, respectively. Because additional USDA approval was not required, we began marketing PURE Control as a direct food contact processing aid for fresh produce following our receipt of FDA approval in January 2016.

In July 2016, we received a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in

pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. In January 2017, we submitted an additional FCN to the FDA to allow use of higher SDC concentrations in poultry processing, allowing the flexibility to adjust to varying plant and processing conditions. In May 2017, we received a Final Letter from the FDA for this FCN as well as a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for the higher concentrations of SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. We are currently focused on completing in-plant validation trials for PURE Control in pre- and post OLR poultry processing applications, which represents approximately 65% to 75% of the total processing aid market for poultry processing. We are also conducting in-plant trials to optimize the application of PURE Control in OLR to attempt to gain USDA approval for use in this stage of poultry processing.

Subject to the results of our focused in-plant validation efforts for our approved produce and poultry solutions, we intend to seek approval to utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork. In addition to our direct sales efforts with PURE Hard Surface and PURE Control, we market and sell our SDC-based products indirectly through third-party distributors.



## **Technology Platform**

The foundation of our technology platform is a proprietary electrochemical process that allows us to generate ionized silver in the presence of organic acid. This process creates a solution containing stabilized ionic silver that can function as an antimicrobial. Our current products all contain SDC, which we produce by ionizing silver in citric acid. SDC is a natural, non-toxic, non-caustic, colorless, odorless antimicrobial agent, which offers 24-hour residual protection, and that formulates well with other compounds. We have also produced ionic silver-based molecular entities using other organic acids, and we believe these compounds may provide a platform for future product development.

### ***Silver as an Antimicrobial***

The use of silver as an antimicrobial dates back to ancient times when water, wine and other beverages were kept in silver vessels to maintain freshness. Ancient Egyptians applied thin strips of beaten silver around wounds to avoid infection, and early royalty ate from silver plates and with silver utensils to stay healthy. In the past half-century, silver in colloidal and ionic forms has been used successfully in a wide array of antimicrobial applications, including water purification and topical treatments for burn victims. Silver must be in an ionic form to be effective at killing microorganisms. The short shelf-life of previous ionic silver solutions has limited the development of ionic-silver based antimicrobials. SDC, as a stabilized silver ion complex, has a shelf life of more than a decade because the weak bond of the silver ion to the citric acid allows the ion to remain stable in solution while at the same time making it bioavailable for antimicrobial action.

### ***Mechanisms of Action***

The rapid and broad-spectrum efficacy of SDC is attributed to its dual mechanisms of action, both with respect to killing bacteria and other microorganisms and acting against viruses. SDC can kill microorganisms at both the extracellular and intracellular levels. SDC attracts bacteria because the citric acid is recognized by the organism as a food source. SDC easily enters the microorganism through membrane transport proteins. Once inside the organism, SDC binds to DNA and intracellular proteins causing irreversible damage to the DNA and protein structure. Metabolic and reproductive functions halt, and the organism dies. SDC can also act on an organism's outer membrane. Silver ions are highly attracted to sulfur-containing thiol groups found in metabolic and structural proteins bound to the membrane surface. SDC targets these critical proteins and destroys their structure. This disruption of the organism's membrane function and integrity leads to its death.

Viruses are much smaller than bacteria and present fewer target sites on which a biocide can act. The efficacy of SDC against enveloped and non-enveloped viruses comes from its ability to destroy not only the viral envelope, preventing the virus from attaching to a host cell, but also the infectious component of the virus, the nucleic acid.

### ***Safety Profile***

Research has shown that silver is an effective antimicrobial and not toxic to humans at the residual levels following the use of our SDC-based products. In addition, our data shows the components of SDC, ionic silver and citric acid, to be non-toxic, particularly at the low concentrations required to eliminate microorganisms. At higher concentrations, citric acid can be an eye irritant. We have tested a concentrated SDC formulation using standard protocols to measure acute toxicity. Acute oral and dermal toxicity was not observed at doses up to and including 5000 mg/kg. Data from eye and skin studies showed only slight irritation and no dermal sensitization.

### ***GRAS Status as Contact Biocide***

A committee of independent experts critically reviewed efficacy and toxicity data for SDC and the SDC-based PURE Hard Surface disinfectant and food contact surface sanitizer. The committee found no evidence that SDC demonstrates a hazard to the public when used as a contact biocide on food contact surfaces and food-use utensils. The committee, therefore, concluded such use to be generally recognized as safe, consistent with the EPA registration (discussed below), allowing for use on food manufacturing and processing equipment and food preparation surfaces.

### ***Efficacy***

Formulations containing SDC provide complete, quick and broad-spectrum antimicrobial efficacy against gram positive and gram negative bacteria, enveloped and non-enveloped viruses, and fungi. In addition to quick kill times, SDC provides residual antimicrobial activity. SDC also provides rapid kill times against multiple drug resistant bacteria, including Methicillin-resistant *Staphylococcus aureus*, or MRSA, Vancomycin resistant *Enterococcus faecium*, or VRE, Carbapenem resistant *Escherichia coli*, Carbapenem resistant *Klebsiella pneumoniae* and Carbapenem resistant *Klebsiella pneumoniae*, NDM-1+. See “EPA Registrations” below for more detailed efficacy data.

### ***Natural and Environmentally Responsible***

SDC is made of simple and all-natural ingredients: water, citric acid and minute amounts of ionic silver. SDC does not present a threat to the environment. If introduced to water systems, the low concentrations of ionic silver in SDC would react with naturally present substances such as chlorides, sulfides and organic matter. These reactions would create insoluble silver complexes and render the silver inert. In addition, we manufacture SDC through a “zero waste” process in which no byproducts or environmental effluent are created.

### **Market Opportunity**

#### ***U.S. Incidence and Cost of Foodborne Illness***

According to an Ohio State University study published in the Journal of Food Protection, completed by Dr. Scharff, a consumer science professor, foodborne illness poses a \$77.7 billion economic burden in the United States annually. This cost estimate includes health related costs, associated medical costs, productivity losses, mortality, and pain and suffering. The study noted that excluding the estimated costs for pain and suffering, health related costs exceeded \$51 billion. The study does not include costs to the food industry, including reduced consumer confidence, reduced brand value, product recall costs, and litigation, nor does it include the cost to public health agencies (local, state and federal) that are required to respond to illnesses and outbreaks. In addition, the study cited *Salmonella* as the most costly pathogen with an economic burden estimated to be in excess of \$11 billion. This is primarily due to its high incidence and mortality rate.

#### ***Increased Regulatory Requirements in the U.S.***

The increasing trend of reported foodborne illness over the last decade has resulted in heightened awareness by various government agencies, national media and social media outlets thereby affecting consumer confidence and elevating federal and state regulatory scrutiny.

In 2011, the Food Safety Modernization Act was passed by the U.S. Congress, resulting in increased regulatory requirements for preventive controls, verification and validation of food safety plans by food processors. Additionally, in December 2013, the Food Safety and Inspection Service (FSIS) of the USDA, announced its *Salmonella* Action Plan (SAP), which is focused on identifying solutions to reduce the incidence of *Salmonella* in meat and poultry. We believe that the implementation of the SAP will increase the need for new, effective interventions to assist in reducing the incidence of *Salmonella* in meat and poultry.

#### ***Limitations of Existing Food Safety Solutions***

The statistics of the U.S. public health problems attributed to pathogens in the food supply chain demonstrate the increasing need for more effective, efficient and safer interventions. The U.S. food industry continues to rely on the use of toxic chemicals as processing aids or interventions during food processing operations for which pathogens are becoming increasingly resistant and rendering current interventions less efficacious. Most of these chemicals carry various warning labels for their toxic and/or caustic characteristics, which can negatively affect the safety of processing plant personnel, plant operating equipment and the plant environment and its surroundings.

Among the chemicals in current use are: peracetic acid, acidified sodium chlorite (ASC), ozone, trisodium phosphate, cetylpyridinium chloride (CPC), organic acid rinses (lactic acid), hypobromous acid and chlorine dioxide. Some of these chemicals can be difficult to work with as a processing aid as they require heating to become effective or are difficult to mix and stabilize prior to use. Additionally, some of these chemicals damage the food being processed, resulting in decreased yields. Further, the use of certain of these chemicals is limited to treating only specific pathogens and/or only certain foods. In addition, some of these chemicals can produce noxious fumes that over time have been linked to upper respiratory illness and typically require in-plant decontamination of their effluence.

Several large and established corporations currently supply these chemicals. They may also provide other related food safety services such as environmental sanitation programs and food safety consultation and audit services.

### ***Our SDC-Based Products as a Food Safety Solution***

Based on the limitations of the existing food safety solutions, we believe that our SDC-based products, including PURE Hard Surface and PURE Control, are well positioned as new and disruptive solutions for the food safety industry. Given their broad spectrum antimicrobial efficacy and non-toxic properties, our SDC-based products provide significant improvements over current chemical interventions that can both strengthen our customers' food safety practices and help them control and eliminate pathogens present during their food processing operations.

Our studies indicate that our SDC-based products are more effective in reducing or eliminating pathogens than existing chemical interventions. Pilot poultry processing studies showed that SDC achieved an average reduction in *Salmonella* of 2.75 log<sub>10</sub> CFU/cm<sup>2</sup> when applied as an OLR spray and 6.28 log<sub>10</sub> CFU/cm<sup>2</sup> when combined with an immersion chilling process simulating current U.S. industry practices. This data suggests that the use of SDC in poultry processing has the potential to achieve non-detectable *Salmonella* levels. We are currently focused on completing in-plant validation trials to test both the effectiveness of PURE Control in actual in-plant use for pre and post OLR poultry processing and to attempt to gain USDA approval for its use in OLR poultry processing.

Similarly, pilot produce processing studies showed that SDC achieved average reductions up to 2.36 log<sub>10</sub> CFU/cm<sup>2</sup> when applied alone as a spray and up to 3.10 log<sub>10</sub> CFU/cm<sup>2</sup> when combined with chlorine wash, simulating current processing practices. Currently, produce processors hope to achieve only a 1 log<sub>10</sub> CFU/cm<sup>2</sup> reduction per intervention treatment. This data suggests that by incorporating SDC, produce processors can improve their results 100-fold with only one step. Moreover, sensory evaluations of both poultry and produce treated with SDC indicated no difference in color, appearance or odor to untreated controls. Additionally, SDC had no effect on the nutritional composition of either poultry or produce.

In addition to providing better efficacy, our SDC-based products can provide users with the following benefits compared to the current processing chemicals they are using:

Easier to handle and dilute;

Non-corrosive to processing equipment;

Non-toxic to manufacturing personnel by not creating noxious fumes or other detrimental environmental effluence;  
and

Neutral to positive yield impact on the processed food

Based on their performance and characteristics, we believe our SDC-based products can provide our customers with significant advantages to the chemical interventions they are currently using and help them achieve their goal of improving the safety of processed foods they offer to consumers.

## **Business Strategy**

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

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

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

***Direct Food Contact*** - commercializing FDA approved PURE Control as a direct food contact processing aid for fresh produce; commercializing FDA approved PURE Control as a food processing and intervention aid for food processors treating raw poultry in pre and post OLR applications. We also intend to continue our on-going in plant trials to optimize the application of PURE Control in OLR to attempt to gain USDA approval for use in this stage of poultry processing. Additionally, subject to the results of our focused in-plant validation efforts for our approved produce and poultry solutions, we intend to seek approval to utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork.

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

Developing additional proprietary products and applications; and

Protecting and enhancing our intellectual property.

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

## **Our Products**

Our near-term focus is on delivering leading antimicrobial products that address food safety risks across the food industry supply chain. We currently offer PURE<sup>®</sup> Hard Surface as a food contact surface sanitizer and disinfectant to restaurant chains, food processors and food transportation companies. We also offer PURE Control<sup>®</sup> as a direct food contact processing aid. We received the required FDA approvals to market PURE Control<sup>®</sup> as a direct food contact

processing aid for raw poultry and fresh produce in December 2015 and January 2016, respectively. Because additional USDA approval was not required, we began marketing PURE Control as a direct food contact processing aid for fresh produce following our receipt of FDA approval in January 2016.

In July 2016, we received a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. In January 2017, we submitted an additional FCN to the FDA to allow use of higher SDC concentrations in poultry processing, allowing the flexibility to adjust to varying plant and processing conditions. In May 2017, we received a Final Letter from the FDA for this FCN as well as a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for the higher concentrations of SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. We are currently focused on completing in-plant validation trials for PURE Control in pre- and post OLR poultry processing applications, which represents approximately 65% to 75% of the total processing aid market for poultry processing. We are also conducting in-plant trials to optimize the application of PURE Control in OLR to attempt to gain USDA approval for use in this stage of poultry processing.



Subject to the results of our focused in-plant validation efforts for our approved produce and poultry solutions, we intend to seek approval to utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork. In addition to our direct sales efforts with PURE Hard Surface and PURE Control, we market and sell our SDC-based products indirectly through third-party distributors.

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

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

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

### ***PURE Control*®**

We have the necessary regulatory approvals from the FDA to offer PURE Control as a direct food contact processing aid for fresh produce and raw poultry. We also have regulatory approvals from the USDA for certain methods of application of PURE Control on poultry and we are also performing additional trials to attempt to gain further USDA approvals for additional food contact applications for poultry. Additionally, subject to the results of our focused in-plant validation efforts for our approved produce and poultry solutions, we intend to seek approval to utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork.

*Poultry Processing Aid.* In December 2015, we received the required approvals from the FDA stating that our FCN (food contact notification) for SDC as a raw poultry processing aid is complete. We have received a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. In January 2017, we submitted an additional FCN to the FDA to allow use of higher SDC concentrations in poultry processing, allowing the flexibility to adjust to varying plant and processing conditions. In May 2017, we received a Final Letter from the FDA for this FCN as well as a “No Objection Letter” from the USDA’s

Food Safety and Inspection Service (FSIS) granting approval for the higher concentrations of SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry.

We are currently focused on completing in-plant validation trials to test the effectiveness of PURE Control in actual in-plant use for pre and post OLR poultry processing. We are also conducting in-plant trials to optimize the application of PURE Control, including with higher concentrations of SDC, in OLR to attempt to gain USDA approval for use in that stage of poultry processing.

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

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

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

SDC has a neutral to positive impact on yield.

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

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

Easier to handle and dilute;

Non-corrosive to processing equipment;

Does not create noxious fumes; and

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

We are currently focused on completing in-plant validation trials to test the effectiveness of PURE Control in actual in-plant use and to optimize the application of PURE Control for poultry processing.

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

Data from testing conducted by Dr. James Marsden at Kansas State University and submitted in support of our FCN for produce showed that SDC achieved average reductions up to  $2.36 \log_{10}$  CFU/cm<sup>2</sup> when applied alone as a spray and up to  $3.10 \log_{10}$  CFU/cm<sup>2</sup> when combined with chlorine wash, simulating current processing practices. Sensory evaluations of produce treated with SDC indicated no difference in color, appearance or odor to untreated controls; and SDC had no effect on the nutritional composition of the produce.

Currently, produce processors target achieving only a  $1 \log_{10}$  CFU/cm<sup>2</sup> reduction per intervention treatment. Data suggests that by incorporating SDC, processors can improve their results 100-fold with only one step. This represents a significant advantage to produce processors as well as improvement to the safety of processed produce going to the consumer.

*Other Processing Aids under Development.* Subject to the results of our focused in-plant validation efforts for our approved produce and poultry solutions, we intend to seek approval to utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork. In addition, we may identify other food processing opportunities for SDC.

#### ***Additional SDC-Based Products***

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

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

***PURE Complete Solution***

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

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

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

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

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

***Axen® 30 (Ready-to-Use)***

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

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

Axenohl is our patented and EPA-registered SDC-based antimicrobial formulation for use as a raw material ingredient in the manufacturing of EPA-registered products. Axenohl is a colorless, odorless and stable solution that provides fast acting efficacy against bacteria, viruses and fungi when manufactured into consumer and commercial disinfecting and sanitizing products. Axenohl is currently sold on a limited basis to distributors who manufacture their own respective end-use products.

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

SILVÉRION is our patented SDC-based antimicrobial formulation for use as a raw material ingredient in the manufacturing of personal care products. It can be used as either an active ingredient or a preservative. SILVÉRION is a colorless, odorless and stable solution that provides ionic silver in a water-soluble form. It provides fast acting efficacy at low concentrations against a broad-spectrum of bacteria, viruses, yeast and molds. SILVÉRION is currently sold domestically and outside of the United States in various personal care products.

**EPA Registrations**

We sell our EPA-regulated products under the following three EPA registrations: (i) SDC3A, our hard surface disinfectant and food contact surface sanitizer, (ii) Axen30, our hard surface disinfectant, and (iii) Axenohl, our antimicrobial formulation for use as a raw material in the manufacturing of EPA-registered products.

**PURE Hard Surface SDC3A Registration**

The EPA registration for SDC3A, marketed as PURE Hard Surface, our disinfectant and food contact surface sanitizer, includes the following efficacy claims:

<b>Organism</b>	<b>Kill Time</b>
<i>Pseudomonas aeruginosa</i>	30 seconds
<i>Salmonella enterica</i>	30 seconds
<i>Staphylococcus aureus</i>	2 minutes
<i>Listeria monocytogenes</i>	2 minutes
Vancomycin resistant <i>Enterococcus faecium</i> (VRE)	2 minutes
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	2 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA)	2 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA-PVL)	2 minutes
<i>Escherichia coli</i> O157:H7	2 minutes
<i>Acinetobacter baumannii</i>	2 minutes
<i>Campylobacter jejuni</i>	2 minutes
Carbapenem resistant <i>Escherichia coli</i>	2 minutes
Carbapenem resistant <i>Klebsiella pneumoniae</i>	2 minutes
Carbapenem resistant <i>Klebsiella pneumoniae</i> , NDM-1 +	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	5 minutes
HIV type 1	30 seconds
Rotavirus	30 seconds
Human Coronavirus	30 seconds
Influenza A (H1N1)	30 seconds
Swine Influenza A (H1N1)	30 seconds
Respiratory Syncytial Virus	30 seconds
Adenovirus Type 2	30 seconds
Avian Influenza A	30 seconds
Influenza A	30 seconds
Hepatitis B Virus (HBV)	60 seconds
Hepatitis C Virus (HCV)	60 seconds
Murine Norovirus	60 seconds
Norovirus	60 seconds
Herpes Simplex Type 1	60 seconds
Rhinovirus	60 seconds
Polio Type 2	60 seconds

The EPA registration for SDC3A also claims 24-hour residual protection against certain bacteria.

***Toxicity Categories***

The EPA categorizes the toxicity of antimicrobial products from Category I to Category IV. The following table shows the EPA toxicity categories and required signal words.

<b>Toxicity Category</b>	<b>Signal Word</b>
I	DANGER, POISON
II	WARNING
III	CAUTION
IV	None required

SDC3A is a Category IV product for which no signal words are required.

***Axen30 Registration***

Axen30 is a hard surface disinfectant and is a predecessor product to SDC3A. It offers similar broad-spectrum efficacy but longer kill times. Axen30 is not approved for use on food contact surfaces. Axen30 is currently sold on a limited basis by distributors under their respective private labels.



### *Axenohl Registration*

Axenohl is registered as a raw material ingredient for the manufacturing of EPA-registered products and as such does not carry specific efficacy claims. Axenohl is sold to distributors who manufacture their own respective end-use products.

### **Intellectual Property**

Our policy is to pursue patents and trademarks, maintain trade secrets and use other means to protect our technology, inventions and improvements that are commercially important to the development of our business.

We have applied for U.S. and foreign patent protection for our SDC technology. Currently, we own twelve U.S. issued patents. Approximately thirty patents have been issued outside of the U.S., and we own approximately four patents pending around the world. The expiration dates for our twelve U.S. issued patents begin in 2018 and end in 2030. In September 2013, we decided to abandon pending and issued patents in non-strategic international territories. We intend to focus our future patent prosecution and defense efforts primarily to North America, Europe, Asia and Mexico.

Additional patent applications may not be granted, or, if granted, may not provide adequate protection to us. We also intend to rely on whatever protection the law affords to trade secrets, including unpatented know-how. Other companies, however, may independently develop equivalent or superior technologies or processes and may obtain patents or similar rights with respect thereto.

Although we believe that we have developed our technology independently and have not infringed, and do not infringe, on the patents of others, third parties may make claims that our technology does infringe on their patents or other intellectual property. In the event of infringement, we may, under certain circumstances, be required to modify our infringing product or process or obtain a license. We may not be able to do either of those things in a timely manner if at all, and failure to do so could have a material adverse effect on our business. In addition, we may not have the financial or other resources necessary to enforce a patent infringement or proprietary rights violation action or to defend ourselves against such actions brought by others. If any of the products we develop infringe upon the patent or proprietary rights of others, we could, under certain circumstances, be enjoined or become liable for damages, which would have a material adverse effect on our business.

We also rely on confidentiality and nondisclosure agreements with our employees, customers, consultants, advisors, licensees and potential partners to protect our technology, intellectual property and other proprietary property. Pursuant to the foregoing and for other reasons, we face the risk that our competitors may acquire information which we consider to be proprietary, that such parties may breach such agreements or that such agreements will be inadequate or unenforceable.

Further, we own the registered trademarks or pending trademark applications for PURE Bioscience®, Powered by SDC Ag+®, PURE®, Axenohl®, Axen®, SILVÉRIION®, and PURE Control®. In addition, we have applications for other trademarks pending around the world, which may or may not be granted. We previously allowed the marks Kinderguard®, Cruise Control®, Staphacide®, Nutripure®, Elderguard®, and Critterguard® to go abandoned, as they were no longer in line with our food safety business strategy.

## **Research and Development**

We recognize the importance of innovation to our business strategy and long-term success. A key aspect of our business strategy is to leverage our technology platform to develop additional proprietary products and applications, including end use products and raw material formulations derived from our technology platform. We conduct our primary research and development activities in-house and use third-party laboratories to conduct independent testing. We also engage development partners to perform research and development activities at their own expense for specific products and processes using SDC. Amounts spent on research and development activities during the fiscal years ended July 31, 2018 and 2017 were \$459,000 and \$779,000, respectively.

## Sales and Marketing

A critical aspect of our business strategy is to leverage the industry experience of our internal sales force, the members of our Board of Directors and our management team in order to maximize the commercial potential of our technology platform in the food industry. During 2015 and 2016, we strengthened our internal sales and marketing capability by adding to our team experienced food industry sales professionals.

According to the CDC, FDA and other food industry sources, food contamination and food borne illnesses have been increasing. We believe our focus on food safety is addressing a significant need to provide safe, non-toxic and effective solutions to mitigate the increase of food contamination and food borne illnesses. We believe our products can be used effectively to prevent or mitigate the risk of food contaminants in various stages of the food supply chain. Our current sales and marketing efforts include demonstrating our SDC products' effectiveness as a hard surface disinfectant and sanitizer for:

1. Foodservice operators and food transportation companies – such as food preparation and cooking surfaces; consumer eating and other common areas; drink and ice dispensers; and trucks used to transport food.
2. Food manufacturers and processors – such as food production and transportation equipment.

Our sales team is actively developing customer relationships with certain segments of foodservice operators, food processors, food manufacturers and food transportation companies. Due to the recent introduction of our food safety products and the importance of food safety to our customers, the sales cycle to secure a new customer is long and unpredictable. We have recently completed and are currently conducting numerous product evaluation trials and comparative testing of our SDC-based products with prospective customers, which we believe will result in future revenue. We believe our products provide superior pathogen and hygiene control performance characteristics as compared with legacy chemical products, which also have higher toxicity profiles than our SDC-based products.

In addition to our direct sales and marketing efforts, we intend to selectively form partnerships with industry leaders for a variety of uses and applications of our products and technology. These partnerships may be for both U.S. and international markets where we believe we may leverage the product development, sales and marketing resources of business partners to commercialize our SDC technology in their respective markets.

A significant portion of our historical revenues were generated by an international chemical distributor who sold our SDC-based formulations to other manufacturers for use as a raw material ingredient in the production of personal care products. Other historical revenues were primarily to U.S. distributors who sold our SDC-based products into the consumer, industrial janitorial and sanitization market.

## Sales Concentration

Net product sales were \$1,774,000 and \$1,831,000 for the years ended July 31, 2018 and 2017, respectively. For the year ended July 31, 2018, three individual customers accounted for 20%, 16% and 11%, of our net product sales, respectively. No other individual customer accounted for 10% or more of our net product sales. For the year ended July 31, 2017, two individual customers accounted for 33% and 19%, of our net product sales, respectively. No other individual customer accounted for 10% or more of our net product sales. For the years ended July 31, 2018 and 2017, all net product sales occurred in the United States.

From time to time, one or a small number of our customers may represent a significant percentage of our revenue. Our three largest customers accounted for 47% of our revenue for the fiscal year ended July 31, 2018. Although we have agreements with many of our customers, these agreements typically do not prohibit customers from purchasing products and services from competitors. A decision by any of our major customers to significantly reduce the amount of product ordered or license fees paid, or their failure or inability to pay amounts owed to us in a timely manner, or at all, could have a significant adverse effect on our business.

## **Competition**

The markets for our SDC-based products and each of their potential applications are highly competitive. We have a number of competitors that vary in size, scope and breadth of products offered. These competitors include some of the largest global corporations, and most of our competitors have significantly greater financial resources than we do and offer multiple service and product offerings as well as consulting services to their customers. We expect to face additional competition from other competitors and technologies in the future.

Because SDC is a new antimicrobial technology to the food industry, our success will depend, in part, upon our ability to achieve a share of our target markets at the expense of established and future products. Even where SDC may have technological competitive advantages over competing products, we, our partners or our distributors, will need to invest significant resources in order to attempt to displace traditional technologies sold by, what are in many cases, well-known industry leaders.

Our SDC-based products (especially at higher silver ion concentration levels) are typically more expensive to produce than existing treatment chemicals, and as a result, customers may not purchase our products for cost reasons, even if we are successful in demonstrating the superior efficacy our products. Further, customers may determine that the other benefits offered by our products (e.g., non-toxic, non-caustic, and neutral to positive yield impact) are not sufficient to overcome the lower cost products offered by our competitors.

## **Manufacturing**

In December 2013, we entered into a five-year strategic collaboration agreement with St. Louis-based Intercon Chemical Company (ICC). The agreement consists of a multi-prong approach to help us accelerate the commercialization of our unique and proprietary SDC-based products. The strategic collaboration agreement provides:

ICC licenses from PURE its patents and technology know-how for the exclusive manufacture of our SDC-based products.

ICC will invest in plant improvements to allow for expanded SDC production.

ICC's R&D team will collaborate on SDC product line development.

ICC licenses the distribution rights for SDC-based products into its core businesses of institutional cleaning and sanitation products.

ICC will also develop a new initiative focused on US hospital, healthcare and medical facilities.

PURE earns royalty income on SDC-products sold by ICC and its affiliates.

The agreement may be terminated by mutual written consent, or by either party upon the material breach of the terms of the agreement by the other party.

Silver is the primary active ingredient in SDC and is a readily available commodity. The other active and inactive ingredients in our products are readily available from multiple sources.

## **Government Regulation**

Our business is subject to various government regulations relating to the protection of public health and the environment. Among these are laws that regulate the manufacture, storage, distribution and labeling of our products, as well as the use, handling, storage and disposal of certain materials in the manufacturing of our products.

### ***Regulation in the United States***

Certain environmental and regulatory matters significant to us are discussed below.

Requirements Imposed by the EPA and Similar State Agencies

We manufacture and sell in the U.S. certain disinfecting products that kill or reduce microorganisms (bacteria, viruses, fungi). The manufacture, labeling, handling and use of these products are regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA. We currently sell three products registered by the EPA under FIFRA, certain of which are approved for use on food contact surfaces and others of which are approved for use on non-food contact hard surfaces. EPA product registration requires meeting certain efficacy, toxicity and labeling requirements and paying ongoing registration fees.

Although states do not generally impose substantive requirements different from those of the EPA, each state in which our products are sold requires registration and payment of a fee. California and certain other states have adopted additional regulatory programs applicable to these types of products that, in some cases, impose a fee on total product sales in the state.

Based on our experience and our knowledge of current trends, we expect the costs and delays in receiving necessary federal and state approvals for these types of products may increase in the coming years.

Requirements Imposed by the FDA and USDA

The FDA's Food Contact Notification ("FCN") Program is intended to ensure the safety of Food Contact Substances (FCS) used in food processing and packaging.

The FCN review period is 120 days from filing, after which, if there are no concerns from the FDA, the FCN automatically becomes effective.

An FCN is considered to be proprietary as it applies only to the specific product and manufacturer or supplier identified in the FCN.

In addition to the FDA's FCN Program, the Company will be required to obtain USDA approval for the use of PURE Control on meat or dairy products.

Upon the FDA's granting of an FCN on a meat or dairy product, PURE will be required to submit the FCN to the Food Safety and Inspection Service (FSIS) of the USDA for a new technology review.

As part of the FSIS review process, PURE may be required to conduct up to three in-plant process validation and optimization trials with the authorization of the USDA.

After successful completion of the in-plant validation trials, the USDA will issue a "Letter of No Objection" and list the Company's SDC-based product as an OLR processing aid in Attachment 1 of FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products.

Requirements Imposed by Ingredient Legislation

Numerous federal, state and local laws regulate the sale of products containing certain identified ingredients that may impact human health and the environment. For instance, California has enacted Proposition 65, which requires the disclosure of specified listed ingredient chemicals on the labels of products. Although none of the ingredients in our current products is reportable under Proposition 65, this and other similar legislation may become more comprehensive in the future and/or new products we may develop could be subject to these regulations.

Requirements Imposed by Other Environmental Laws

A number of federal, state and local environmental, health and safety laws govern the use, handling, storage and disposal of certain materials. Our current manufacturing process for SDC-based products is a "zero waste" process, meaning that no byproducts are created, and we do not use hazardous materials, as defined by applicable environmental laws, in the manufacturing of these products. As such, some of these U.S. environmental laws are not generally applicable to us in their current form. However, these laws may in the future identify as hazardous materials certain materials that we use in our manufacturing processes, or we may opt to or be forced to change our manufacturing procedures in a way that subjects our products or operations to these laws.



*Requirements Imposed by the FDA and USDA*

Various laws and regulations have been enacted by federal, state, local and foreign jurisdictions regulating certain products we anticipate manufacturing and selling for controlling microbial growth in or on foods. In the United States, these requirements generally are administered by the FDA. However, the U.S. Department of Agriculture and EPA also may share in regulatory jurisdiction of antimicrobials applied directly to food as it pertains to poultry and meats.

*Regulation Outside the United States*

The commercialization of SDC-based products in countries other than the U.S. may require that we, or companies with whom we partner for such foreign commercialization, obtain necessary approvals from foreign regulatory authorities comparable to the EPA and USDA, among others. Applicable approval processes and ongoing requirements vary from country to country and may involve more time and expense than that required to obtain approvals in the U.S. In international markets, we currently sell our products under active registrations held by us, or by our distributors. We intend to continue to process registrations ourselves or through distributors as required.

We currently hold a registration from Health Canada for our disinfectant product. Other third-party distributors hold registrations in China and are actively pursuing registrations for our disinfectant products in various Asian markets. Additionally, an opinion has been granted under the Scientific Committee on Consumer Products to sell SDC in the European Union for use in cosmetics, which includes personal care products.

**Employees**

As of October 25, 2018, we employed 9 full-time and 2 part-time employees. We believe that we have been successful in attracting skilled and experienced personnel, but competition for personnel is intense and there can be no assurance that we will be able to attract and retain qualified personnel in the future. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

**Company Information**

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

Our corporate offices are located at 1725 Gillespie Way, El Cajon, California 92020. Our telephone number is (619) 596-8600. Our website address is [www.purebio.com](http://www.purebio.com). We make available free of charge on our website our periodic and current reports, proxy statements and other information as soon as reasonably practicable after such reports are filed with the Securities and Exchange Commission, or SEC. Information contained on, or accessible through, our website is not part of this report or our other filings with the SEC. Our SEC filings are also available to the public from the SEC's website at [www.sec.gov](http://www.sec.gov).

### **Item 1A. Risk Factors**

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

## Risks Related to Our Business and Industry

*As a result of our historical lack of financial liquidity, we do not currently have sufficient working capital to fund our planned operations and may not be able to continue as a going concern.*

We have a history of recurring losses, and as of July 31, 2018, we have incurred a cumulative net loss of approximately \$117 million. As of July 31, 2018, we had \$851,000 in cash and cash equivalents and \$608,000 in accounts payable.

On August 16, 2018, we completed a closing of a private placement financing to accredited investors. We raised approximately \$1.5 million in net proceeds from the private placement and issued an aggregate of 3,333,964 shares of our common stock at a purchase price of \$0.45 per share, including the conversion of approximately \$0.5 million held in the form of a promissory note as of July 31, 2018. The shares issued in the private placement financing were issued pursuant to a securities purchase agreement entered into with the investors. Mr. Tom Y. Lee, a member of the Company's Board of Directors invested approximately \$1.0 million through his affiliates, including approximately \$0.5 million of cash and the cancellation of existing indebtedness in the amount of approximately \$0.5 million that was held in the form of a promissory note payable as of July 31, 2018. During year ended July 31, 2018, our cash outflows for operating activities and for investments in patents and fixed assets were \$3.9 million. As a result, our existing cash resources are not sufficient to meet our anticipated needs over the next twelve months from the date hereof, and we will need to raise additional capital to continue our operations and to implement our business plan, which capital may not be available on acceptable terms or at all. To help extend our operating window, we have reduced our headcount and limited our research and product development activities. Based on our current plans and available resources, we believe we can maintain our current operations through the end of January 2019. We estimate that the costs to wind-down our operations in an orderly manner will cost approximately \$500,000. As a result, we need to secure significant additional capital to continue to fund our operations beyond January 2019.

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

the market acceptance of, and demand for, our products;

the timing and costs of executing our sales and marketing strategies;

our ability to successfully complete the in-plant validation trials requested by potential customers and our ability to convert these trials into customer orders for our products;

the costs and time required to obtain the necessary regulatory approvals for our products, including the required USDA approval for use of PURE Control in OLR processing of raw poultry;

the extent to which we invest in new testing and product development, including in-plant optimization trials;

the extent to which our customers continue to place product orders as expected and expand their existing use of our products;

the cost and time to satisfy unique customer requirements regarding validation trials or to support the value proposition and benefits of our products;

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

our ability to control the timing and amount of our operating expenses, including the costs to attract and retain personnel with the skills required to implement our business plan; and

the costs to file, prosecute and defend our intellectual property rights.

The above factors, along with our history and near term forecast of incurring net losses and negative operating cash flows, raise substantial doubt about our ability to continue as a going concern.

If we do not obtain additional capital from external sources, we will not have sufficient working capital to fund our planned operations or be able to continue as a going concern. Further, if we further reduce our expenses and capital expenditures, we may not be able to effectively execute our business plan. We cannot assure you that additional financing will be available when needed or that, if available, we can obtain financing on terms favorable to us or to our stockholders. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. Further, any contracts or license arrangements we enter into to raise funds may require us to relinquish our rights to our products or technology, and we cannot assure you that we will be able to enter into any such contracts or license arrangements on acceptable terms, or at all. Having insufficient funds may require us to delay or scale back our marketing, distribution and other commercialization activities or cease our operations altogether.

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

We had a loss of \$7.4 million for the fiscal year ended July 31, 2018, and a loss of \$6.3 million for the fiscal year ended July 31, 2017. As of July 31, 2018, we have incurred a cumulative net loss of approximately \$117 million. Although we believe we are making progress on implementing our business plan focused on the food safety market, we expect to continue to have losses in future periods. None of our existing agreements, including those with Subway and Chipotle, contain provisions that guarantee us any minimum revenues. If the penetration into the marketplace of PURE Hard Surface, PURE Control and our other SDC-based products is unsuccessful, our revenue growth is slower than anticipated or our 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 our sales and marketing efforts, our product testing and optimization, and our product development and regulatory initiatives, 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. Given our recent introduction of our SDC-based products in the food safety market, we are unable to predict the extent of our future losses or when we will generate sufficient revenues to become profitable, and it is possible we will never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

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

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

As of October 25, 2018, we have 84,419,311 shares of common stock issued and outstanding or reserved for issuance under equity compensation plans, vested and unvested options, warrants, and unvested restricted stock units. Our current authorized capital stock is limited to 100,000,000 shares of common stock and 5,000,000 shares of preferred stock. Any increase in our authorized capital stock would require the approval of a majority of our shareholders as well as the approval of our Board of Directors. If we were unable to increase our authorized capital stock for any reason, our ability to raise additional capital through the issuance of equity or convertible debt would be severely

compromised and we may be unable to obtain equity or convertible debt capital at all.

*Because we only recently focused our business on the food safety market, it is difficult to evaluate our prospects.*

Our success will depend on our ability to increase customer awareness and adoption of our food safety product offerings, PURE Hard Surface and PURE Control. We only began focusing our business on developing and offering products that address food safety risks across the food industry supply chain in August 2013. In addition, we only recently received the required FDA and USDA approvals to market PURE Control as a direct food contact processing aid for fresh produce and as a spray or dip applied to raw poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing. We are still pursuing the required USDA approval for use of PURE Control in OLR processing of raw poultry. Further, we are currently working on completing in-plant validation trials to test the effectiveness of PURE Control in actual in-plant use and to optimize the application of PURE Control for poultry processing. Due to the recent introduction of our food safety products and the importance of food safety to our customers, the sales cycle to secure new customers is long and unpredictable. We have encountered and likely will continue to encounter risks and difficulties associated with introducing or establishing new commercial products in this highly competitive and rapidly evolving market. These risks include the following, among others:

we may not be successful in demonstrating the effectiveness of PURE Control in actual in-plant use situations or satisfy the requirements of our potential customers;

we may not be successful in converting in-plant trials into customer product orders;

our SDC-based product offerings (especially at higher silver-ion concentrations) are typically more expensive to produce than existing treatment chemicals, and as a result, customers may not purchase our products for cost reasons, even if we are successful in demonstrating the superior efficacy or other benefits of our products;

our customers may not continue to place product orders as expected or may not expand their use of our products;

we may not be successful in demonstrating the value proposition of our products, including its non-corrosive and non-toxic characteristics and its neutral to positive processing yield impact;

we may not succeed in materially penetrating the food safety markets with our SDC products and technology;

we may not be successful in developing an effective sales and marketing infrastructure to commercialize our products;

we may not generate sufficient revenues or raise sufficient funds to support our operations or the implementation of our business plan;

we may not be successful in controlling our operating expenses;

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

we may not attract and retain key sales and marketing, technical and management personnel;

we may not successfully comply with or maintain the regulatory approvals we obtain for our technology and products;

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

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

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

Any failure to successfully address these risks and uncertainties could seriously harm our business and prospects.

***We may not be able to correctly estimate our future revenues and operating expenses, which could lead to cash shortfalls, and require us to secure additional financing sooner than planned.***

We may not correctly predict the amount or timing of future revenues and our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

our expectations regarding revenues from sales of our products;

the time and resources required to complete in-plant validation and optimization trials;

the time and cost of obtaining any necessary regulatory approvals;

the cost and time to develop and obtain regulatory approvals for additional products as part of our long-term business plan;

the cost and time required to create effective sales and marketing capabilities and commercialization strategies;

the expenses we incur to maintain and improve our platform technology;

the cost and time to satisfy unique customer requirements regarding validation and optimization trails;

the costs to attract and retain personnel with the skills required for effective operations; and

the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

In addition, our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our products and services, and from collaborations with third parties. However, we may not correctly predict the amount or timing of future revenues. In addition, we may not be able to adjust our operations in a timely manner to compensate for any unexpected shortfall in our revenues or we may increase our expenses as part of implementing our long-term business plan. As a result, a significant shortfall in our planned revenues or a significant increase in our planned expenses could have an immediate and material adverse effect on our business and financial condition. In such case, we may be required to issue additional equity or debt securities or enter into other commercial arrangements, including relationships with corporate and other partners, sooner than anticipated to secure the additional financial resources to support our development efforts and future operations.

***Our quarterly operating results may vary, which could negatively affect the market price of our common stock.***



Because of our limited operating history and the early commercial stage of our SDC-based products in the food safety market, we have limited insight into trends that may emerge and affect our business. Forecasting future revenues is difficult, especially because our products are novel, and market acceptance of our products is reliant on our customers' confidence, based on scientific data and actual in-plant trials, that our product can improve their food safety efforts. Because food safety is such a critical factor to our customers and potential customers, we often experience long sales cycles and our customers often require extensive evaluation and in-plant trial periods before agreeing to use our products throughout their systems. In addition, 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. Additional factors that could cause our financial results to fluctuate unexpectedly, include: the mix of product sales, the cost of product sales, our ability to meet customer demand, delays in achieving our regulatory milestones, changes in our operating expenses, including non-cash expenses such as the fair value of stock options granted to our employees, and manufacturing or supply issues. As a result, our quarterly operating results may vary, which could negatively affect the market price of our common stock.

***If we are unable to obtain the required regulatory approvals from the FDA and USDA, or if such efforts are delayed, our ability to commercialize PURE Control as a direct food contact processing aid will be harmed and our business and operating results will suffer.***

We received the required FDA approvals to market PURE Control as a direct food contact processing aid for raw poultry and fresh produce in December 2015 and January 2016, respectively. No additional approval from the USDA is required for fresh produce. In July 2016, we received a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. In January 2017, we submitted an additional FCN to the FDA to allow use of higher SDC concentrations in poultry processing, allowing the flexibility to adjust to varying plant and processing conditions. In May 2017, we received a Final Letter from the FDA for this FCN as well as a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for the higher concentrations of SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. We have not, however, received the required approval from the USDA to utilize PURE Control in OLR poultry processing. We are continuing our on-going plant trials to optimize the application of PURE Control, including with higher concentrations of SDC, in OLR to attempt to gain USDA approval for use in that stage of poultry processing, but there is no assurance that we will obtain such approval on a timely basis, or at all. Further, even if we elect to seek regulatory approval, there is no assurance we will be successful in obtaining the required approvals from the FDA and USDA to utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork. If we are unable to obtain the required regulatory approvals from the FDA and USDA, or if such efforts are delayed, our ability to commercialize PURE Control as a direct food contact processing aid for poultry and as a direct food contact processing aid for raw meats will be restricted and our business and operating results will suffer.

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

From time to time, one or a small number of our customers may represent a significant percentage of our revenue. Our three largest customers accounted for 47% of our net product sales for the fiscal year ended July 31, 2018. Our two largest customers accounted for 20% and 16% of net product sales, respectively. No other individual customer accounted for 10% or more of our net product sales. Although we have agreements with many of our customers, these agreements typically do not prohibit customers from purchasing products and services from competitors or contain minimum purchase obligations. A decision by any of our major customers to significantly reduce the amount of product ordered or license fees paid, or their failure or inability to pay amounts owed to us in a timely manner, or at all, could have a significant adverse effect on our business.

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

We have and are currently focusing substantially all of our time and financial resources in the development and commercialization of our core SDC technology to address food safety risks across the food industry supply chain. Although our SDC technology has applications in multiple industries, we expect that sales of SDC and SDC-based products as a food safety solution will constitute a substantial portion, or all, of our revenues in future periods. We are marketing our SDC-based products to restaurant chains, food manufacturers, food processors and food transportation companies. Our SDC-based products have not yet been broadly accepted into the food safety market, and may never be broadly accepted. Any material decrease or significant delay in the overall level of sales or expected sales of, or the prices for, our SDC-based products, whether as a result of competition, delays in obtaining regulatory approvals, long sales cycles, change in customer demands or requirements, or any other factor, would have a materially adverse effect on our business, financial condition and results of operations. 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 by competitors that are more favorably received than our products, are more cost-effective or otherwise render our products less attractive or obsolete.

***We are subject to intense competition in the food safety market.***

Our SDC-based products compete in the highly competitive food safety market. Our SDC-based product offerings (especially at higher silver ion concentration levels) are typically more expensive to produce than existing treatment chemicals, and as a result, customers may not purchase our products for cost reasons, even if we are successful in demonstrating the superior efficacy of our products. In addition, customers may determine that the other benefits offered by our products (e.g., non-toxic, non-caustic, and neutral to positive yield impact) are not sufficient to overcome the lower cost products offered by our competitors. Further, most of our competitors have been in business for a longer period of time than we have, and offer a greater number of products and services than we do and have greater financial, technical, sales and other resources than we do. Many of our competitors already have well established brands and distribution capabilities, and in some cases are able to leverage the sale of other products with more favorable terms for products competing with our own. We also have significantly fewer sales personnel than virtually all of our competitors. Furthermore, recent trends in this industry are for large food safety companies to consolidate into a smaller number of very large entities, which further concentrates financial, technical and market strength and increases competitive pressure in the industry. If we directly compete with these very large entities for the same markets and/or products, their financial strength could prevent or delay us from capturing a meaningful share the food safety market. It is also possible that developments by our competitors will make our technologies or products noncompetitive or obsolete. Our ability to compete will depend upon our ability, and the ability of our distributors and other partners, to develop brand recognition, develop the scientific and plant trial data to demonstrate the efficacy of our products, and to displace existing, established and future products in our relevant target markets. We, or our distributors and partners, may not be successful in doing so, which would have a materially adverse effect on our business, financial condition and results of operations.

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

We have limited experience in the sales, marketing and distribution of our products in the food safety market. We began to focus on the food safety market in August 2013. We received the required FDA approvals to market PURE Control as a direct food contact processing aid for fresh produce in January 2016. We received the required USDA and FDA approvals to market PURE Control for use as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry in July 2016 and May 2017, respectively. We have not, however, received the required approval from the USDA to utilize PURE Control in OLR poultry processing, and there is no assurance we will receive USDA approval, which limits our ability to market PURE Control for poultry processing. As a result, our sales and marketing experience with these products are limited, and our current sales, distribution and marketing strategies and programs may not be successful. Further, due to the recent introduction of our food safety products and the importance of food safety to our customers, the sales cycle to secure a new customer is long and unpredictable. Potential customers typically require that we complete extensive in-plant validation studies with our products. We may not be successful in demonstrating the effectiveness of PURE Control in actual in-plant use situations or satisfy the requirements of our potential customers. Moreover, we may not be successful in converting in-plant trials into customer product orders. We also have a relatively small sales and marketing organization and a limited number of distributors. We may not be able to establish the sales, marketing, and distribution capabilities necessary to build our business and generate sufficient revenues to support our operations and the implementation of our business plan.

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

In December 2013, we entered into a five-year strategic collaboration agreement with St. Louis-based Intercon Chemical Company (“ICC”) where we granted ICC the right to be the exclusive manufacturer for all our SDC-based products. We do not have any manufacturing facilities ourselves and we currently rely on ICC to manufacture our SDC-based products and may in the future rely on one or more third-party manufacturers to properly manufacture our products. We may not be able to quickly replace our manufacturing capacity if ICC is unable to manufacture our products as a result of a fire, natural disaster (including an earthquake), equipment failure or other difficulty, or if such ICC facilities are deemed not in compliance with current “good manufacturing practices,” and the noncompliance could not be rapidly rectified. ICC is our single manufacturer for our SDC-based products and may not be replaced without significant effort and delay in production. A supply interruption or an increase in demand beyond our current manufacturer’s capabilities could harm our ability to manufacture such products until new manufacturers are identified and qualified, which would have a significant adverse effect on our business and results. Any third-party manufacturer that we find may not match our quality standards or be able to meet customer requirements.

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

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

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

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

We are generally unable to increase our product prices to our customers, partners and distributors quickly in order 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.

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

***If we are not able to manage any growth we achieve effectively, our business and operating results will be harmed.***

In order to implement our business plan and achieve and maintain market acceptance of our SDC-based products, we will need to expand our business operations and hire additional sales and support personnel. We may not have sufficient resources to do so. If we hire additional personnel and invest in additional infrastructure, we may not be effective in expanding our operations and our systems, procedures or controls may not be adequate to support any such expansion. Failure to properly manage our growth could have a material adverse effect on our business and our operating results.

***The industries in which we operate are heavily regulated.***

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

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

Some potential applications of SDC, such as those aimed at healthcare, veterinary and certain food preparation markets, may require approval of other government agencies prior to marketing or sale in the U.S. or in foreign markets, such as the U.S. Food and Drug Administration, or FDA, or the United States Department of Agriculture, or USDA. Obtaining FDA and/or USDA approval is a complicated and expensive process and such approvals may never be obtained for any SDC products. If FDA and/or USDA approvals are obtained, the approvals may limit the uses for which SDC products may be marketed such that they may not be profitable to us, and the applicable products would be subject to pervasive and continuing regulation by the FDA and/or USDA that could lead to withdrawal or limitation of any product approvals.

For example, in November 2014, we withdrew, without prejudice, our FCN for raw poultry due to receipt of a Deficiency Letter from the FDA stating that the agency has developed new data that is currently under review, which data calls into question the long established safety levels of the dietary intake of silver in the U.S. from food contact uses previously approved by the FDA. As a result, the FDA indicated that it would not approve our FCN absent new data or additional information that adequately addresses its new toxicity concerns. We also received a similar Deficiency Letter from the FDA for the FCN we submitted in October 2014 for the use of SDC to reduce Salmonella, E. coli and Listeria in the processing of produce. In January 2015, we withdrew, without prejudice, our produce FCN and postponed the filing of our FCN for the use of SDC as a processing aid for beef and pork. We resubmitted our poultry FCN in June 2015. In September 2015, we received an Acknowledgement Letter from the FDA stating that our FCN for SDC as a raw poultry processing aid is complete and setting an effective date of December 2015. Following the completion of additional testing demonstrating further reduction of silver residues to levels approaching non-detectable, and subsequent encouraging discussions held with the FDA, we resubmitted our produce FCN in September 2015. We received the required FDA approvals to market PURE Control as a direct food contact processing aid for raw poultry and fresh produce in December 2015 and January 2016, respectively. In July 2016, we received a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. In January 2017, we submitted an additional FCN to the FDA to allow use of higher SDC concentrations in poultry processing, allowing the flexibility to adjust to varying plant and processing conditions. In May 2017, we received a Final Letter from the FDA for this FCN as well as a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for the higher concentrations of SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. We have not, however, received the required approval from the USDA to utilize PURE Control in OLR poultry processing. We are continuing our



on-going plant trials to optimize the application of PURE Control, including with higher concentrations of SDC, in OLR to attempt to gain USDA approval for use in that stage of poultry processing, but there is no assurance that we will obtain such approval on a timely basis, or at all. Further, even if we elect to seek regulatory approval, there is no assurance we will be successful in obtaining the required approvals from the FDA and USDA to utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork. If we are unable to obtain the required regulatory approvals from the FDA and USDA, or if such efforts are delayed, our ability to commercialize PURE Control as a direct food contact processing aid for poultry and as a direct food contact processing aid for raw meats will be restricted and our business and operating results will suffer.

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

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

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

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

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

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

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

*We may become subject to product liability claims.*

As a business that manufactures and markets products for use by consumers and institutions, we may become liable for any damage caused by our products, whether used in the manner intended or not, including potentially damage to our customers' businesses. Regardless of merit or potential outcome, product liability claims against us may result in, among other effects, the inability to commercialize our products, impairment of our business reputation, and distraction of management's attention from our primary business. If we cannot successfully defend ourselves against product liability claims we could incur substantial liabilities. Although we maintain general and product liability insurance, our insurance may not cover potential claims and may not be adequate to indemnify for liabilities that may be imposed. Any imposition of liability that is not covered by insurance or is in excess of insurance coverage could harm our business and operating results.

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

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

***Compliance with the reporting requirements of federal securities laws can be expensive.***

We are a public reporting company in the United States, and accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the compliance obligations of the Sarbanes-Oxley Act. The costs of complying with the reporting requirements of the federal securities laws, including preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders, can be substantial.

***If we fail to maintain an effective system of internal controls, we may not be able to accurately determine our financial results or prevent fraud. As a result, the Company's stockholders could lose confidence in our financial results, which could harm our business and the value of the Company's common shares.***

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate and report on our internal controls over financial reporting. Our internal controls and financial reporting are not subject to attestation by our independent registered public accounting firm pursuant to the exemption provided to issuers that are not "large accelerated filers" or "accelerated filers" under the Dodd-Frank Act of 2010. We cannot be certain that we will be successful in maintaining adequate internal controls over our financial reporting and financial processes in the future. We may in the future discover areas of our internal controls that need improvement. Furthermore, to the extent our business grows, our internal controls may become more complex, and we would require significantly more resources to ensure our internal controls remain effective. If we or our independent auditors discover a material weakness, the disclosure of that fact, even if quickly remedied, could reduce the market value of the Company's common stock. Additionally, the existence of any material weakness or significant deficiency would require management to devote significant time and incur significant expense to remediate any such material weaknesses or significant deficiencies and management may not be able to remediate any such material weaknesses or significant deficiencies in a timely manner.

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

Our success depends largely on the execution of our business strategy by our management team and the members of our Board of Directors. Our Board and management will be evaluating how to best execute our near-term strategy to drive customer adoption in the food industry by addressing food safety solutions across the supply chain in order to prevent or mitigate food contamination or the potential for food-borne illness with specific customer focus in foodservice providers, food processors and food manufacturers. Our directors, executive officers and key personnel could terminate their services with us at any time without notice and without penalty. For example in August 2018, Mr. Pfanzelter retired from the Board and his position as Chairman of the Board. Additionally, we do not maintain key person life insurance policies on our directors, executive officers or other employees. The loss of one or more of our directors, executive officers or key employees could seriously harm our ability to execute on our business strategy, which could 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. Even if we were able to replace any such individuals in a timely manner, if we are unable to effectively integrate new executive officers or key employees, our operations and prospects could be harmed.

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

To successfully meet our objectives, we must attract and retain highly qualified sales and marketing and management 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 personnel, it will be difficult for us to sell our products or to license our technology or to achieve or maintain regulatory approvals, and we may experience a shortfall in revenue and not achieve our anticipated, or any, growth.

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

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

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

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

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

At July 31, 2018, we had federal and state tax net operating loss carry-forwards of approximately \$106.1 million and \$60.9 million, respectively. Utilization of these net operating loss carry-forwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred, including with respect to our recent private placements, or that could occur in the future, as required by Section 382 of the Internal Revenue Code as well as similar state provisions. These ownership changes may limit the amount of net operating loss carry-forwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 of the Internal Revenue Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Since our formation, we have raised capital through the issuance of capital stock on several occasions (both before and after our initial public offering in 1996) which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future based upon subsequent disposition. While we believe that we have not experienced an ownership change, the pertinent tax rules related thereto are complex and subject to varying interpretations, and thus the applicable taxing authorities may take an alternative position.

Our current federal tax loss carry-forwards begin expiring in the year ended July 31, 2019 and, unless previously utilized, will completely expire in the year ending July 31, 2038. The balance of our current federal net operating loss carry-forwards will expire between July 31, 2019 and July 31, 2038. Our state tax loss carry-forwards began to expire in the year ending July 31, 2018, and will completely expire in the year ending July 31, 2038. If we are unable to earn sufficient profits to utilize the carry-forwards by these dates, they will no longer be available to offset future profits, if any.

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

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

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

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

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

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

In addition, to the extent that we operate internationally, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the U.S. Many countries have a “first-to-file” trademark registration system, which may prevent us from registering or using our trademarks in certain countries if third parties have previously filed applications to register or have registered the same or similar trademarks. Additionally, changes in the patent and/or trademark laws or interpretations of such laws in the U.S. or other countries could diminish the value of our



intellectual property rights. Moreover, our competitors may develop competing technologies that are not covered by the claims of, and therefore do not infringe upon, our issued patents, which could render our patents less valuable to us. If our proprietary rights cannot be, or are not sufficiently, protected by patent and trademark registrations, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products.

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

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

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

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

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

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications

covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO, to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

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

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

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

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

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

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

*The price of our common stock may be volatile.*

Our common stock is approved for quotation on the OTC Markets' OTCQB marketplace under the symbol "PURE." The OTCQB is a regulated quotation service that displays real-time quotes, last-sale prices and volume information in over-the-counter equity securities and provides significantly less liquidity than a listing on the Nasdaq Stock Markets

or other national securities exchange. The OTCQB securities are traded by a community of market makers that enter quotes and trade reports. This market is limited in comparison to the national stock exchanges and any prices quoted may not be a reliable indication of the value of our common stock. Quotes for stocks included on the OTCQB are not listed in the financial sections of newspapers as are those for the Nasdaq Stock Market or the NYSE. Therefore, prices for securities traded solely on the OTCQB may be difficult to obtain.

Trading on the OTCQB Marketplace as opposed to a national securities exchange has resulted and may continue to result in a reduction in some or all of the following, each of which could have a material adverse effect on the price of our common stock and our company:

the liquidity of our common stock;

the market price of shares of our common stock;

our ability to obtain financing to support our operations and the implementation of our business plan;

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

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

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

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

The price and trading volume of our common stock have historically been volatile.

In addition, the market price and trading volume of our common stock may be subject to wide fluctuations in the future in response to:

actual or anticipated fluctuations in our results of operations;

announcements regarding the status of our regulatory efforts;

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

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

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

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

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

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

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

conditions and trends in our industry;

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

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

general economic conditions.

In addition, the stock market in general, the OTCQB, and the market for shares of novel technology companies in particular, have experienced extreme price and volume fluctuations that in some cases may be unrelated or disproportionate to the operating performance of those companies. 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.

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

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

***Our common stock is deemed to be “penny stock,” which may make it more difficult for investors to sell their shares due to suitability requirements.***

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

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

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

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

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

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

#### **Item 1B. Unresolved Staff Comments**

None.



**Item 2. Properties**

We lease a facility in El Cajon, California covering a total of approximately 7,400 square feet. This is our only facility and it includes our corporate offices, research and development laboratory and warehouse. Our current lease on this facility expires in December 2019.

### **Item 3. Legal Proceedings**

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

### **Item 4. Mine Safety Disclosures**

Not applicable.

## **PART II**

### **Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

#### **Information About Our Common Stock**

Our common stock is approved for quotation on the OTC Markets' OTCQB marketplace under the symbol "PURE." The OTCQB is a regulated quotation service that displays real-time quotes, last-sale prices and volume information in over-the-counter equity securities. The OTCQB securities are traded by a community of market makers that enter quotes and trade reports. This market is limited in comparison to the national stock exchanges and any prices quoted may not be a reliable indication of the value of our common stock.

On October 24, 2018, the closing price of our common stock reported on the OTCQB was \$0.47 per share. The following table sets forth, for each of the quarterly periods indicated, the high and low sales prices of our common stock, as reported on the OTCQB.

	High	Low
Year Ended July 31, 2018		
First Quarter	\$1.30	\$0.93
Second Quarter	\$1.16	\$0.84
Third Quarter	\$0.95	\$0.55
Fourth Quarter	\$0.89	\$0.55

	High	Low
Year Ended July 31, 2017		
First Quarter	\$1.28	\$0.78
Second Quarter	\$1.10	\$0.75
Third Quarter	\$1.09	\$0.83
Fourth Quarter	\$1.36	\$0.92

## Holders

As of October 24, 2018, we had approximately 234 holders of record of our common stock. This does not include beneficial owners holding common stock in street name.

## Dividend Policy

We have never paid dividends and have no current plans to do so. We currently anticipate that we will retain all of our future earnings, if any, for use in the development and expansion of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our Board and will depend upon our results of operations, financial condition and other factors that the Board, in its discretion, may deem relevant.

## Repurchase of Equity Securities

None.

## Information About Our Equity Compensation Plans

The information required under this heading is incorporated herein by reference to the applicable information set forth in Item 12 of this Annual Report on Form 10-K.



## **Item 6. Selected Financial Data**

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

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*All references to "PURE," "we," "our," "us" and the "Company" in this Item 7 refer to PURE Bioscience, Inc. and our wholly owned subsidiary.*

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

## Overview

We are focused on developing and commercializing proprietary antimicrobial products that provide safe and cost-effective solutions to the health and environmental challenges of pathogen and hygienic control. Our technology platform is based on patented stabilized ionic silver, and our initial products contain silver dihydrogen citrate, or SDC. SDC is a broad-spectrum, non-toxic antimicrobial agent, which offers 24-hour residual protection and formulates well with other compounds. As a platform technology, we believe SDC is distinguished from existing products in the marketplace because of its superior efficacy, reduced toxicity, non-causticity, and the inability of bacteria to form a resistance to it.

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

Based on these statistics, we believe there is a significant market opportunity for our safe, non-toxic and effective SDC-based solutions. We currently offer PURE<sup>®</sup> Hard Surface as a food contact surface sanitizer and disinfectant to restaurant chains, food processors, and food transportation companies. We also offer PURE Control<sup>®</sup> as a direct food contact processing aid. We received the required FDA approvals to market PURE Control<sup>®</sup> as a direct food contact processing aid for raw poultry and fresh produce in December 2015 and January 2016, respectively. Because additional USDA approval was not required, we began marketing PURE Control as a direct food contact processing aid for fresh produce following our receipt of FDA approval in January 2016.

In July 2016, we received a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. In January 2017, we submitted an additional FCN to the FDA to allow use of higher SDC concentrations in poultry processing, allowing the flexibility to adjust to varying plant and processing conditions. In May 2017, we received a Final Letter from the FDA for this FCN as well as a “No Objection Letter” from the USDA’s Food Safety and Inspection Service (FSIS) granting approval for the higher concentrations of SDC-based PURE Control to be used as a spray or dip applied to poultry carcasses, parts and organs in pre-OLR (on-line reprocessing) and post chill processing of fresh poultry. We are currently focused on completing in-plant validation trials for PURE Control in pre- and post OLR poultry processing applications, which represents approximately 65% to 75% of the total processing aid market for poultry processing.

We are also conducting in-plant trials to optimize the application of PURE Control in OLR to attempt to gain USDA approval for use in this stage of poultry processing.

Subject to the results of our focused in-plant validation efforts for our approved produce and poultry solutions, we intend to seek approval to utilize PURE Control as a direct food contact processing aid for raw meats, including beef and pork. In addition to our direct sales efforts with PURE Hard Surface and PURE Control, we market and sell our SDC-based products indirectly through third-party distributors.

### **Liquidity & Going Concern Uncertainty**

Our consolidated financial statements have been prepared and presented on a basis assuming we will continue as a going concern. The factors below raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

Since our inception, we have financed our operations primarily through public and private offerings of securities, debt financing, and revenue from product sales and license agreements. We have a history of recurring losses, and as of July 31, 2018, we have incurred a cumulative net loss of \$116,924,000.

We do not have, and may never have, significant cash inflows from product sales or from other sources of revenue to fund our operations. As of July 31, 2018, we had \$851,000 in cash and cash equivalents, and \$1,281,000 of current liabilities, including \$608,000 in accounts payable. On August 16, 2018, we completed a private placement financing to accredited investors. We raised approximately \$1.5 million in net proceeds from the private placement financing and issued an aggregate of 3,333,964 shares of our common stock at a purchase price of \$0.45 per share, including the conversion of approximately \$0.5 million held in the form of a promissory note as of July 31, 2018. The shares issued in the private placement financing were issued pursuant to a securities purchase agreement entered into with the investors. Mr. Tom Y. Lee, a member of the Company's Board of Directors invested approximately \$1.0 million through his affiliates, including approximately \$0.5 million of cash and the cancellation of existing indebtedness in the amount of approximately \$0.5 million that was held in the form of a promissory note payable as of July 31, 2018. We do not currently believe that our existing cash resources are sufficient to meet our anticipated needs over the next twelve months from the date hereof. We believe we have sufficient cash resources to fund our operations through January 2019.

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

Until we can generate significant cash from operations, we expect to continue to fund our operations with the proceeds of offerings of our equity and debt securities. However, we cannot assure you that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. Further, any contracts or license arrangements we enter into to raise funds may require us to relinquish our rights to our products or technology, and we cannot assure you that we will be able to enter into any such contracts or license arrangements on acceptable terms, or at all. Having insufficient funds may require us to delay or scale back our marketing, distribution and other commercialization activities or cease our operations altogether.

We do not have any unused credit facilities or other sources of capital available to us at this time. We intend to secure additional working capital through sales of additional debt or equity securities. Our intended financing initiatives are subject to risk, and we cannot provide any assurance about the availability or terms of these or any future financings.

If we are unable to obtain sufficient capital, it will have a material adverse effect on our business and operations. It could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to



competitive pressures or customer requirements. It also may require us to significantly modify our business model and operations to reduce spending to a sustainable level, which may include delaying, scaling back or eliminating some or all of our ongoing and planned investments in corporate infrastructure, research and development projects, regulatory submissions, business development initiatives, and sales and marketing activities, among other investments. If adequate funds are not available when needed, we may be required to reduce or cease operations altogether.

### ***Financial Overview***

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

### **Net Product Sales**

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

### **Cost of Goods Sold**

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

*Selling, General and Administrative*

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

*Research and Development*

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

*Other Income (Expense)*

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

**Results of Operations – Comparison of the Years Ended July 31, 2018 and 2017**

***Fluctuations in Operating Results***

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our results of operations will be affected for the foreseeable future by several factors that may contribute to these periodic fluctuations, including fluctuations in the buying patterns of our current or potential customers for which we have no visibility, the mix of product sales including a change in the percentage of higher or lower margin formulations and packaging configurations of our products, the cost of product sales including component costs, our inability for any reason to be able to meet demand, the achievement and timing of research and development and regulatory milestones, unforeseen changes in expenses, including non-cash expenses such as the fair value of equity awards granted and the fair value change of derivative liabilities, the calculation of which includes several variable assumptions, and unforeseen manufacturing or supply issues, among other issues. Due

to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a reliable indication of our future performance. As of the date of this filing, we are not aware of any trends in these factors or events or conditions that we believe are reasonably likely to impact our results of operations in the future.

***Net Product Sales***

Net product sales were \$1,774,000 and \$1,831,000 for the years ended July 31, 2018 and 2017, respectively. The decrease of \$57,000 was primarily attributable to reduced sales within our existing legacy, non-food safety, customer base. Our top three customers accounted for \$845,000 of net product sales for the year ended July 31, 2018.

For the year ended July 31, 2018, three individual customers accounted for 20%, 16% and 11%, of our net product sales, respectively. No other individual customer accounted for 10% or more of our net product sales. All of our net product sales occurred in the United States.

For the year ended July 31, 2017, two individual customers accounted for 33% and 19%, of our net product sales, respectively. No other individual customer accounted for 10% or more of our net product sales. All of our net product sales occurred in the United States.

***Cost of Goods Sold***

During the year ended July 31, 2018 and 2017, we wrote-off \$58,000 and \$50,000 for damaged and slow moving finished goods inventory, respectively.

Cost of goods sold was \$763,000 and \$760,000 for the years ended July 31, 2018 and 2017, respectively. Cost of goods sold, excluding the inventory write-off discussed above, was \$705,000 and \$710,000 for the years ended July 31, 2018 and 2017, respectively.

Gross margin, as a percentage of net product sales, excluding the inventory write-off discussed above, was 60% and 61% for the years ended July 31, 2018 and 2017, respectively. The decrease in gross margin percentage was primarily attributable to the sale of higher margin formulations and packaging configurations of our products during the fiscal year ended July 31, 2017 as compared with the current year.

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

Selling, general and administrative expense was \$5,235,000 and \$5,230,000 for the years ended July 31, 2018 and 2017, respectively. The increase of \$5,000 was primarily attributable to increased business development and board of director's expense, offset by reduced personnel costs.

***Research and Development Expense***

Research and development expense was \$459,000 and \$779,000 for the years ended July 31, 2018 and 2017, respectively. The decrease of \$320,000 was primarily attributable to reduced personnel costs and reductions in third-party testing and research supporting our FDA approval efforts.

***Share-Based Compensation***

Share-based compensation expense was \$2,359,000 and \$1,070,000 for the years ended July 31, 2018 and 2017, respectively. The increase of \$1,289,000 is primarily attributable to incremental expense recognized due to the modification to existing stock options, as well as, the vesting of stock options and restricted stock units granted to employees, directors and consultants supporting our selling, general and administrative, and research and development functions

***Change in Derivative Liability***

Change in derivative liabilities for the fiscal year ended July 31, 2018 and 2017 was a decrease of \$459,000 and an increase of \$277,000, respectively. The overall decrease in the derivative liability is due to updates to the assumptions used in the fair value pricing model for warrants at the date the warrants were settled.

***Inducement to Exercise Warrants***

During the fiscal year ended July 31, 2018, we completed a tender offer to amend outstanding warrants held by the investors participating in our 2014, 2015 and 2017 private placement financings. In accordance with the terms of the tender offer, the strike price for all three series of warrants was reduced. As a result, we recorded a one-time inducement expense of \$876,000.

***Interest Expense, net***

Interest expense for the years ended July 31, 2018 and 2017 was \$8,000 and \$5,000, respectively.

***Other Income, net***

Other income for the years ended July 31, 2018 and 2017 was \$25,000 and \$27,000, respectively.

## **Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily through public and private offerings of securities, debt financing, and revenue from product sales and license agreements. We have a history of recurring losses, and as of July 31, 2018 we have incurred a cumulative net loss of \$116,924,000.

### ***Warrant Tender Offer***

On October 10, 2017, we closed a tender offer on Schedule TO, pursuant to which we had offered existing warrant holders the opportunity to (i) reduce the exercise price of the warrants to purchase 4,104,980 shares of common stock issued to investors participating in our private placement financing completed on August 29, 2014, as amended (the “2014 Warrants”) from \$0.75 per share to \$0.60 per share of common stock in cash, (ii) reduce the exercise price of outstanding warrants to purchase 1,986,101 shares of common stock issued to investors participating in our private placement financing completed on November 23, 2015 (the “2015 Warrants”) from \$0.45 per share to \$0.40 per share of common stock in cash, (iii) reduce the exercise price of the outstanding warrants to purchase 1,572,941 shares of common stock issued to investors participating in our private placement financing completed on January 23, 2017 (the “2017 Warrants”, together with the 2014 Warrants and 2015 Warrants, the “Original Warrants”) from \$1.25 per share to \$0.85 per share of common stock in cash, (iv) shorten the exercise period of the Original Warrants so that they expired concurrently with the expiration of the tender offer and (v) make certain other changes and amendments.

In connection with the initial and subsequent closings of the tender offer, we issued 1,491,649 shares of common stock upon exercise of 2014 Warrants, 1,858,044 shares of common stock upon exercise of 2015 Warrants and 1,396,470 shares of common stock upon exercise of 2017 Warrants, for aggregate gross proceeds to us of approximately \$2,830,000. Original Warrants to purchase an aggregate of 4,756,163 shares of common stock were tendered and exercised in the tender offer for aggregate net proceeds to us of approximately \$2,632,000. Garden State Securities Inc. assisted the Company as warrant solicitation agents with respect to the 2017 Warrants. 2014 Warrants to purchase 2,533,331 shares of common stock and 2017 Warrants to purchase 176,471 shares of common stock at exercise prices of \$0.75 per share and \$1.25 per share, respectively, continue to remain outstanding and no 2015 Warrants remain outstanding.

### ***Promissory Note***

On June 28, 2018, we raised \$500,000 to support our continued operations by issuing a one-year promissory note to Tom Y. Lee, a member of the Company’s Board of Directors and our largest stockholder. The note accrued interest at 6.5% per annum, compounded annually. As of July 31, 2018, \$500,000 of principal and \$3,000 of accrued and unpaid

interest remained payable (See Note 12 to the consolidated financial statements).

*Private Placement*

On August 16, 2018, we completed a closing of a private placement financing to accredited investors. We raised approximately \$1.5 million in net proceeds in the private placement financing and issued an aggregate of 3,333,964 shares of our common stock at a purchase price of \$0.45 per share, including the conversion of approximately \$0.5 million held in the form of a promissory note as of July 31, 2018. The shares issued in the private placement financing were issued pursuant to a securities purchase agreement entered into with the investors. Mr. Tom Y. Lee, a member of the Company's Board of Directors invested approximately \$1.0 million through his affiliates, including approximately \$0.5 million of cash and the cancellation of existing indebtedness in the amount of approximately \$0.5 million that was held in the form of a promissory note payable as of July 31, 2018.

As of July 31, 2018, we had \$851,000 in cash and cash equivalents compared with \$1,640,000 in cash and cash equivalents as of July 31, 2017. The net decrease in cash and cash equivalents was primarily attributable to the use of cash to fund our operations. Additionally, as of July 31, 2018, we had \$1,281,000 of current liabilities, including \$608,000 in accounts payable, compared with \$2,528,000 of current liabilities, including \$426,000 in accounts payable as of July 31, 2017. The net decrease in current liabilities was primarily due to the derivative liability removal.

The following table summarizes our contractual obligations as of July 31, 2018.

Total	Payments due by period			
	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	\$ 151,000	\$ 106,000	\$ 45,000	—
	\$ 151,000	\$ 106,000	\$ 45,000	—

In addition, from time to time we have entered into employment agreements with our executives that, under certain cases, provide for the continuation of salary and certain other benefits if these executives are terminated under specified circumstances. These agreements generally expire upon termination for cause or when we have met our obligations under these agreements. As of July 31, 2018, no events have occurred resulting in the obligation of any such payments.

We do not have, and may never have, significant cash inflows from product sales or from other sources of revenue to fund our operations. Our existing cash resources are not sufficient to meet our anticipated needs over the next twelve months from the date hereof. The uncertainties surrounding our ability to continue to fund our operations raise substantial doubt about our ability to continue as a going concern.

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

Until we can generate significant cash from operations, we expect to continue to fund our operations with the proceeds of offerings of our equity and debt securities. However, we cannot assure you that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. Further, any contracts or license arrangements we enter into to raise funds may require us to relinquish our rights to our products or technology, and we cannot assure you that we will be able to enter into any



such contracts or license arrangements on acceptable terms, or at all. Having insufficient funds may require us to delay or scale back our marketing, distribution and other commercialization activities or cease our operations altogether.

We do not have any unused credit facilities or other sources of capital available to us at this time. We intend to secure additional working capital through sales of additional debt or equity securities, including through private placements of our securities. Our intended financing initiatives are subject to risk, and we cannot provide any assurance about the availability or terms of these or any future financings.

If we are unable to obtain sufficient capital, it will have a material adverse effect on our business and operations. It could cause us to fail to execute our business plan, fail to take advantage of future opportunities, or fail to respond to competitive pressures or customer requirements. It also may require us to significantly modify our business model and operations to reduce spending to a sustainable level, which may include delaying, scaling back or eliminating some or all of our ongoing and planned investments in corporate infrastructure, research and development projects, regulatory submissions, business development initiatives, and sales and marketing activities, among other investments. If adequate funds are not available when needed, we may be required to reduce or cease operations altogether.

### **Critical Accounting Policies and Estimates**

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

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

### ***Revenue Recognition***

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

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

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

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

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

*Impairment of Long-Lived Assets*

In accordance with GAAP, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and we record the impairment as a reduction in the carrying value of the related asset and a charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment, and assumptions could differ materially from actual results. There were no patent impairments during the fiscal years ended July 31, 2018 or 2017.

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

- an asset group's inability to continue to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to an asset;
- significant changes in our strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry or economic trends.

Additionally, on a quarterly basis we review the significant assumptions underlying our impairment assessment to determine that our previous conclusions remain valid. As part of our review, we consider changes in revenue growth rates, operating margins, working capital needs and other expenditures. With the exception of the impairment discussed above we have not identified any asset groups where undiscounted cash flows were not substantially in excess of carrying value.

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.

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

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

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

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

their face value.

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

### ***Going Concern***

We assess and determine our ability to continue as a going concern under the provisions of ASC Topic 205-40, Presentation of Financial Statements—Going Concern, which requires us to evaluate whether there are conditions or events that raise substantial doubt about our ability to continue as a going concern within one year after the date that our annual and interim financial statements are issued. Certain additional financial statement disclosures are required if such conditions or events are identified. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting.

Determining the extent, if any, to which conditions or events raise substantial doubt about our ability to continue as a going concern, or the extent to which mitigating plans sufficiently alleviate any such substantial doubt, as well as whether or not liquidation is imminent, requires significant judgment by us. We have determined that there is substantial doubt about our ability to continue as a going concern for the one-year period following the date that our financial statements for the year ended July 31, 2018 were issued, which have been prepared assuming that we will continue as a going concern. We have not made any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of us to continue as a going concern.

### **Recent Accounting Pronouncements**

Information regarding recent accounting pronouncements is contained in Note 2 to the Consolidated Financial Statements, included elsewhere in this report.

### **Off Balance Sheet Arrangements**

We do not have any off balance sheet arrangements.



### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

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

### **Item 8. Consolidated Financial Statements and Supplementary Data**

The consolidated financial statements and supplementary data required by this Item 8 are set forth at the end of this Annual Report.

### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

### **Item 9A. Controls and Procedures**

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

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

As required by Rule 13a-15(e) under the Exchange Act, our management conducted an evaluation, under the supervision and with the participation of our Principal Executive Officer and our Principal Financial Officer, of the

effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report. Based on the foregoing evaluation, our principal executive officer and principal financial officer concluded that as of the end of the period covered by this report our disclosure controls and procedures were effective.

### **Changes in Our Internal Controls over Financial Reporting**

There were no changes in our internal controls over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

### **Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). With the participation of our Principal Executive Officer and Principal Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of July 31, 2018.



### **Inherent Limitations on Effectiveness of Controls**

Our management, including our Principal Executive Officer and Principal Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

### **Item 9B. Other Information**

None.

## **PART III**

### **Item 10. Directors, Executive Officers and Corporate Governance**

#### **Information Regarding Our Board of Directors**

Pursuant to our bylaws, the number of directors is fixed and may be increased or decreased from time to time by resolution of our Board of Directors, or the Board. The Board has fixed the number of directors at six members.

Information with respect to our directors as of October 25, 2018 is shown below.

<b>Name</b>	<b>Age</b>	<b>Director Since</b>	<b>Position(s) Held</b>
Henry R. Lambert	67	2013	Director, Chief Executive Officer
Gary D. Cohee	72	2013	Director
Tom Y. Lee, CPA	69	2014	Director
Janet Risi Field	58	2017	Director
Elisabeth Hagen M.D	49	2018	Director
Ivan Chen	36	2018	Director

**Henry R. Lambert** was appointed to our Board and appointed as our Chief Executive Officer on September 10, 2013. Mr. Lambert is an accomplished food industry and consumer products executive with broad management skills, including strategic planning and business development, go-to-market execution, business integration and food safety. He has over 35 years of food industry experience, having worked at such notable companies as Heublein Inc., RJ Reynolds, Nabisco, Inc. and, Pinnacle Foods. He has held various business unit leadership positions servicing the foodservice and leading consumer food brands markets. Mr. Lambert has also served on boards and as a member of various food industry associations, including the International Foodservice Manufacturers Association (IFMA), Institute of Food Technologists and Safe Supply of Affordable Food Everywhere (SSAFE). From 2010 through June 2013, Mr. Lambert served as General Manager of the Global Food and Water Business of Underwriter Laboratories, where he was responsible for the start-up of the company's food safety services business. From 2007 to 2010, Mr. Lambert served as Senior Vice President of Business Development, and then President, of Arrowstream Transportation, Inc., a provider of innovative supply chain management solutions to the foodservice industry whose key customers included Wendy's, Applebee's, Arby's, TGIF, Sysco, and DMA. Prior to 2007, Mr. Lambert held executive positions with a number of high profile companies in the foodservice industry. Mr. Lambert earned his MBA in Finance from the University of Chicago, Booth School of Business, and his BA in Economics (with Honors) from Union College, Schenectady, N.Y.

**Gary D. Cohee** was appointed to our Board on August 13, 2013. He has over 40 years of experience as an investment banker, having started his career in 1973 with Blyth, Eastman Dillon & Co. Since 2004, Mr. Cohee has served as President and CEO of PMB Securities Corp. From 2011 until 2012, Mr. Cohee served on the Advisory Board of Force Fuels, Inc. During his career in the investment banking business, Mr. Cohee worked for a number of prestigious firms, including Bateman Eichler and Paulson Investment Company. Mr. Cohee graduated from California State University-Long Beach in 1968 with a BS degree in Business Administration. He previously served as President of the Long Beach Bond Club, the Southern California Options Society and the Long Beach Century Club.

**Tom Y. Lee, CPA** was appointed to our Board on October 24, 2014. Mr. Lee is currently the Chairman and CEO of Swabplus, Inc., a contract manufacturer of single-dose applicator and formulation OEM products, and has served as Chairman and CEO since 2008. Mr. Lee has experience in manufacturing and selling applicator and formulation OEM products, manufacturing and distributing products in Asia and is experienced in accounting matters. Mr. Lee was formerly audit committee chairman at First Continental Bank (which merged with United Commercial Bank in 2003). Mr. Lee has been an active CPA since 1983 and earned his Master of Science in accounting from California State University Long Beach and his Bachelors in Business Administration from TamKang University in Taipei, Taiwan.

**Janet Risi Field** was appointed to our Board on July 26, 2017. Ms. Risi currently serves as President and Chief Executive Officer of Independent Purchasing Cooperative ("IPC"), a supply chain management organization, which she founded in 1996. IPC supplies all goods and services to the international fast food company, SUBWAY®. Risi formed IPC when SUBWAY had 7,000 restaurants, and has served on the SUBWAY Strategic Planning Council to help grow the brand to over 40,000+ units worldwide. IPC now manages in excess of \$5 billion annually, covering food, packaging, equipment supplies, distribution, Gift and Loyalty card sales and marketing management, and services such as technology implementation. Prior to founding IPC, Ms. Risi was a commodities buyer for Ralston Purina. Ms. Risi also serves on the board of directors for Coral Gables Trust Bank and The Florida House. Ms. Risi received a B.A

in English and a minor in Business from DePauw University.

**Elisabeth Hagen M.D.** was appointed to our Board on November 2, 2017. Dr. Hagen’s wide-ranging food safety experience includes service in various positions at the United States Department of Agriculture (USDA) beginning in 2006 and as a consultant beginning in 2014. From August 2010 until December 2013, Dr. Hagen served as the USDA Under Secretary for Food Safety where she oversaw Food Safety and Inspection Service (FSIS) policies and programs. She also served as Chief Medical Officer for the USDA, where one of her primary focuses sought ways to reduce foodborne illness. Since January 2014, Dr. Hagen has served as a consultant advising a range of companies on food safety strategy, food trends, regulatory issues and crisis management. She serves as Food Safety Advisory Board Member for Chipotle Mexican Grill, Animal Welfare Advisory Board Member for Tyson Foods, and Advisory Board Member, Food Safety, at Yum Brands. Dr. Hagen holds an M.D. from Harvard Medical School and a bachelor’s degree from Saint Joseph’s University. She is specialty trained in internal medicine and infectious diseases.

**Ivan Chen** was appointed to our Board on June 29, 2018. Mr. Chen, an attorney and entrepreneur, brings extensive experience in the healthcare and technology industries, with deep legal and strategic experience in areas including licensing, joint ventures, mergers & acquisitions, securities and corporate governance, and has been admitted to the bar in the states of California and New York. His experience includes serving as Director, Mergers & Acquisitions at eBay, Inc., a publicly-traded e-commerce platform. In this role, he led the negotiation and execution of numerous US and cross-border transactions. Prior to eBay, Mr. Chen focused on transactional, securities, and corporate governance matters while serving as an associate at Morrison & Foerster LLP and at Skadden, Arps, Meagher & Flom LLP, both large international law firms. Mr. Chen earned a J.D. from Harvard Law School, a master’s degree from the University of Cambridge, and a bachelor’s degree from Northwestern University.

### Information Regarding Our Executive Officers

Information with respect to our executive officers as of October 25, 2018 is shown below. Since Henry R. Lambert and David J. Pfanzelter also serve on the Board, their respective biographies are set forth under “Information Regarding the Board of Directors” above.

<b>Name</b>	<b>Age</b>	<b>Position(s) Held</b>	<b>Position(s) Held Since</b>
Henry R. Lambert	67	Chief Executive Officer	2013
Mark Elliott	43	Vice President, Finance	2015
Tom Meyers	66	Chief Operating Officer	2018

**Mark Elliott** was appointed as our Vice President Finance and Principal Financial and Accounting Officer on July 31, 2015. Mr. Elliott joined the Company in 2004 and has been responsible for managing all accounting and regulatory reporting activities since he was promoted to Controller in May 2006. He has also been responsible for establishing all current financial and reporting systems. Prior to joining the Company, Mr. Elliott worked in government accounting. He earned a Bachelor of Science, Business Administration-Accountancy at California State University-San Marcos.

**Mr. Myers** was appointed as our Chief Operating Officer on October 4, 2018 had been serving as the Company's Executive Vice President, Technical Support and Services since September 2016 and had previously served as Executive Vice President, Marketing and Product Development since August 2011 when he joined the Company. In his previous role, Mr. Myers led the implementation and application of the Company's SDC-based technology in customer facilities, the development of the Company's food transport sanitation solution and other marketing and sales efforts. Prior to joining the Company, Mr. Myers served as the President and Principal of Idaho Milk Products. Mr. Myers has also held executive management roles at Weider Nutrition International, Puritan Quartz Pharmaceuticals, FruitSource Associates and FruitSource Confections, Nancy's Specialty Foods, Izaki Glico and Berkshire Hathaway Corporation. Mr. Myers holds a Bachelor of Science degree from California State University Long Beach.

## **Family Relationships**

Mr. Ivan Chen is the nephew of Mr. Tom Y. Lee. There are no other family relationships between any current director executive officer, or any director or executive officer during the fiscal year ended July 31, 2018.

## **Corporate Governance**

### **Overview**

We are committed to maintaining high standards of business conduct and corporate governance, which we believe are fundamental to the overall success of our business, serving our stockholders well and maintaining our integrity in the marketplace. Our Corporate Governance Guidelines and Code of Business Conduct and Ethics, together with our Certificate of Incorporation, Bylaws and the charters of our Board Committees, form the basis for our corporate governance framework. As discussed below, our Board of Directors has established two standing committees to assist it in fulfilling its responsibilities to the Company and its stockholders: the Audit Committee and the Compensation Committee. The Board of Directors performs the functions typically assigned to a Nominating and Corporate Governance Committee.

## **Corporate Governance Guidelines**

Our Corporate Governance Guidelines are designed to ensure effective corporate governance of our Company. Our Corporate Governance Guidelines cover topics including, but not limited to, director qualification criteria, director responsibilities, director compensation, director orientation and continuing education, communications from stockholders to the Board, succession planning and the annual evaluations of the Board and its Committees. Our Corporate Governance Guidelines are reviewed regularly by the Board and revised when appropriate. The full text of our Corporate Governance Guidelines can be found in the “Corporate Governance” section of our website accessible at [www.purebio.com](http://www.purebio.com). A printed copy may also be obtained by any stockholder upon request to our Corporate Secretary.

## **Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors. This Code constitutes a “code of ethics” as defined by the rules of the SEC. This Code also contains “whistle blower” procedures adopted by our Audit Committee regarding the receipt, retention and treatment of complaints related to accounting, internal accounting controls or auditing matters and procedures for confidential anonymous employee complaints related to questionable accounting or auditing matters. Copies of the code may be obtained free of charge from our website, [www.purebio.com](http://www.purebio.com). Any amendments to, or waivers from, a provision of our code of ethics that applies to any of our executive officers will be posted on our website in accordance with the rules of the SEC. Other than as specifically referenced herein, the information contained on, or that can be accessed through, our website is not a part of this Report.

## **Director Independence**

We are not currently listed on any national securities exchange or in an inter-dealer quotation system that has established a standard for independence. However, in evaluating the independence of our members and the composition of the committees of our Board of Directors, our Board utilizes the definition of “independence” as that term is defined by applicable listing standards of the NYSE MKT. As of the date hereof, our Board consists of six members, four of whom are considered independent as that term is defined by applicable listing standards of the NYSE MKT. Our independent directors include: Messrs. Chen and Lee and Ms. Risi and Dr. Hagen.

## **Board and Committee Attendance**

During the fiscal year ended July 31, 2018, the Board of Directors met eight times and it took action by unanimous written consent two times. During the fiscal year ended July 31, 2018 our Compensation Committee took action by unanimous written consent twice and our Audit Committee met four times. Each of the directors attended 95% of the meetings of the Board of Directors.

## **Director Attendance at Annual Meeting**

We believe the annual meeting of stockholders provides a good opportunity for our directors to hear any feedback the stockholders may share with the Company at the meeting. As a result, we encourage our directors to attend our annual meeting. We reimburse our directors for the reasonable expenses incurred by them in attending the annual meeting.

## **Executive Sessions**

Executive sessions of our independent directors are held at each regularly scheduled meeting of our Board and at other times as necessary and are chaired by the Chairman of the Board. The Board's policy is to hold executive sessions without the presence of management, including our President and Chief Executive Officer, who is the only non-independent director on the Board. Our Board Committees also generally meet in executive session at the end of each committee meeting.

## **Board Committees**

*Compensation Committee.* The Compensation Committee of the Board of Directors currently consists of Ms. Risi (Chair) and Dr. Hagen. Ms. Risi was appointed Chair of the Compensation Committee after Mr. Otis retired from the Board. Dr. Hagen was appointed to the Compensation Committee in June 2018. The functions of the Compensation Committee include the approval of the compensation offered to our executive officers and recommending to the full Board of Directors the compensation to be offered to our directors, including our Chairman. The Board has determined that Ms. Risi and Dr. Hagen are each an "independent director" under the listing standards of the NYSE MKT and had previously determined that Mr. Otis was also an "independent director" under the listing standards of the NYSE MKT. In addition, the members of the Compensation Committee (and Mr. Otis while he served on the Board and the Compensation Committee) qualify as a "non-employee director" for purposes of Rule 16b-3 under the Exchange Act and as an "outside director" for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended. The

Compensation Committee is governed by a written charter approved by the Board of Directors, a copy of which is available on our website at [www.purebio.com](http://www.purebio.com).

*Audit Committee.* The Audit Committee of the Board of Directors, currently consists of Messrs. Cohee (Chair), Lee and Chen. Mr. Chen was appointed to the Audit Committee in June 2018 after Mr. Otis retired from the Board. The functions of the Audit Committee include the retention of our independent registered public accounting firm, reviewing and approving the planned scope, proposed fee arrangements and results of the Company's annual audit, reviewing the adequacy of the Company's accounting and financial controls and reviewing the independence of the Company's independent registered public accounting firm. The Board has determined that each of Messrs. Chen and Lee is an "independent director" under the listing standards of the NYSE MKT. Mr. Cohee is not independent because the Company has retained Mr. Cohee to provide financial advisory services to the Company. See "Certain Relationships and Related Transactions" for additional information regarding the Company's retention of Mr. Cohee. The Board determined that it was in the Company's and its stockholders best interests for Mr. Cohee to continue to serve on the audit committee, based on his accounting and financial expertise, until the Board adds additional independent directors. The Board of Directors has also determined that Messrs. Cohee, Lee and Chen are each an "audit committee financial expert" within the applicable definition of the SEC. The Audit Committee is governed by a written charter approved by the Board of Directors, a copy of which is available on our website at [www.purebio.com](http://www.purebio.com).

*Nominating Committee.* The Board has not established a Nominating Committee, and as a result performs the functions typically assigned to a Nominating Committee, including the identification, recruitment and nomination of candidates for the Board and its committees, determining the structure, composition and functioning of the Board and its committees including the reporting channels through which the Board receives information and the quality and timeliness of the information, developing and recommending to the Board corporate governance guidelines applicable to the Company and annually reviewing and recommending changes, as necessary or appropriate, overseeing the annual evaluation of the Board's effectiveness and performance.



## **Board and Committee Effectiveness**

The Board and each of its Committees performs an annual self-assessment to evaluate their effectiveness in fulfilling their obligations. The Board and Committee evaluations cover a wide range of topics, including, among others, the fulfillment of the Board and Committee responsibilities identified in the Corporate Governance Guidelines and charters for each Committee.

## **Board Leadership Structure**

Our Bylaws provide our Board with flexibility to combine or separate the positions of Chairman of the Board and Chief Executive Officer in accordance with its determination that utilizing one or the other structure would be in the best interests of our company. Due to Mr. Pfanzelter's retirement from the Board and his position as Chairman of the Board, we do not currently have a chairman of the Board. The independent members of our Board currently serve in the Chairman role and believe this leadership structure enhances the accountability of our Chief Executive Officer to the Board and encourages balanced decision making. Our Board also separated the roles in recognition of the differences in responsibilities. While our Chief Executive Officer is responsible for the day-to-day leadership of the Company and its business operations, the role of Chairman is intended to provide overall guidance to the Board and management. The Board intends to carefully evaluate from time to time whether an independent member of our Board should be appointed as Chairman based on what the Board believes is best for the Company and its stockholders.

## **Board Oversight of Risk**

The Board is actively involved in the oversight of risks that could affect the Company. The Board as a whole has responsibility for risk oversight of the Company's risk management policies and procedures, with reviews of certain areas being conducted by the relevant Board committee. The Board satisfies this responsibility through reports by each Committee Chair regarding the Committee's considerations and actions, as well as through regular reports directly from management responsible for oversight of particular risks within the Company. Specifically, the Board committees address the following risk areas:

The Compensation Committee is responsible for overseeing the management of risks related to the Company's executive compensation plans and arrangements.

The Audit Committee discusses with management the Company's major financial risk exposures and the steps management has taken to monitor and control such exposures.

The Board as a whole considers risks related to regulatory and compliance matters as well as risks related to the Company's sales and marketing and research and development initiatives.

The Board encourages management to promote a corporate culture that incorporates risk management into the Company's day-to-day business operations.

### **Stockholder Recommendations for Director Nominees**

In nominating candidates for election as a director, the Board will consider a reasonable number of candidates recommended by a single stockholder who has held over 20% of PURE Bioscience Common Stock for over one year and who satisfies the notice, information and consent provisions set forth in our Bylaws and Corporate Governance Guidelines. Stockholders who wish to recommend a candidate may do so by writing to the Board of Directors in care of the Corporate Secretary, PURE Bioscience, Inc., 1725 Gillespie Way, El Cajon, California 92020. The Board of Directors will use the same evaluation process for director nominees recommended by stockholders as it uses for other director nominees. A printed copy of our Bylaws may be obtained by any stockholder upon request to our Corporate Secretary.

## **Identification and Evaluation of Director Nominees**

In evaluating nominees for membership on our Board, our Board applies the Board membership criteria set forth in our Corporate Governance Guidelines. Under these criteria, the Board takes into account many factors, including an individual's business experience and skills (including skills in core areas such as operations, management, technology, accounting and finance, strategic planning and international markets), as well as independence, judgment, knowledge of our business and industry, professional reputation, leadership, integrity and ability to represent the best interests of the Company's stockholders. In addition, the Board also considers the ability to commit sufficient time and attention to the activities of the Board, as well as the absence of any potential conflicts with the Company's interests. The Board does not assign specific weights to particular criteria and no particular criterion is necessarily applicable to all prospective nominees. The Board does not have a formal policy with respect to diversity of nominees. Rather, our Board considers Board membership criteria as a whole and seeks to achieve diversity of occupational and personal backgrounds on the Board.

Our Board regularly assesses the appropriate size of our Board, and whether any vacancies on our Board are expected due to retirement or otherwise. In the event that vacancies are anticipated, or otherwise arise, the Board will consider various potential candidates who may come to the attention of the Board through current Board members, professional search firms, stockholders or other persons. Each candidate brought to the attention of the Board, regardless of who recommended such candidate, is considered on the basis of the criteria set forth in our corporate governance guidelines. As stated above, our Board will consider candidates proposed for nomination by our significant stockholders. Stockholders may propose candidates by submitting the names and supporting information to: Corporate Secretary, PURE Bioscience, Inc., 1725 Gillespie Way, El Cajon, California 92020. Supporting information should include (a) the name and address of the candidate and the proposing stockholder, (b) a comprehensive biography of the candidate and an explanation of why the candidate is qualified to serve as a director taking into account the criteria identified in our corporate governance guidelines, (c) proof of ownership, the class and number of shares, and the length of time that the shares of our voting securities have been beneficially owned by each of the candidate and the proposing stockholder, and (d) a letter signed by the candidate stating his or her willingness to serve, if elected.

## **Item 11. Executive Compensation**

### **Summary Compensation Table**

The following table sets forth a summary of cash and non-cash compensation awarded, earned or paid for services rendered to us during the fiscal years ended July 31, 2018 and July 31, 2017 by our named executive officers, consisting of (i) each individual serving as principal executive officer during the fiscal year ended July 31, 2018 and (ii) our other two most highly compensated officers serving during the fiscal year ended July 31, 2018.



Name and Principal Position	Fiscal Year	Salary (\$)(1)	Bonus	Option Awards (\$)(2)	Stock Awards (\$)(3)	All Other Compensation (\$)(4)	Total Compensation (\$)
Henry R. Lambert	2018	\$ 301,000	—	\$68,000 (5)	\$	\$ 59,000	\$ 428,000
Chief Executive Officer	2017	\$ 350,000	—	\$438,000(6)	\$238,000(7)	\$ 56,000	\$ 1,082,000
Mark S. Elliott	2018	\$ 185,000	—	\$51,000 (8)	\$—	\$ —	\$ 236,000
Vice President Finance	2017	\$ 182,000	—	\$62,000 (9)	\$—	\$ —	\$ 244,000
Dave J. Pfanzelter (10)	2018	\$ 150,000	—	\$68,000 (11)	\$	\$ —	\$ 218,000
Chairman of the Board	2017	\$ 150,000	—	\$972,000(12)	\$595,000(13)	\$ —	\$ 1,717,000

(1) Amounts reflect salary earned during the respective fiscal years. On April 1, 2018, Mr. Lambert's base salary was reduced from \$350,000 to \$175,000 per year.

(2) Amounts for the years ended July 31, 2018 and 2017 reflect the grant date fair value for financial statement reporting purposes with respect to stock options granted during the respective fiscal years, calculated in accordance with authoritative guidance.

(3) Amounts for the years ended July 31, 2018 and 2017 reflect the grant date fair value for financial statement reporting purposes with respect to stock awards granted during the respective fiscal years, calculated in accordance with authoritative guidance.

(4) Represents amounts reimbursed to Mr. Lambert for housing expenses in San Diego, where the Company is headquartered. Mr. Lambert maintains a permanent residence in Lake Forest, Illinois and he rents a corporate apartment in San Diego. The Company reimburses Mr. Lambert on a monthly basis for the housing expense.

(5) Represents an award consisting of an option to purchase two hundred thousand (200,000) shares of common stock.

(6) Represents two awards consisting of an option to purchase two hundred thousand (200,000) shares of common stock and an option to purchase four hundred thousand (400,000) shares of common stock.

(7) Represents an award consisting of two hundred thousand (200,000) restricted stock units ("RSUs")

(8) Represents an award consisting of an option to purchase one hundred fifty thousand (150,000) shares of common stock.

(9) Represents an award consisting of an option to purchase one hundred fifty thousand (150,000) shares of common stock.

(10) Due to his service as Chairman of the Board, the Company considered Mr. Pfanzelter an executive officer. Mr. Pfanzelter retired from the Board and as Chairman of the Board on August 16, 2018. There were no disagreements between Mr. Pfanzelter and the Company regarding his retirement.

(11) Represents an award consisting of an option to purchase two hundred thousand (200,000) shares of common stock.

(12) Represents an award consisting of an option to purchase two hundred thousand (200,000) shares of common stock and an award consisting of an option to purchase one million (1,000,000) shares of common stock.

(13) Represents an award consisting of five hundred thousand (500,000) RSUs.

### **Narrative to Summary Compensation Table**

The compensation program established for the Company's executive officers consisted of the following elements:

**Base Salary:** The base salaries of our named executive officers depend on their job responsibilities, the market rate of compensation paid by companies in our industry for similar positions, our financial position and performance, and the strength of our business. Base salaries provide a fixed means of compensation in order to attract and retain talent. On April 1, 2018, Mr. Lambert's base salary was reduced from \$350,000 to \$175,000 per year. The base salary for Mr. Elliott was \$185,000 per year. Additionally, Mr. Pfanzelter received \$150,000 per year for his service as Chairman of the Board.

**Performance-Based Cash Awards:** As part of the Company's executive compensation program, our executive officers are eligible to receive performance-based cash awards. The annual performance-based cash awards are based on the executive officer's individual performance and the Company's actual performance compared to the corporate goals approved by the Board and the Compensation Committee. Following the end of each fiscal year, the Board and the Compensation Committee is responsible for determining the bonus amount payable to an executive officer based on that executive officer's individual performance during the fiscal year and its determination of the Company's actual performance compared to the corporate goals established for that fiscal year. Due to the Company's limited financial resources and performance, our named executive officers did not receive any bonuses for the years ended July 31, 2018 and 2017.

**Long-Term Equity Awards:** Equity ownership by our executive officers and key employees encourages them to create long-term value and aligns their interests with those of our stockholders. As a result, our executive compensation program provides for the issuance of stock options and restricted stock units (“RSUs”).

### Outstanding Equity Awards at Year-End

The following table provides a summary of all equity awards held by our named executive officers that were outstanding as of July 31, 2018.

Name	Option Awards				Stock Awards		Market Value of shares or Units of stock that have not vested (\$)(1)
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of shares or Units of stock that have not vested(#)		
Henry R. Lambert	50,000	150,000	\$0.78	2/26/2023	(2)		
	200,000	—	\$0.88	3/22/2022	(3)	200,000	\$112,000 (4)
Mark S. Elliott		400,000	\$1.19	6/22/2027	(3)	—	\$—
	200,000	—	\$1.05	5/27/2021	(5)	—	\$—
	37,500	112,500	\$0.78	2/26/2023	(6)	—	\$—
	150,000	—	\$0.88	3/1/2022	(7)	—	\$—
	150,000	—	\$1.15	5/11/2018	(8)	—	\$—
	2,500	—	\$18.72	5/14/2019		—	\$—
	2,500	—	\$28.00	5/19/2020		—	\$—
	6,875	—	\$6.72	7/14/2021		—	\$—
Dave J. Pfanzer	10,000	—	\$0.86	1/24/2023		—	\$—
	50,000	150,000	\$0.78	2/26/2023	(9)	—	\$—
	200,000	—	\$0.88	3/22/2022	(10)	500,000	\$280,000 (11)
		1,000,000	\$1.19	6/22/2027	(10)	—	\$—
	200,000	—	\$1.05	5/27/2021	(12)	—	\$—
	40,000	—	\$0.73	2/6/2023		—	\$—

(1)

## Edgar Filing: PURE BIOSCIENCE, INC. - Form 10-K

The market value was determined by multiplying the number of shares underlying the awards by the closing price for our common stock on July 31, 2018, which was \$0.56.

(2) During the year ended July 31, 2018, we granted Mr. Lambert an award consisting of an option to purchase two hundred thousand (200,000) shares of common stock. The option has a five-year term and vests in four quarterly installments.

(3) During the year ended July 31, 2017, we granted Mr. Lambert an award consisting of an option to purchase two hundred thousand (200,000) shares of common stock. The option has a five-year term and vests in four quarterly installments. In addition, we granted Mr. Lambert an award consisting of an option to purchase four hundred thousand (400,000) shares of common stock. The option has a ten-year term and vests 25% on December 31, 2018 with the remaining shares vesting in three equal annual installments thereafter.

(4) During the year ended July 31, 2017, we granted Mr. Lambert an award consisting of two hundred thousand (200,000) RSUs. 25% of the RSUs vest on December 31, 2018 with the remaining shares vesting in three equal annual installments thereafter.

(5) During the year ended July 31, 2016, we granted Mr. Lambert a five year award consisting of an option to purchase two hundred thousand (200,000) shares of common stock. 33% vested on July 31, 2016; 33% vested on October 31, 2016; and 34% vested on January 31, 2017.

(6) During the year ended July 31, 2018, we granted Mr. Elliott an award consisting of an option to purchase one hundred fifty thousand (150,000) shares of common stock. The option has a five-year term and vests in four quarterly installments.

(7) During the year ended July 31, 2017, we granted Mr. Elliott an award consisting of an option to purchase one hundred fifty thousand (150,000) shares of common stock. The option has a five-year term and vests in four quarterly installments.

(8) During the year ended July 31, 2016, we granted Mr. Elliott a two year award consisting of an option to purchase one hundred fifty thousand (150,000) shares of common stock. The options vested quarterly over a one year period.

(9) During the year ended July 31, 2018, we granted Mr. Pfanzelter an award consisting of an option to purchase two hundred thousand (200,000) shares of common stock. The option has a five-year term and vests in four quarterly installments.

(10) During the year ended July 31, 2017, we granted Mr. Pfanzelter an award consisting of an option to purchase two hundred thousand (200,000) shares of common stock. The option has a five-year term and vests in four quarterly installments. In addition, we granted Mr. Pfanzelter an award consisting of an option to purchase one million (1,000,000) shares of common stock. The option has a ten-year term and vests 25% on December 31, 2018 with the remaining shares vesting in three equal annual installments thereafter.

(11) During the year ended July 31, 2017, we granted Mr. Pfanzelter an award consisting of five hundred thousand (500,000) RSUs. 25% of the RSUs vest on December 31, 2018 with the remaining shares vesting in three equal annual installments thereafter.

(12) During the year ended July 31, 2016, we granted Mr. Pfanzelter a five year award consisting of an option to purchase two hundred thousand (200,000) shares of common stock. The options vested in three installments: 33% on July 31, 2016; 33% on October 31, 2016; and 34% on January 31, 2017.



During the year ended July 31, 2018, Messrs. Lambert and Pfanzelter and Mr. Elliott had 150,000 and 112,500 option awards vest, respectively. The respective value on vesting was \$13,000 and \$9,750, respectively.

### **Employment Agreements; Potential Payments Upon Termination or a Change in Control for Current Executive Officers**

#### *Agreement with our Chief Executive Officer*

On September 10, 2013, we appointed Henry R. Lambert to serve as Chief Executive Officer and a member of the Board. The terms of Mr. Lambert's employment agreement provides that such agreement continues until termination by either the Company or Mr. Lambert. During the term of Mr. Lambert's employment agreement, he is entitled to an annual base salary, which may be increased, but not decreased, by the Board or the Compensation Committee in their discretion. The annual base salary of Mr. Lambert was \$350,000 until April 1, 2018 when his base salary was reduced to \$175,000.

The employment agreement provides that, during the term of the agreement, Mr. Lambert is eligible for equity compensation grants to be awarded at the discretion of the Compensation Committee and the Board, and also provided for annual bonus targets equal to, as applicable, 50% of Mr. Lambert's current annual base salary, to be awarded at the sole discretion of the Compensation Committee and the Board. Additionally, pursuant to the terms of Mr. Lambert's employment agreement, we granted Mr. Lambert 500,000 RSUs, 200,000 of which subsequently expired by their terms. The award agreement for the 500,000 RSUs had provided Mr. Lambert with the right to require us to pay his state and federal withholding and other employment taxes upon the vesting and settlement of these RSUs in exchange for Mr. Lambert cancelling that number of shares of common stock having a value equal to the tax obligations we pay on his behalf. In December 2016, we entered into an RSU Cancellation Agreement with Mr. Lambert and our other officers and directors who received restricted stock unit awards (the "RSUs") in October 2013 as compensation for their continued services to us over a required vesting period. Mr. Lambert in his individual capacity, voluntarily agreed to cancel his RSUs based on his determination that cancelling the RSUs would be in the best interests of the Company and our stockholders. Mr. Lambert reached this conclusion in order to conserve our available cash resources and to reduce pressure on our stock price.

In January 2017, we entered into an amendment (the “First Amendment”) to Mr. Lambert’s employment agreement. The employment agreement, as amended, provided for certain compensation to be paid to Mr. Lambert if his employment is terminated by the Company without Cause or terminated by the executive for Good Reason or there occurs a Change in Control of the Company. However, in September 2018, we entered into a second amendment (the “Second Amendment”) to Mr. Lambert’s employment agreement, pursuant to which Mr. Lambert agreed to reduce the severance payments he is entitled to receive if he is terminated by the Company without cause or he terminates his employment for good reason. Under the employment agreement as amended by the first amendment, he was entitled to receive 24 months of base salary plus a \$1,000,000 lump sum payment. Under the Second Amendment, he is entitled to receive six months of base salary. In addition, under the Second Amendment, Mr. Lambert agreed to waive his rights to: (i) receive 24 months of base salary plus a \$1,000,000 lump sum payment in the event he is terminated in connection with or following a change in control of the Company and (ii) receive “gross-up” payments from the Company in the event any payment or distribution he receives from the Company is subject to an excise tax under Section 4999 of the Internal Revenue Code.

Under the Second Amendment, the term of Mr. Lambert’s employment with the Company was extended to June 30, 2020. During such term, Mr. Lambert’s employment with the Company remains “at-will.” Either party may terminate Mr. Lambert’s employment early, for any or no reason, and with or without cause, by providing the other party with 30 days’ advance written notice. Additionally, the Second Amendment provides that Mr. Lambert will be entitled to accelerated vesting of his outstanding equity awards, and a period of 12 months to exercise any outstanding stock options, if his employment terminates at the expiration of his employment term on June 30, 2020.

On June 22, 2017, we granted Mr. Lambert (i) 200,000 RSUs for Common Stock and (ii) an option to purchase 400,000 shares of Common Stock, which were granted outside the Company’s 2007 Amended and Restated Equity Incentive Plan pursuant to an RSU Agreement and Option Agreement, respectively. The RSU Agreement and Option Agreement provide that 25% of the RSUs and Options vest on December 31, 2018, and the remainder vest in three equal annual installments thereafter and any unvested shares are subject to accelerated vesting in connection with a termination without Cause or resignation for Good Reason, upon grantee’s death or Complete Disability or upon a Change in Control (as the terms are defined in the RSU Agreement and Option Agreement as applicable). Additionally, the RSUs settle on the earlier (i) ten years from the date of grant, (ii) 60 days after the date that the grantee’s service ceases for any reason, (iii) the date of the grantee’s death or Complete Disability or (iv) a Change in Control.

The foregoing description of the employment agreement, as amended, does not purport to be complete and is qualified in its entirety by the terms and conditions of the employment agreement filed as Exhibit 10.33 to the Annual Report on Form 10-K for the year ended July 31, 2013 filed with the SEC on October 24, 2013, Exhibit 99.1 to the Current Report on Form 8-K filed with the SEC on January 20, 2017 and Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 7, 2018, which are incorporated herein by reference. The foregoing description of the RSU Agreement and Option Agreement does not purport to be complete and is qualified in its entirety by the terms and conditions of such RSU Agreement and Option Agreement filed as Exhibits 99.1 and 99.2, respectively, to the Current Report on Form 8-K filed with the SEC on June 23, 2017, which are incorporated herein by reference.



*Agreements with our Chairman*

On August 13, 2013, we appointed Dave J. Pfanzelter to serve as Chairman of the Board. On October 23, 2013, we entered into a Chairman Agreement with Mr. Pfanzelter (the “Chairman Agreement”). On August 13 2018, Mr. Pfanzelter retired from the Board as further described below.

The Chairman Agreement provided that Mr. Pfanzelter was to serve as Chairman of the Board, effective as of August 13, 2013, until his earlier resignation or removal. Pursuant to the Chairman Agreement, Mr. Pfanzelter was entitled to receive \$12,500 per month for his services as Chairman of the Board, payable on a quarterly basis (collectively “Chairman Compensation”). Mr. Pfanzelter was also eligible to receive annual and periodic bonuses in the discretion of the Board. Additionally, pursuant to the terms of the Chairman Agreement, we granted Mr. Pfanzelter 2,800,000 RSUs. Due to his service as Chairman, we considered Mr. Pfanzelter an executive officer of the Company. The award agreement for the 2,800,000 RSUs had provided Mr. Pfanzelter with the right to require us to pay his state and federal withholding and other employment taxes upon the vesting and settlement of these RSUs in exchange for Mr. Pfanzelter cancelling that number of shares of common stock having a value equal to the tax obligations we pay on his behalf. In December 2016, we entered into an RSU Cancellation Agreement with Mr. Pfanzelter and our other officers and directors who received restricted stock unit awards (the “RSUs”) in October 2013 as compensation for their continued services to us over a required vesting period. Mr. Pfanzelter in his individual capacity voluntarily agreed to cancel his RSUs based on his determination that cancelling the RSUs would be in the best interests of the Company and our stockholders. Mr. Pfanzelter reached this conclusion in order to conserve our available cash resources and to reduce pressure on our stock price.

In January 2017, we entered into an amendment to the Chairman Agreement. The Chairman Agreement, as amended, provided for certain compensation to be paid to Mr. Pfanzelter if he is removed by the Board without Cause or Mr. Pfanzelter resigns for Good Reason or there occurs a Change in Control of the Company

Upon any such event and subject to Mr. Pfanzelter’s execution of a release of claims in favor of the Company, Mr. Pfanzelter would have been entitled to receive (i) a payment equal to \$3,000,000, (ii) a payment equal to 200% of his annual chairman compensation then in effect and (iii) the acceleration of then outstanding equity awards. Additionally, the amendment to the Chairman Agreement provides Mr. Pfanzelter a tax gross-up payment in the event that any payment or distribution made to Mr. Pfanzelter in connection with his separation from the Company or upon a change of control of the Company becomes subject to an excise tax pursuant to Section 280G and Section 4999 of the Internal Revenue Code. In addition, all outstanding vested stock options held by Mr. Pfanzelter at the date of such termination would continue to be exercisable for a period of up to 90 days following such termination, but in no event beyond the maximum permitted expiration date.

On June 22, 2017, we granted Mr. Pfanzelter (i) 500,000 RSUs for Common Stock and (ii) an option to purchase 1,000,000 shares of Common Stock, which were granted outside the Company's 2007 Amended and Restated Equity Incentive Plan pursuant to an RSU Agreement and Option Agreement respectively. The RSU Agreement and Option Agreement provided that 25% of the RSUs and Options vest on December 31, 2018, and the remainder vest in three equal annual installments thereafter and any unvested shares are subject to accelerated vesting in connection with a termination without Cause or resignation for Good Reason, upon grantee's death or Complete Disability or upon a Change in Control (as the terms are defined in the RSU Agreement and Option Agreement as applicable). Additionally, the RSUs settle on the earlier (i) ten years from the date of grant, (ii) 60 days after the date that the grantee's service ceases for any reason, (iii) the date of the grantee's death or Complete Disability or (iv) a Change in Control. Additionally, the RSU Agreement and the Option Agreement provide a tax gross-up payment in the event that any payment or distribution made to Mr. Pfanzelter in connection with his separation from the Company or upon a Change in Control becomes subject to an excise tax pursuant to Section 280G and Section 4999 of the Internal Revenue Code.

On August 13, 2018, in connection with his retirement, Mr. Pfanzelter entered into a Consulting Agreement (the "Consulting Agreement") with the Company for a term of three years pursuant to which he agreed to assist the Company's management to develop marketing and commercialization strategies, support the Company's financing activities and provide other services reasonably requested by the Board and Chief Executive Officer. Pursuant to the terms of the Consulting Agreement and his delivery of a waiver and release of claims, Mr. Pfanzelter (i) waived any rights he had to severance or change in control benefits under the terms of the Chairman Agreement, (ii) will receive a monthly consulting fee of \$5,000 and (iii) fully vested in his outstanding equity awards. The Consulting Agreement is terminable by either party at any time upon 30 days prior written notice, subject to certain conditions.

The foregoing description of the Chairman Agreement, as amended and the Consulting Agreement does not purport to be complete and is qualified in its entirety by the terms and conditions of such Chairman Agreement filed as Exhibit 10.35 to the Annual Report on Form 10-K for the year ended July 31, 2013 filed with the SEC on October 24, 2013 and Exhibit 99.1 to the Current Report on Form 8-K filed with the SEC on January 20, 2017 and the terms and conditions of the Consulting Agreement filed as Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on August 17, 2018, which are incorporated herein by reference. The foregoing description of the RSU Agreement and Option Agreement does not purport to be complete and is qualified in its entirety by the terms and conditions of such RSU Agreement and Option Agreement filed as Exhibits 99.1 and 99.2, respectively, to the Current Report on Form 8-K filed with the SEC on June 23, 2017, which are incorporated herein by reference.

### **Code Section 162(m) Provisions**

Section 162(m) of the U.S. Internal Revenue Code, or the Code, generally disallows a tax deduction to public companies for compensation in excess of \$1 million paid to the Chief Executive Officer or any of the four most highly compensated officers. Prior to changes in tax law taking effect in 2018, there was an exception to the \$1.0 million limitation for performance-based compensation, including stock options, meeting certain requirements. Before such amendments we had not adopted a policy that all compensation must qualify as deductible under Section 162(m) of the Code. The exemption from the Section 162(m) deduction limit for performance-based compensation has been repealed, effective for taxable years beginning after December 31, 2017, such that compensation paid to our Chief Executive Officer and certain other executive officers in excess of \$1.0 million will not be deductible unless it qualifies for transition relief applicable to certain arrangements in place as of November 2, 2017.

### **Compensation of Directors**

Each non-employee director of the Company receives cash fees from the Company for their services as members of the Board and any committee of the Board as follows:

Each non-employee director receives an annual fee of \$60,000 payable for such director's service on the Board and each member of the Audit Committee and Compensation Committee receives an additional annual fee of \$4,000 and \$2,500, respectively, payable for such director's service on the committee.

The Chair of the Audit Committee receives an additional annual fee of \$10,000 for such Chair's service and the Chair of the Compensation Committee receives an additional annual fee of \$5,000 for such Chair's service.

Annual fees are paid to each non-employee director in four equal installments on a quarterly basis. Any non-employee directors serving a portion of the year are entitled to receive such fees on a pro rata basis based on their length of

service during the year. Messrs. Lambert and Pfanzelter do not receive any additional compensation for their board service.

New non-employee directors receive an initial grant of 150,000 restricted stock units and 200,000 stock options. Currently, all non-employee director grants of restricted stock units and stock options generally vest fifty percent (50%) on the date of the next annual meeting and fifty percent (50%) on the date of the following year's annual meeting. Additionally, in the fiscal year ended July 31, 2018, we also granted each of our directors an option to purchase 100,000 shares of Common Stock that vest in accordance with the annual meeting dates discussed above.

In the past, our Board has approved each year, generally in the first or second calendar quarter of the year, an annual option or stock grant for our non-employee directors. Any such grant is at the discretion of the Board, which considers the recommendation of our Compensation Committee. Upon the Board's approval of any such grant, each non-employee director generally may elect whether to receive the grant as an option or stock award.

The following table sets forth compensation earned in the fiscal year ended July 31, 2018 by each of our non-employee directors who are not named executive officers.

Name	Fees	Stock Awards	Option Awards	All Other Compensation	Total Compensation
	Earned or Paid in Cash				
	(\$)	\$(1)	\$(2)	(\$)	(\$)
Gary D. Cohee	\$70,000	\$—	\$37,000	—	\$ 107,000
William Otis (3)	\$63,000	\$—	\$37,000	—	\$ 100,000
Tom Y. Lee	\$64,000	\$—	\$37,000	—	\$ 101,000
Janet Risi Field	\$63,000	\$182,000	\$208,000	—	\$ 453,000
Dr. Hagen	\$45,000	\$166,000	\$190,000		\$ 401,000
Ivan Chen	\$6,000	\$98,000	\$89,000		\$ 193,000

(1) Amounts for the year ended July 31, 2018 reflect the grant date fair value for financial statement reporting purposes with respect to stock awards granted during the fiscal year, calculated in accordance with authoritative guidance.

(2) Amounts for the year ended July 31, 2018 reflect the grant date fair value for financial statement reporting purposes with respect to stock options granted during the fiscal year, calculated in accordance with authoritative guidance.

(3) Mr. Otis retired from the Board on June 29, 2018.

## Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table provides information regarding the beneficial ownership of our common stock as of October 25, 2018, or the Evaluation Date, by: (i) each of our current directors, (ii) each of our named executive officers as set forth in Item 11 of this Annual Report, (iii) all such directors and executive officers as a group and (iv) our five percent or greater stockholders. The table is based upon information supplied by our officers, directors and principal stockholders and a review of Schedules 13D and 13G, if any, filed with the SEC. Unless otherwise indicated in the footnotes to the table and subject to community property laws where applicable, we believe that each of the stockholders named in the table has sole voting and investment power with respect to the shares indicated as beneficially owned.



Applicable percentages are based on 71,582,122 shares outstanding as of the Evaluation Date, adjusted as required by rules promulgated by the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of our common stock issuable pursuant to the exercise of stock options or warrants or settlement of restricted stock units that are either immediately exercisable or exercisable within 60 days of the Evaluation Date. These shares are deemed to be outstanding and beneficially owned by the person holding those securities for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Name (1)	Number of		Percent	
	Shares		of	
	Beneficially		Common	
	Owned		Stock	
David J. Pfanzelter	2,196,000	(2)	2.98	%
Henry R. Lambert	848,056	(3)	1.18	%
Mark S. Elliott	469,225	(4)	*	%
Tom Myers	367,600	(5)	*	%
Gary D. Cohee	790,643	(6)	1.1	%
Janet Risi	189,140	(7)	*	%
Tom Y. Lee	28,516,341	(8)	38.49	%
Elisabeth Hagen	100,000	(9)	*	%
Ivan Chen	—		*	%
All of our named executive officers and directors as a group (9 persons)	33,477,005	(10)	45.36	%

\* Indicates less than one percent of the outstanding shares of the Company's common stock.

(1) Unless, noted below, the address for each person listed in the table is c/o PURE Bioscience, Inc., 1725 Gillespie Way, El Cajon, California 92020.

(2) Consists of 1,640,000 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and 556,000 shares of common stock held directly by Mr. Pfanzelter. Mr. Pfanzelter retired from the Board and from his position as Chairman of the Board on August 16, 2018.

(3) Consists of 550,000 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and 298,056 shares of common stock held directly by Mr. Lambert.

(4) Consists of 396,875 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and 72,350 shares of common stock held directly by Mr. Elliott.

(5) Consists of 280,000 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and 87,600 shares of common stock held directly by Mr. Myers.

(6) Consists of 300,000 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and 490,643 shares of common stock held directly by Mr. Cohee.

(7) Consists of 100,000 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and 89,140 shares of common stock held directly by Ms. Risi.

(8) Consists of (a) 300,000 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, (b) 26,083,008 shares of common stock and (c) warrants to purchase 2,133,333 shares of common stock held directly by Mr. Lee and his spouse.

- (9) Consists of 100,000 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date.

(10) Consists of (a) 3,666,875 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, (b) warrants to purchase 2,133,333 shares of common stock which are currently exercisable and (c) 27,676,797 shares of common stock, held by all directors and executive officers as a group.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended (the “Act”), requires our executive officers and directors and persons who beneficially own more than 10% of our Common Stock to file initial reports of beneficial ownership and reports of changes in beneficial ownership with the SEC. Such persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms filed by such persons.

To the Company’s knowledge, other than as described below, no person who, during the fiscal year ended July 31, 2018, was a director or officer of the Company, or beneficial owner of more than ten percent of the Company’s Common Stock (which is the only class of securities of the Company registered under Section 12 of the Act), failed to file on a timely basis reports required by Section 16 of the Act during such fiscal year.

## Equity Compensation Plan Information

### 2007 Equity Incentive Plan

In February 2016, we amended and restated our 2007 Equity Incentive Plan, the (“2007 Plan”), to, among other changes, increase the number of shares of common stock issuable under the 2007 Plan by 4,000,000 shares and extend the term of the 2007 Plan until February 4, 2026. The 2007 Plan provides for the grant of incentive and non-qualified stock options, as well as other share-based payment awards, to our employees, directors, consultants and advisors. These awards have up to a 10-year contractual life and are subject to various vesting periods, as determined by the Compensation Committee of the Board of Directors.

### 2017 Equity Incentive Plan

In January 2018 our stockholders approved our 2017 Equity Incentive Plan, the (“2017 Plan”), which has a share reserve of 5,000,000 shares of common stock. The shares of common stock were registered under a Form S-8 filed with the SEC in February 2018. The 2017 Plan provides for the grant of incentive and non-qualified stock options, as well as other share-based payment awards, to our employees, directors, consultants and advisors. These awards have up to a 10-year contractual life and are subject to various vesting periods, as determined by the Compensation Committee of the Board of Directors.

All of our equity incentive plans are administered by the Compensation Committee. The exercise price for stock options is always at or above the fair market value of our common stock on the date the award is granted. Fair market value is defined by the Plan and is based on prevailing market prices of our common stock as reported by the OTCQB. The term of stock options granted and their vesting schedules are determined by the Compensation Committee, subject to any limitations defined in the Plan. The Compensation Committee also determines the vesting of other, non-option, stock awards.

On June 23, 2017 we filed a Form S-8 to register shares of Common Stock underlying equity awards granted to our directors and officers outside the 2007 Amended and Restated Equity Incentive Plan. The S-8 registered 3,150,000 shares with respect to RSUs and options, which were also granted on the same date.

On August 23, 2017 we filed a Form S-8 to register shares of Common Stock underlying equity awards granted to our directors, officers and consultants outside the 2007 Amended and Restated Equity Incentive Plan. The S-8 registered

850,000 shares with respect to RSUs and options, which were also granted on the same date.

The following table sets forth, as of July 31, 2018, information with respect to our equity compensation plans, and with respect to certain other options and warrants.

Plan Category	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)(1)</b>	Weighted average exercise price of outstanding options, warrants and rights (b)	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</b>
Equity compensation plans approved by stockholders	5,226,093	\$ 1.05	3,754,221
Equity compensation plans not approved by stockholders	2,400,000	1.19	—
<b>Total</b>	<b>7,626,093</b>	<b>\$ 1.09</b>	<b>3,754,221</b>

(1) Includes options only and does not include restricted stock units

### Item 13. Certain Relationships and Related Transactions, and Director Independence

Except as described below and other than Board or employment relationships and compensation resulting from those employment relationships, no director, executive officer, 5% stockholder or immediate family member of any of the foregoing, was a party to any transaction or series of transactions since August 1, 2016 (the beginning of the year

ended July 31, 2017), or is to be a party to any currently proposed transaction or series of proposed transactions, in which (i) we were or are to be a participant, (ii) the amount involved exceeds the lesser of \$120,000 or one percent of the average of our total assets at fiscal year-end for the fiscal years ended July 31, 2018 and 2017, which is \$32,020, and (iii) any director, executive officer, or immediate family member of any of the foregoing had or will have a direct or indirect material interest.

For information with respect to the compensation paid to our executive officers and directors, see heading “Executive Compensation” of this annual report.

## **Equity Transactions with our Directors and Officers**

Since August 1, 2016, the Company has entered into the following equity investment transactions with its directors and officers:

On May 20, 2016, Mr. Lee and his spouse exercised an outstanding warrant for 487,115 shares of Common Stock for an aggregate exercise price of \$219,202.

On September 25, 2017, Mr. Lee and his spouse exercised warrants to purchase 694,703 shares of Common Stock for an aggregate exercise price of \$341,881 in connection with the Company's warrant tender offer to holders of the Company's warrants.

On September 25, 2017, Bill Otis exercised warrants to purchase 9,066 shares of Common Stock for an aggregate exercise price of \$5,440 in connection with the Company's warrant tender offer to holders of the Company's warrants. Mr. Otis retired from the Board in June 2018.

On September 25, 2017, Dave Pfanzelter exercised warrants to purchase 16,000 shares of Common Stock for an aggregate exercise price of \$9,600 in connection with the Company's warrant tender offer to holders of the Company's warrants. Mr. Pfanzelter retired from the Board in August 2018.

On August 16, 2018, we completed a closing of a private placement financing to accredited investors. We raised approximately \$1.5 million in net proceeds in the private placement financing and issued an aggregate of 3,333,964 shares of our common stock at a purchase price of \$0.45 per share, including the conversion of approximately \$0.5 million held in the form of a promissory note as of July 31, 2018. The shares issued in the private placement financing were issued pursuant to a securities purchase agreement entered into with the investors. Mr. Lee invested approximately \$1.0 million through his affiliates, including approximately \$0.5 million of cash and the cancellation of existing indebtedness in the amount of approximately \$0.5 million that was held in the form of a promissory note payable as of July 31, 2018.

## **Compensation of Our Current Directors and Executive Officers**

For information with respect to the compensation offered to our current directors and executive officers, please see the descriptions under the heading "Executive Compensation" of this annual report.

## **Related Party Transaction Policy and Procedures**

Pursuant to our Related Party Transaction and Procedures, our executive officers, directors, and principal stockholders, including their immediate family members and affiliates, are prohibited from entering into a related party transaction with us without the prior consent of our Audit Committee or our independent directors. Any request for us to enter into a transaction with an executive officer, director, principal stockholder, or any of such persons' immediate family members or affiliates, must first be presented to our Audit Committee for review, consideration and approval. In approving or rejecting the proposed agreement, our Audit Committee will consider the relevant facts and circumstances available and deemed relevant, including, but not limited, to the risks, costs and benefits to us, the terms of the transaction, the availability of other sources for comparable services or products, and, if applicable, the impact on a director's independence. Our Audit Committee shall approve only those agreements that, in light of known circumstances, are in, or are not inconsistent with, our best interests, as our Audit Committee determines in the good faith exercise of its discretion.



### **Compensation Committee Interlocks and Insider Participation**

None of the members of our Compensation Committee are or have been an officer or employee of us. During fiscal 2018, 2017 and 2016, no member of our Compensation Committee had any relationship with us requiring disclosure under Item 404 of Regulation S-K, except as set forth above, none of our executive officers served on the Compensation Committee (or its equivalent) or board of directors of another entity any of whose executive officers served on our Compensation Committee or board of directors.

### **Board Composition**

We are not currently listed on any national securities exchange or in an inter-dealer quotation system that has established a standard for independence. However, in evaluating the independence of our members and the composition of the committees of our Board of Directors, our Board utilizes the definition of “independence” as that term is defined by applicable listing standards of the NYSE MKT. As of the date of this annual report, our Board consists of six members, four of whom are considered independent as that term is defined by applicable listing standards of the NYSE MKT. Our independent directors include: Messrs. Chen and Lee and Ms. Risi and Dr. Hagen.

Our directors are appointed annually, and hold office until their successors have been elected and qualified or until their earlier death, resignation, disqualification, or removal.

### **Item 14. Principal Accounting Fees and Services**

#### **Independent Registered Public Accounting Firm’s Fee Summary**

The following table provides information regarding the fees billed to us by Mayer Hoffman McCann P.C. for the years ended July 31, 2018 and 2017. Mayer Hoffman McCann P.C. leases substantially all of its personnel, who work under the control of Mayer Hoffman McCann P.C. shareholders, from wholly-owned subsidiaries of CBIZ, Inc., including CBIZ MHM, LLC, in an alternative practice structure. All fees described below were approved by the Board or the Audit Committee:

	For the years ended	
	July 31,	
	2018	2017
Audit Fees (1)	\$ 164,000	\$ 173,000
Tax Fees (2)	\$ 13,000	\$ 13,000
Total Fees	\$ 177,000	\$ 186,000

Audit Fees include fees for services rendered for the audit and quarterly reviews of our financial statements, (1)including our Annual Report on Form 10-K and our periodic reports, and fees incurred related to the filings of registration statements.

(2) Tax Fees consist of amounts billed by an affiliate of our independent auditors for services in connection with the preparation of our federal and state tax returns.

### **Pre-Approval Policies and Procedures**

Our Audit Committee's policy is to pre-approve all audit and permissible non-audit services provided by our independent auditors. These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year and any pre-approval is detailed as to the particular service or category of services. The independent auditor and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent auditor in accordance with this pre-approval. Any proposed services not included within the list of pre-approved services or any proposed services that will cause the Company to exceed the pre-approved aggregate amount requires specific pre-approval by the Audit Committee. All audit fees, audit-related fees, tax fees, and other fees listed in the table above were approved by the Audit Committee pursuant to its pre-approval policies and procedures.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

- (a)(1) The list of financial statements filed in response to Part II, Item 8 is set forth at the end of this Annual Report.
- (2) Schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.
- (3) The following exhibits are filed as part of this Annual Report pursuant to Item 601 of Regulation S-K:
- 2.1 Agreement and Plan of Merger, dated as of March 24, 2011, by and between PURE Bioscience and PURE Bioscience, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K, filed with the SEC on March 25, 2011)
  - 3.1 Certificate of Incorporation of PURE Bioscience, Inc. (incorporated by reference to Exhibit 3.1 to the Annual Report on Form 10-K, filed with the SEC on October 29, 2012)
  - 3.1.1 Certificate of Amendment to Certificate of Incorporation of PURE Bioscience, Inc. (incorporated by reference to Exhibit 3.1.1 to the Annual Report on Form 10-K, filed with the SEC on October 29, 2012)
  - 3.2 Bylaws of PURE Bioscience, Inc. (incorporated by reference to Exhibit 3.2 to the Annual Report on Form 10-K, filed with the SEC on October 29, 2012)
  - 3.2.1 Amendment to the Bylaws of PURE Bioscience, Inc. (incorporated by reference to Exhibit 3.2.1 to the Annual Report on Form 10-K, filed with the SEC on October 29, 2012)
  - 4.1 Wharton Capital Markets LLC Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC on March 16, 2012)
  - 4.2 Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC on September 13, 2012)
  - 4.3 Morrison & Foerster LLP Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC on January 31, 2013)
  - 4.4 Form of Investor Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC April 23, 2013)
  - 4.5 Warrant, dated February 3, 2012, issued by PURE Bioscience, Inc. to Wharton Capital Markets LLC (incorporated by reference to Exhibit 4.1 of the Quarterly Report on Form 10-Q filed with the SEC on March 16, 2012)

- 4.6 Form of Investor Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed with the SEC August 27, 2014)
- 4.7 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.5 of the Current Report on Form 8-K filed with the SEC on June 29, 2012)
- 4.8 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on July 6, 2012)
- 4.9 Form of Five-Year Warrant (incorporated by reference to Exhibit 4.11 of the Annual Report on Form 10-K filed with the SEC on October 28, 2015)

- 4.10 Form of Six-Month Warrant (incorporated by reference to Exhibit 4.12 of the Annual Report on Form 10-K filed with the SEC on October 28, 2015)
- 4.11 Form of Warrant (incorporated by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the SEC on December 7, 2016).
- 4.12 Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 of the Current Report on Form 8-K filed with the SEC on December 7, 2016).
- 10.1 Amended and Restated PURE Bioscience 2007 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K, filed with the SEC on February 5, 2016)
- 10.2 # Form of Indemnification Agreement (incorporated by reference to Exhibit 10.2 to the Annual Report on Form 10-K filed with the SEC on October 24, 2013)
- 10.3 Letter Agreement, dated as of January 25, 2013, between PURE Bioscience, Inc., and Morrison & Foerster LLP (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on January 31, 2013)
- 10.4 Promissory Note, dated as of January 25, 2013, in favor of Morrison & Foerster LLP (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on January 31, 2013)
- 10.5 Services Agreement dated as of August 13, 2013, between PURE Bioscience, Inc. and Pillar Marketing Group, Inc. (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on August 20, 2013)
- 10.6 Voting Support Agreement and Irrevocable Proxy dated as of August 13, 2013 between PURE Bioscience, Inc. and Michael L. Krall (incorporated by reference to Exhibit 10.4 of the Current Report on Form 8-K filed with the SEC on August 20, 2013)
- 10.7 Voting Support Agreement and Irrevocable Proxy dated as of August 13, 2013 between PURE Bioscience, Inc. and Donna Singer (incorporated by reference to Exhibit 10.6 of the Current Report on Form 8-K filed with the SEC on August 20, 2013)
- 10.8 # Director Agreement dated as of September 17, 2013 between PURE Bioscience, Inc. and Gary D. Cohee (incorporated by reference to Exhibit 10.32 to the Annual Report on Form 10-K filed with the SEC on October 24, 2013)
- 10.9 # Employment Agreement dated as of October 23, 2013 between PURE Bioscience, Inc. and Henry R. Lambert (incorporated by reference to Exhibit 10.33 to the Annual Report on Form 10-K filed with the SEC on October 24, 2013)
- 10.10 # Chairman Agreement dated as of October 23, 2013 between PURE Bioscience, Inc. and Dave J. Pfanzelter (incorporated by reference to Exhibit 10.35 to the Annual Report on Form 10-K filed with the SEC on October 24, 2013)

- 10.11 Form of RSU Agreement between PURE Bioscience, Inc. and Non-employee directors (incorporated by  
# reference to Exhibit 10.36 to the Annual Report on Form 10-K filed with the SEC on October 24, 2013)
- 10.12 RSU Agreement dated as of October 23, 2013 between PURE Bioscience, Inc. and Henry R. Lambert  
# (incorporated by reference to Exhibit 10.37 to the Annual Report on Form 10-K filed with the SEC on  
October 24, 2013)

- 10.13 RSU Agreement dated as of October 23, 2013 between PURE Bioscience, Inc. and Dave J. Pfanzelter (incorporated by reference to Exhibit 10.39 to the Annual Report on Form 10-K filed with the SEC on October 24, 2013)  
#
- 10.14 Form of Officer and Director Indemnification Agreement (incorporated by reference to Exhibit 10.2 of the Annual Report on Form 10-K filed with the SEC on October 24, 2013)
- 10.15 Strategic Collaboration Agreement, dated December 11, 2013, by and between PURE Bioscience, Inc. and Intercon Chemical Company (incorporated by reference to Exhibit 10.3 of the Quarterly Report on Form 10-Q filed with the SEC on March 13, 2014)
- 10.16 Amendment to Director Agreement dated as of April 24, 2014, between PURE Bioscience, Inc. and Gary D. Cohee (incorporated by reference to Exhibit 10.2 of the Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014)
- 10.17 Securities Purchase Agreement, dated August 22, 2014 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on August 27, 2014)
- 10.18 Amendment to Services Agreement, dated October 2, 2014, between PURE Bioscience, Inc. and Pillar Marketing Group, Inc. (incorporated by reference to Exhibit 10.48 of the Registration Statement on Form S-1 filed with the SEC on October 10, 2014)
- 10.19 Securities Purchase Agreement, dated October 8, 2015, by and between the Company and the purchaser party thereto (incorporated by reference to Exhibit 10.30 of the Annual Report on Form 10-K filed with the SEC on October 28, 2015)
- 10.20 Registration Rights Agreement, dated October 8, 2015, by and between the Company and the purchaser party thereto (incorporated by reference to Exhibit 10.31 of the Annual Report on Form 10-K filed with the SEC on October 28, 2015)
- 10.21 Form of RSU Agreement between PURE Bioscience, Inc. and executive officers (incorporated by reference to Exhibit 10.32 of the Annual Report on Form 10-K filed with the SEC on October 28, 2015)  
#
- 10.22 Securities Purchase Agreement, dated December 1, 2016, between the Company and the purchasers party thereto (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on December 7, 2016)
- 10.23 Registration Rights Agreement, dated December 1, 2016, by and between the Company and the purchasers party thereto (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on December 7, 2016)
- 10.24 RSU Cancellation Agreement, dated as of December 13, 2016, by and among the Company and the parties thereto (incorporated by reference to Exhibit 10.3 of the Quarterly Report on Form 10-K filed with the SEC on December 14, 2016)
- 10.24 Amendment to Chairman Agreement, dated January 19, 2017, by and between the Company and Dave Pfanzelter (incorporated by reference to Exhibit 99.1 of the Current Report on Form 8-K filed with the SEC

on January 20, 2017)

10.25 Amendment to Executive Employment Agreement, dated January 19, 2017, by and between the Company and Hank Lambert (incorporated by reference to Exhibit 99.2 of the Current Report on Form 8-K filed with the SEC on January 20, 2017)

10.26 Amendment to Registration Rights Agreement, dated January 20, 2017, between the Company and the purchasers party thereto (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on January 24, 2017)



- 10.27 Chairman RSU Agreement, dated as of June 22, 2017, by and between the Company and Dave Pfanzelter (incorporated by reference to Exhibit 99.1 of the Current Report on Form 8-K filed with the SEC on June 23, 2017)
- 10.28 Chairman Option Agreement, dated as of June 22, 2017, by and between the Company and Dave Pfanzelter (incorporated by reference to Exhibit 99.2 of the Current Report on Form 8-K filed with the SEC on June 23, 2017)
- 10.29 CEO RSU Agreement, dated as of June 22, 2017, by and between the Company and Hank Lambert (incorporated by reference to Exhibit 99.3 of the Current Report on Form 8-K filed with the SEC on June 23, 2017)
- 10.30 CEO Option Agreement, dated as of June 22, 2017, by and between the Company and Dave Pfanzelter (incorporated by reference to Exhibit 99.4 of the Current Report on Form 8-K filed with the SEC on June 23, 2017)
- 10.31 Form of Non-Employee Director RSU Agreement (Non-plan) (incorporated by reference to Exhibit 99.5 of the Current Report on Form 8-K filed with the SEC on June 23, 2017)
- 10.32 Form of Non-Employee Director Option Agreement (Non-plan) (incorporated by reference to Exhibit 99.6 of the Current Report on Form 8-K filed with the SEC on June 23, 2017)
- 10.33 Pure Bioscience, Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on January 18, 2018)
- 10.34 Promissory Note, dated June 28, 2018, issued to Tom Y. Lee (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on July 2, 2018)
- 10.35 Consulting Agreement, dated June 28, 2018, by and between the Company and William Otis (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on July 2, 2018)
- 10.36 Consulting Agreement, dated August 13, 2018, by and between the Company and Dave Pfanzelter (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on August 7, 2018)
- 10.37 Second Amendment to Employment Agreement, dated September 5, 2018, by and between the Company and Henry R. Lambert (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on September 7, 2018)
- 21.1 Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K, filed with the SEC on October 13, 2009)
- 23.1  
\* Consent of Mayer Hoffman McCann P.C.
- 31.1  
\* Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

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

32.1  
\* Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2  
\* Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101 \* The following materials from the Company's Annual Report on Form 10-K for the annual period ended July 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as at July 31, 2018 and 2017; (ii) Consolidated Statements of Operations for the years ended July 31, 2018 and 2017; (iii) Consolidated Statements of Stockholders' Equity for the years ended July 31, 2018 and 2017, (iv) Consolidated Statements of Cash Flows for the years ended July 31, 2018 and 2017; and (v) Notes to Consolidated Financial Statements.

\* Filed herewith

# Management contract or compensatory plan or arrangement

**Signatures**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**PURE BIOSCIENCE, INC. DATE**

*/s/ HENRY R. LAMBERT*      October 25, 2018  
 Henry R. Lambert  
 Chief Executive Officer

**Power of Attorney**

NOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Henry R. Lambert and Mark S. Elliott, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report is signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>NAME</b>	<b>TITLE</b>	<b>DATE</b>
<i>/s/ HENRY R. LAMBERT</i> Henry R. Lambert	Chief Executive Officer, Director Principal Executive Officer	October 25, 2018
<i>/s/ MARK S. ELLIOTT</i> Mark S. Elliott	Vice President, Finance Principal Financial and Accounting Officer	October 25, 2018
<i>/s/ IVAN CHEN</i> Ivan Chen	Director	October 25, 2018

Edgar Filing: PURE BIOSCIENCE, INC. - Form 10-K

<i>/s/ GARY D. COHEE</i> Gary D. Cohee	Director	October 25, 2018
<i>/s/ JANET RISI</i> Janet Risi	Director	October 25, 2018
<i>/s/ Dr. Elisabeth Hagen</i> Dr. Elisabeth Hagen	Director	October 25, 2018
<i>/s/ TOM Y. LEE</i> Tom Y. Lee	Director	October 25, 2018

**Index to Consolidated Financial Statements**

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of July 31, 2018 and 2017</u>	F-3
<u>Consolidated Statements of Operations for the years ended July 31, 2018 and 2017</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for the years ended July 31, 2018 and 2017</u>	F-5
<u>Consolidated Statements of Cash Flows for the years ended July 31, 2018 and 2017</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

F-1

## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of

**PURE Bioscience, Inc.**

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of PURE Bioscience, Inc. (“the Company”) as of July 31, 2018 and 2017, and the related consolidated statements of operations, stockholders’ equity and cash flows for each of the two years in the period ended July 31, 2018, and related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of July 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended July 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

### **Going Concern Uncertainty**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans regarding those matters are also described in Note 1 to the financial statements. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

### **Basis for Opinion**

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2007.

*/s/ Mayer Hoffman McCann P.C.*

San Diego, California  
October 25, 2018

F-2

**PURE Bioscience, Inc.****Consolidated Balance Sheets**

	July 31, 2018	July 31, 2017
Assets		
Current assets		
Cash and cash equivalents	\$851,000	\$1,640,000
Accounts receivable	275,000	297,000
Inventories, net	197,000	273,000
Restricted cash	75,000	75,000
Prepaid expenses	58,000	174,000
Total current assets	1,456,000	2,459,000
Property, plant and equipment, net	461,000	548,000
Patents, net	658,000	822,000
Total assets	\$2,575,000	\$3,829,000
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$608,000	\$426,000
Promissory note payable	503,000	—
Accrued liabilities	170,000	249,000
Derivative liabilities	—	1,853,000
Total current liabilities	1,281,000	2,528,000
Deferred rent	13,000	11,000
Total liabilities	1,294,000	2,539,000
Commitments and contingencies (See Note 4)		
Stockholders' equity		
Preferred stock, \$0.01 par value: 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, \$0.01 par value: 100,000,000 shares authorized, 68,248,158 shares issued and outstanding at July 31, 2018, and 63,093,153 shares issued and outstanding at July 31, 2017	683,000	631,000
Additional paid-in capital	117,522,000	110,141,000
Accumulated deficit	(116,924,000)	(109,482,000)
Total stockholders' equity	1,281,000	1,290,000
Total liabilities and stockholders' equity	\$2,575,000	\$3,829,000

*See accompanying notes.*



**PURE Bioscience, Inc.****Consolidated Statements of Operations**

	Year ended	
	July 31,	
	2018	2017
Net product sales	\$1,774,000	\$1,831,000
Operating costs and expenses		
Cost of goods sold	763,000	760,000
Selling, general and administrative	5,235,000	5,230,000
Research and development	459,000	779,000
Share-based compensation	2,359,000	1,070,000
Total operating costs and expenses	8,816,000	7,839,000
Loss from operations	(7,042,000 )	(6,008,000 )
Other income (expense)		
Inducement to exercise warrants	(876,000 )	—
Change in derivative liabilities	459,000	(277,000 )
Interest expense, net	(8,000 )	(5,000 )
Other income, net	25,000	27,000
Total other expense	(400,000 )	(255,000 )
Net loss	\$(7,442,000 )	\$(6,263,000 )
Basic and diluted net loss per share	\$(0.11 )	\$(0.10 )
Shares used in computing basic and diluted net loss per share	67,279,124	63,492,406

*See accompanying notes.*

**PURE Bioscience, Inc.****Consolidated Statements of Stockholders' Equity**

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Stockholders' Equity
Balance July 31, 2016	64,823,917	\$649,000	\$107,593,000	\$(103,219,000)	\$5,023,000
Issuance of common stock in private placements, net	1,572,941	16,000	1,033,000	—	1,049,000
Share-based compensation expense - stock options	—	—	968,000	—	968,000
Share-based compensation expense - restricted stock units	—	—	102,000	—	102,000
Warrant liability removed due to warrant exercise	—	—	226,000	—	226,000
Issuance of common stock upon vesting of restricted stock units	150,000	1,000	(1,000 )	—	—
Issuance of common stock upon exercise of warrants	346,295	3,000	182,000	—	185,000
Restricted stock unit cancellation	(3,800,000 )	(38,000 )	38,000	—	—
Net loss	—	—	—	(6,263,000 )	(6,263,000 )
Balance July 31, 2017	63,093,153	\$631,000	\$110,141,000	\$(109,482,000)	\$1,290,000
Share-based compensation expense - stock options	—	—	1,525,000	—	1,525,000
Share-based compensation expense - restricted stock units	—	—	834,000	—	834,000
Warrant liability removed due to warrant exercise	—	—	1,394,000	—	1,394,000
Issuance of common stock upon exercise of warrants	4,914,505	49,000	2,583,000	—	2,632,000
Stock issued for services	240,500	3,000	169,000	—	172,000
Inducement to exercise warrants	—	—	876,000	—	876,000
Net loss	—	—	—	(7,442,000 )	(7,442,000 )
Balance July 31, 2018	68,248,158	\$683,000	\$117,522,000	\$(116,924,000)	\$1,281,000

*See accompanying notes.*

**PURE Bioscience, Inc.****Consolidated Statements of Cash Flows**

	Year ended	
	July 31,	
	2018	2017
Operating activities		
Net loss	\$(7,442,000)	\$(6,263,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	2,359,000	1,070,000
Amortization of stock issued for services	122,000	144,000
Stock issued for services	121,000	—
Depreciation and amortization	285,000	276,000
Inventory write-off	58,000	50,000
Gain on inventory recovery	(19,000 )	—
Change in fair value of derivative liabilities	(459,000 )	277,000
Inducement to exercise warrants	876,000	—
Interest expense on promissory note	3,000	—
Changes in operating assets and liabilities:		
Accounts receivable	22,000	(34,000 )
Inventories	37,000	27,000
Prepaid expenses	45,000	(58,000 )
Accounts payable and accrued liabilities	103,000	(59,000 )
Deferred rent	2,000	8,000
Net cash used in operating activities	(3,887,000)	(4,562,000)
Investing activities		
Investment in patents	(15,000 )	(20,000 )
Purchases of property, plant and equipment	(19,000 )	(206,000 )
Net cash used in investing activities	(34,000 )	(226,000 )
Financing activities		
Net proceeds from the exercise of warrants	2,632,000	185,000
Net proceeds from promissory note financing	500,000	—
Net proceeds from the sale of common stock	—	1,049,000
Net cash provided by financing activities	3,132,000	1,234,000
Net decrease in cash and cash equivalents	(789,000 )	(3,554,000)
Cash and cash equivalents at beginning of year	1,640,000	5,194,000
Cash and cash equivalents at end of year	\$851,000	\$1,640,000
Supplemental disclosure of cash flow information		
Cash paid for taxes	\$3,000	\$7,000
Noncash investing and financing activities		
Warrant liability removed due to settlements	\$1,394,000	\$226,000
Common stock issued for prepaid services	\$51,000	—
Restricted stock unit cancelation	\$—	\$38,000

*See accompanying notes.*

F-6

**PURE Bioscience, Inc.**

**Notes to Consolidated Financial Statements**

**1. Organization and Business**

All references to “PURE,” “we,” “our,” and “us” refer to PURE Bioscience, Inc. and our wholly owned subsidiary.

PURE Bioscience, Inc. is focused on developing and commercializing our proprietary antimicrobial products that provide solutions to the health and environmental challenges of pathogen and hygienic control. Our technology platform is based on patented stabilized ionic silver, and our initial products contain silver dihydrogen citrate, or SDC. SDC is a broad-spectrum, non-toxic antimicrobial agent that is manufactured as a liquid delivered in various concentrations. We currently distribute and contract the manufacture and distribution of our SDC-based disinfecting and sanitizing products. We also contract manufacture and sell SDC-based formulations to manufacturers for use as a raw material ingredient in the production of personal care products. We believe our technology platform has potential application in a number of industries. We intend to focus our current resources on providing food safety solutions to the food industry.

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

**Liquidity & Going Concern Uncertainty**

These consolidated financial statements have been prepared and presented on a basis assuming we will continue as a going concern. The factors below raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

Since our inception, we have financed our operations primarily through public and private offerings of securities, debt financing, and revenue from product sales and license agreements. We have a history of recurring losses, and as of July 31, 2018, we have incurred a cumulative net loss of \$116,924,000.

We do not have, and may never have, significant cash inflows from product sales or from other sources of revenue to fund our operations. As of July 31, 2018, we had \$851,000 in cash and cash equivalents, and \$1,281,000 of current liabilities, including \$608,000 in accounts payable. On August 16, 2018, we completed a closing of a private placement financing to accredited investors. We raised approximately \$1.5 million in net proceeds from the private placement financing and issued an aggregate of 3,333,964 shares of our common stock at a purchase price of \$0.45 per share, including the conversion of approximately \$0.5 million held in the form of a promissory note as of July 31, 2018. The shares issued in the private placement financing were issued pursuant to a securities purchase agreement entered into with the investors. Mr. Tom Y. Lee, a member of the Company's Board of Directors invested approximately \$1.0 million through his affiliates, including approximately \$0.5 million of cash and the cancellation of existing indebtedness in the amount of approximately \$0.5 million that was held in the form of a promissory note payable as of July 31, 2018. We do not currently believe that our existing cash resources are sufficient to meet our anticipated needs over the next twelve months from the date hereof.

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

Until we can generate significant cash from operations, we expect to continue to fund our operations with the proceeds of offerings of our equity and debt securities. However, we cannot assure you that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. Further, any contracts or license arrangements we enter into to raise funds may require us to relinquish our rights to our products or technology, and we cannot assure you that we will be able to enter into any such contracts or license arrangements on acceptable terms, or at all. Having insufficient funds may require us to delay or scale back our marketing, distribution and other commercialization activities or cease our operations altogether.

We do not have any unused credit facilities or other sources of capital available to us at this time. We intend to secure additional working capital through sales of additional debt or equity securities. Our intended financing initiatives are subject to risk, and we cannot provide any assurance about the availability or terms of these or any future financings.

The consolidated financial statements do not include any adjustment relating to recoverability or classification of recorded assets and classification of recorded liabilities.

## **2. Summary of Significant Accounting Policies**

### *Basis of Presentation*

The accompanying consolidated financial statements include the consolidated accounts of PURE Bioscience, Inc. and its wholly owned subsidiary, ETIH2O Inc., a Nevada corporation. ETIH2O Inc. has no business and no material assets or liabilities and there have been no significant transactions related to ETIH2O Inc. during the periods presented in the consolidated financial statements. All inter-company balances and transactions have been eliminated.

### *Use of Estimates*

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements, and the disclosures made in the accompanying notes to the consolidated financial statements. Actual results could differ materially from those estimates.

### *Reclassification*

Certain reclassifications have been made to prior period amounts to conform to current period presentation. These reclassifications did not have an impact on our results of operations or financial condition as of and for the year ended July 31, 2017.

### *Cash and Cash Equivalents*

Cash and cash equivalents consist of cash and highly liquid investments with original maturities from the purchase date of three months or less.

Restricted Cash

The Company is required to maintain \$75,000 in a restricted certificate of deposit account in order to fully collateralize four revolving credit card accounts.

Fair Value of Financial Instruments

Certain of our financial instruments—including cash and cash equivalents, accounts receivable, inventories, prepaid expenses, accounts payable, accrued liabilities, and deferred rent are carried at cost, which is considered to be representative of their respective fair values because of the short-term nature of these instruments. Our derivative liabilities are carried at estimated fair value (See Notes 5 and 6 to these consolidated financial statements).

Derivative Financial Instruments

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

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

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



The discount from the face value of any convertible debt, together with the stated interest on the instrument, is amortized over the life of the instrument through periodic charges to interest expense, using the effective interest method.

#### Accounts Receivable

Trade accounts receivable are recorded net of allowances for doubtful accounts. Estimates of allowances for doubtful accounts are determined based on historical payment patterns and individual customer circumstances. The allowance for doubtful accounts was zero at July 31, 2018 and 2017.

#### Inventories

Inventories are stated at the lower of cost or net realizable value, and net of a valuation allowance for potential excess or obsolete material. Cost is determined using the average cost method.

#### Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. The estimated useful lives of our property, plant, and equipment range from three to ten years. Capitalized costs associated with leasehold improvements are depreciated over the lesser of the useful life of the asset or the remaining life of the lease. Depreciation is generally included in selling, general and administrative expense. Depreciation related to manufacturing is systematically allocated to inventory produced, and expensed through cost of goods sold at the time inventory is sold.

#### Patents

We have filed a number of patent applications with the United States Patent and Trademark Office and in foreign countries. Certain legal and related costs incurred in connection with pending patent applications have been capitalized. Costs related to successful patent applications are amortized over the lesser of the remaining useful life of the related technology or the remaining patent life, commencing on the date the patent is issued. Capitalized costs related to patent applications are expensed in the period in which a determination is made not to pursue such

applications.

#### Impairment of Long-Lived Assets

In accordance with GAAP, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the fair value of the asset and we record the impairment as a reduction in the carrying value of the related asset and a charge to operating results. Estimating the undiscounted future cash flows associated with long-lived assets requires judgment, and assumptions could differ materially from actual results. There were no patent impairments during the years ended July 31, 2018 or 2017.

#### Revenue Recognition

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

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

F-9

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

#### Shipping and Handling Costs

Shipping and handling costs incurred by us for product shipments are included in cost of goods sold and were minimal for the years ended July 31, 2018 and 2017.

#### Research and Development Costs

Research and development costs are expensed as incurred.

#### Share-Based Compensation

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

#### Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on marketable securities and foreign currency translation adjustments. For the years ended July 31, 2018 and 2017, our comprehensive loss consisted only of net loss.

Income Taxes

We recognize deferred tax assets and liabilities for temporary differences between the tax basis of assets and liabilities and the amounts at which they are carried in the financial statements based upon the enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established to reduce deferred tax assets to the amount expected to be realized.

Net Loss Per Share

Basic net loss per common share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Our diluted net loss per common share is the same as our basic net loss per common share because we incurred a net loss during each period presented, and the potentially dilutive securities from the assumed exercise of all outstanding stock options, restricted stock units, and warrants would have an antidilutive effect. For the years ended July 31, 2018 and 2017, the number of shares issuable upon the exercise of stock options, the vesting of restricted stock units, and the exercise of warrants, none of which are included in the computation of basic net loss per common share, was 12,012,189 and 16,098,679, respectively.

Recent Accounting Pronouncements

In July 2017, the Financial Accounting Standards Board (“FASB”) issued a two-part Accounting Standards Update (“ASU”) No. 2017-11, I. Accounting for Certain Financial Instruments With Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception (“ASU 2017-11”). ASU 2017-11 amends guidance in FASB ASC 260, Earnings Per Share, FASB ASC 480, Distinguishing Liabilities from Equity, and FASB ASC 815, Derivatives and Hedging. The amendments in Part I of ASU 2017-11 change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments in Part II of ASU 2017-11 re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. ASU 2017-11 is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018 with early adoption permitted. We are evaluating the effect that this update will have on our consolidated financial statements and related disclosures.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard was originally effective for public companies for annual reporting periods beginning after December 15, 2016, with no early application permitted. In August 2015, the FASB issued ASU No. 2015-14 that defers by one year the effective date for all entities, with application permitted as of the original effective date. The updated standard becomes effective for us on August 1, 2018. The standard permits the use of either the retrospective or cumulative effect transition method. We adopted the new standard for the fiscal year beginning August 1, 2018 using the modified retrospective application method. We have substantially completed the assessment of the new standard and believe that there will not be a material impact on our consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. This ASU requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the Statement of Cash Flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with early adoption permitted. The new guidance must be applied on a retrospective basis. We have evaluated the effect of adopting this new accounting guidance and determined that adoption will not have a material impact on our Statement of Cash Flows.

In December 2017, the United States (“U.S.”) enacted the Tax Cuts and Jobs Act (the “2017 Act”), which changes existing U.S. tax law and includes various provisions that are expected to affect public companies. The 2017 Act (i) changes U.S. corporate tax rates, (ii) generally reduces a company’s ability to utilize accumulated net operating losses, and (iii)

requires the calculation of a one-time transition tax on certain previously unrepatriated foreign earnings and profits (“E&P”). The 2017 Act will also impact estimates of a company’s deferred tax assets and liabilities. On December 22, 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 (“SAB 118”) to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act (“U.S. Tax Cuts and Jobs Act of 2017”). This new law did not have a significant impact on our consolidated financial statements for the year ended July 31, 2018 because we maintain a valuation allowance on the entirety of our deferred tax assets. However, the reduction of the U.S. federal corporate tax rate from 35% to 21% resulted in a remeasurement of our deferred tax assets.

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation: Scope of Modification Accounting, which provides clarity and guidance around which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those annual reporting periods. The adoption of this guidance will have no impact on our consolidated financial statements unless we have modification accounting in accordance with Topic 718.

### 3. Balance Sheet Details

Inventories consist of the following:

	July 31,	
	2018	2017
Raw materials	\$39,000	\$82,000
Finished goods	158,000	191,000
	\$197,000	\$273,000

During the year ended July 31, 2018, we wrote-off \$58,000 of finished goods inventory damaged at our contract manufacturer’s facility. In addition we wrote-off \$26,000 of inventory destroyed in a third-party warehouse fire. We received \$45,000 from an insurance claim for the replacement cost of the inventory destroyed in the fire. As a result, we recorded a gain of \$19,000 reflected in the other income section of our consolidated statements of operations.

During the year ended July 31, 2017, we wrote-off \$50,000 for slow moving finished goods inventory manufactured in prior years.

Property, plant, and equipment consist of the following:

Edgar Filing: PURE BIOSCIENCE, INC. - Form 10-K

	July 31,	
	2018	2017
Computers and equipment	\$1,064,000	\$1,045,000
Furniture and fixtures	21,000	21,000
	1,085,000	1,066,000
Less accumulated depreciation	(624,000 )	(518,000 )
	\$461,000	\$548,000

F-11

Depreciation expense was \$106,000 and \$98,000 for the years ended July 31, 2018 and 2017, respectively.

Patents consist of the following:

	July 31,	
	2018	2017
Patents	\$3,500,000	\$3,485,000
Less accumulated amortization	(2,842,000)	(2,663,000)
	\$658,000	\$822,000

Patent amortization expense for the years ended July 31, 2018 and 2017 was \$179,000 and \$178,000, respectively.

At July 31, 2018, future patent amortization expense is expected to be as follows:

2019	\$135,000
2020	87,000
2021	76,000
2022	48,000
2023	42,000
Thereafter	270,000
	\$658,000

#### 4. Commitments and Contingencies

##### Operating Leases

During August 2016, we amended the lease of our primary facility in El Cajon, California under a noncancelable operating lease that now expires in December 2019. This facility includes our corporate offices, research and development laboratory, and warehouse. Rent expense, including common area maintenance, was \$121,000 and \$116,000 for the years ended July 31, 2018 and 2017, respectively.



Future minimum annual lease payments for our primary facility as of July 31, 2018 are as follows:

2019	\$ 106,000
2020	\$ 45,000
	\$ 151,000

## 5. Fair Value of Financial Instruments

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

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

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

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

In connection with the October and November 2015 Private Placements, we issued warrants with derivative features. These instruments were accounted for as derivative liabilities (See Note 6 to these consolidated financial statements).

We used Level 3 inputs for the valuation methodology of the derivative liabilities. The estimated fair values were computed using a Monte Carlo option pricing model based on various assumptions. Our derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the fair value of the derivative liabilities. Various factors are considered in the pricing models we use to value the warrants, including the Company's current stock price, the remaining life of the warrants, the volatility of the Company's stock price, and the risk free interest rate.

The following table provides a reconciliation of the beginning and ending balances of the derivative liabilities for the years ended July 31, 2018 and 2017:

### Fair Value of Significant Unobservable Inputs (Level 3)

	Warrant Liability
Balance at July 31, 2016	\$1,802,000
Issuances	—
Settlement of warrant liability	(226,000 )
Adjustments to estimated fair value	277,000
Balance at July 31, 2017	\$1,853,000
Issuances	—
Settlement of warrant liability	(1,394,000)
Adjustments to estimated fair value	(459,000 )
Balance at July 31, 2018	\$—

### 6. Derivative Liability

On October 23, 2015, we completed a first closing of a private placement financing (the “2015 Private Placement Financing”), where we issued, among other securities, a warrant to purchase up to an aggregate of 6,666,666 shares of common stock with a term of five years and a warrant to purchase up to an aggregate of 8,666,666 shares of common stock with a term of six months.

On November 23, 2015, we completed a second and final closing of the 2015 Private Placement Financing, where we issued, among other securities, a warrant to purchase up to an aggregate of 2,222,217 shares of common stock with a term of five years and a warrant to purchase up to an aggregate of 2,820,670 shares of common stock with a term of six months.

We accounted for the combined 20,376,219 warrants issued in connection with the 2015 Private Placement Financing in accordance with the accounting guidance for derivatives. The applicable accounting guidance sets forth a two-step model to be applied in determining whether a financial instrument is indexed to an entity’s own stock, which would qualify such financial instruments for a scope exception. This scope exception specifies that a contract that would otherwise meet the definition of a derivative financial instrument would not be considered as such if the contract is both (i) indexed to the entity’s own stock and (ii) classified in the stockholders’ equity section of the entity’s balance sheet. We determined the warrants were ineligible for equity classification due to anti-dilution provisions set forth

therein.

During the fiscal year ended July 31, 2016, (i) all 2,820,670 of the six-month warrants issued in the second and final closing were exercised, (ii) the six-month warrants issued in the first closing expired and (iii) the five-year warrants issued in the first closing were cancelled.

On September 25, 2017, we completed the first closing of a tender offer (the "Tender Offer") to amend and exercise outstanding warrants to purchase shares of our common stock held by the investors participating in the 2015 Private Placement Financing and our 2014 and 2017 private placement financings. As a result, 1,599,135 warrants issued in connection with the 2015 Private Placement Financing were exercised for cash. In addition, there was a net exercise on 118,057 warrants which resulted in the issuance of 63,811 shares of our common stock. The net exercised warrants were issued in connection with the 2015 Private Placement Financing. The change in fair value of the warrant liabilities on September 25, 2017 was recorded as a change in derivative liabilities in the consolidated statements of operations. The fair value on the exercise date was returned to additional paid-in capital and is reflected in the settlement of warrant liability section on the table in Note 5. The following assumptions were used as inputs to the fair value model at September 25, 2017: stock price of \$1.00 per share and a warrant exercise price of \$0.45 per share as of the valuation date; our historical stock price volatility of 70.00%; risk free interest rate on U.S. treasury notes of 1.6%; warrant expiration of 3.2 years (See Note 7 to these consolidated financial statements).

F-13

On October 10, 2017, we completed a second and final closing of the Tender Offer. As a result, 268,909 warrants issued in connection with the 2015 Private Placement Financing were exercised. The change in fair value of the warrant liabilities on October 10, 2017 was recorded as a change in derivative liabilities in the consolidated statements of operations. The fair value on the exercise date was returned to additional paid-in capital and is reflected in the settlement of warrant liability section on the table in Note 5. The following assumptions were used as inputs to the fair value model at October 10, 2017: stock price of \$1.03 per share and a warrant exercise price of \$0.45 per share as of the valuation date; our historical stock price volatility of 70.00%; risk free interest rate on U.S. treasury notes of 1.6%; warrant expiration of 3.1 years (See Note 7 to these consolidated financial statements).

During the fiscal year ended July 31, 2018, all remaining warrants containing derivative features issued in connection with the 2015 Private Placement Financing were exercised.

As of July 31, 2018, the total value of the derivative liabilities was zero. The change in fair value of the warrant liabilities for fiscal years ended July 31, 2018 and 2017, was a decrease of \$459,000 and an increase \$277,000, respectively, which was recorded as a change in derivative liabilities in the consolidated statements of operations.

## **7. Stockholders' Equity**

### Preferred Stock

As of July 31, 2018, the Company's Board of Directors is authorized to issue 5,000,000 shares of preferred stock with a par value of \$0.01 per share, in one or more series. As of July 31, 2018 and July 31, 2017, there were no shares of preferred stock issued and outstanding.

### Common Stock

As of July 31, 2018, 100,000,000 shares of common stock with a par value of \$0.01 per share are authorized for issuance.

### Schedule TO and Warrant Exercises

On October 10, 2017, we closed the Tender Offer. Specifically, we filed a Schedule TO with the SEC on August 25, 2017 offering to (i) reduce the exercise price of the warrants to purchase 4,104,980 shares of common stock issued to investors participating in our private placement financing completed on August 29, 2014, as amended (the “2014 Warrants”) from \$0.75 per share to \$0.60 per share of common stock in cash, (ii) reduce the exercise price of outstanding warrants to purchase 1,986,101 shares of common stock issued to investors participating in our private placement financing completed on November 23, 2015 (the “2015 Warrants”) from \$0.45 per share to \$0.40 per share of common stock in cash, (iii) reduce the exercise price of the outstanding warrants to purchase 1,572,941 shares of common stock issued to investors participating in our private placement financing completed on January 23, 2017 (the “2017 Warrants”, together with the 2014 Warrants and 2015 Warrants, the “Original Warrants”) from \$1.25 per share to \$0.85 per share of common stock in cash, (iv) shorten the exercise period of the Original Warrants so that they expired concurrently with the expiration of the Offer to Amend and Exercise at 5:00 p.m. (Pacific Time) on September 25, 2017 (“Expiration Date”) unless extended until the Subsequent Expiration Date (as defined below), (v) delete the cashless exercise provisions in the Original Warrants and (vi) delete the price-based anti-dilution provisions contained in the 2015 Warrants.

Additionally, we requested the holders of a majority of the shares issuable upon exercise of the 2014 Warrants (the “2014 Requisite Majority”), 2015 Warrants (the “2015 Requisite Majority”) and 2017 Warrants (the “2017 Requisite Majority”) to approve an amendment of all of the outstanding 2014 Warrants, 2015 Warrants and 2017 Warrants, respectively, to amend such Original Warrants in the same manner as set forth above (the “Aggregate Warrant Amendment”), except the Expiration Date would be extended until October 10, 2017 (the “Subsequent Expiration Date”) if such Aggregate Warrant Amendment was approved with respect to such class of Original Warrants. The 2015 Requisite Majority approved an amendment of all of the outstanding 2015 Warrants and holders of 2015 Warrants had until the Subsequent Expiration Date to exercise their 2015 Warrants (the “Subsequent Offer Period”).

The Offer to Amend and Exercise with respect to the 2014 Warrants and 2017 Warrants expired on the Expiration Date of September 25, 2017. As of September 25, 2017, 1,491,649 shares of common stock were issued upon exercise of 2014 Warrants, 1,599,135 shares of common stock were issued upon exercise of 2015 Warrants and 1,396,470 shares of common stock were issued upon exercise of 2017 Warrants, for aggregate gross proceeds to us of approximately \$2,720,000. During the Subsequent Offer Period, 2015 Warrants to purchase 268,909 shares of common stock were exercised for aggregate gross proceeds to us of approximately \$107,000. 2014 Warrants to purchase 2,533,331 shares of common stock and 2017 Warrants to purchase 176,471 shares of common stock at exercise prices of \$0.75 per share and \$1.25 per share, respectively, continue to remain outstanding and no 2015 Warrants remain outstanding.

Original Warrants (including 2015 Warrants exercised during the Subsequent Offer Period) to purchase an aggregate of 4,756,163 shares of common stock were tendered and exercised in the Offer to Amend and Exercise for aggregate net proceeds to us of approximately \$2,632,000. Garden State Securities Inc. assisted the Company as warrant solicitation agents with respect to the 2017 Warrants.

Due to the reduction in exercise price for the Original Warrants issued in connection with the Schedule TO, we determined it was appropriate to record \$876,000 of expense in the consolidated statement of operations for the inducement to exercise the Original Warrants.

#### Prior Year Private Placements

On December 1, 2016, we completed an initial closing (the “Initial Closing”) of a private placement financing (the “Private Placement Offering”) to accredited investors. We raised aggregate gross proceeds of \$1,000,000 from the sale of (i) an aggregate of 1,176,472 shares of the Company’s common stock at a purchase price of \$0.85 per share and (ii) warrants to purchase up to an aggregate of 1,176,472 shares of common stock with a term of five years at an exercise price of \$1.25 per share. We determined the warrants issued in connection with the Initial Closing were equity instruments and did not represent derivative instruments.

On January 23, 2017, we closed on a second and final closing (the “Final Closing”) of the Private Placement Offering. In the Final Closing we raised aggregate gross proceeds of approximately \$337,000 from the sale of (i) an aggregate of 396,469 shares of the Company’s common stock at a purchase price of \$0.85 per share and (ii) warrants to purchase up to an aggregate of 396,469 shares of common stock with a term of five years at an exercise price of \$1.25 per share. The securities issued in the Private Placement Offering were issued pursuant to a securities purchase agreement entered into with the accredited investors. We determined the warrants issued in connection with the Final Closing were equity instruments and did not represent derivative instruments.

We utilized the services of a placement agent for the Private Placement Offering. In connection with the Private Placement Offering, we paid such placement agent an aggregate cash fee of \$128,600 and issued to such placement agent or its designees warrants to purchase 151,294 shares of common stock at an exercise price of \$1.275 per share. The terms of the placement agent warrants are substantially identical to the investor warrants, other than the exercise price and the holders' ability to exercise the placement agent warrants on a cashless basis at its discretion. Additionally, we agreed to pay the placement agent a \$12,000 due diligence fee and to reimburse the placement agent for fees of counsel up to \$35,000.

The net proceeds from the Private Placement Offering was approximately \$1,049,000.

Other Activity

On October 1, 2017, we entered into a two-year service agreement for business development services. In accordance with the agreement we issued 50,000 shares of common stock, with a value of \$51,000. The value was capitalized to prepaid expense and is being amortized over the term of the agreement. During the fiscal year ended July 31, 2018, we recognized \$21,000 of expense related to these services.

On April 13, 2016, we entered into a two-year service agreement for general financial advisory services. In accordance with the agreement we issued 250,000 shares of common stock, with a value of \$290,000. The value was capitalized to prepaid expense and is being amortized over the term of the agreement. For the years ended July 31, 2018 and 2017, we recognized \$101,000 and \$144,000 of expense related to these services, respectively.

Warrants

During the fiscal year ended July 31, 2018, in addition to the 4,756,163 Original Warrants exercised, there were net exercises on 573,057 warrants which resulted in the issuance of 158,342 shares of our common stock. As these warrants were net exercised, as permitted under the respective warrant agreement, we did not receive any cash proceeds. 198,057 of the warrants exercised during the period were issued in connection with the Original Warrants discussed above.

During the fiscal year ended July 31, 2017, we received approximately \$185,000 from the exercise of warrants to purchase 342,116 shares of common stock. 236,116 of the warrants exercised contained derivative features, while 106,000 of the warrants exercised were considered equity instruments. In addition, there was a net exercise on 5,335 warrants which resulted in the issuance of 4,179 shares of our common stock.

A summary of our warrant activity and related data is as follows:

	Shares
Outstanding at July 31, 2016	7,056,426
Issued	1,724,235
Exercised	(347,451 )
Expired/Cancelled	(129,374 )
Outstanding at July 31, 2017	8,303,836
Issued	—
Exercised	(5,329,220)
Expired/Cancelled	(113,520 )
Outstanding at July 31, 2018	2,861,096

The following table summarizes information related to warrants outstanding at July 31, 2018:

Expiration Exercise



Date	Price	Shares
08/29/19	\$ 0.75	2,533,331
12/01/21	\$ 1.25	58,824
12/01/21	\$ 1.28	117,647
01/23/22	\$ 1.25	117,647
01/23/22	\$ 1.28	33,647
		2,861,096

## 8. Share-Based Compensation

### Restricted Stock Units

During the fiscal year ended July 31, 2018, the Compensation Committee of the Board of Directors authorized the issuance of 450,000 Restricted Stock Units (“RSUs”) to newly appointed members of our Board of Directors. RSUs issued to directors vest in two 50% installments on or before our annual meeting of stockholders, typically held in January. In addition, we issued 300,000 performance based RSUs to third-party consultants. We currently do not expect the 300,000 RSUs to vest. Each RSU represents the right to receive one share of common stock, issuable at the time the RSU is delivered and subsequently settles, as set forth in the Restricted Stock Unit Agreement.

During the fiscal year ended July 31, 2017, the Compensation Committee of the Board of Directors authorized the issuance of 1,150,000 RSUs to our officers and directors. RSUs granted to our officers vest over a four year period while RSUs granted to our directors vest in two 50% installments on or before our annual meeting of stockholders, typically held in January.

A summary of our restricted stock unit activity and related data is as follows:

	Shares
Outstanding at July 31, 2016	1,285,000
Granted	1,150,000
Vested	(150,000 )
Forfeited	(250,000 )
Outstanding at July 31, 2017	2,035,000
Granted	750,000
Vested	(375,000 )
Forfeited	(885,000 )
Outstanding at July 31, 2018	1,525,000

Of the 1,525,000 unvested RSUs outstanding at July 31, 2018, we currently expect 1,225,000 to vest. As of July 31, 2018, there was \$960,000 of unrecognized non-cash compensation cost related to RSUs we expect to vest, which will be recognized over a weighted average period of 2.64 years. During the fiscal year ended July 31, 2018, 375,000 RSUs vested, based on service conditions. All of the RSUs that vested during the fiscal year ended July 31, 2018 have not been delivered and remain outstanding, as set forth in the RSU agreements.

During the fiscal year ended July 31, 2017, 150,000 RSUs vested based on service conditions that were satisfied during the period, resulting in the issuance of 150,000 shares of common stock.

For the years ended July 31, 2018 and 2017, share-based compensation expense for RSUs was \$834,000 and \$102,000, respectively.

#### RSU Termination

On December 13, 2016, we entered into an RSU Cancellation Agreement with our officers and directors who received RSUs in October 2013 as compensation for their continued services to us over a required vesting period. Under this

Agreement, our officers and directors agreed to cancel RSUs representing the right to receive an aggregate of 3.9 million vested shares of our common stock. Pursuant to the terms of the cancelled RSUs, we would have been required to settle and deliver these vested shares to the individual officers and directors prior to January 1, 2017, which would have triggered a taxable event. Our officers and directors, in their individual capacities, voluntarily agreed to cancel their respective RSUs based on their determination that cancelling the RSUs would be in the best interests of the Company and our stockholders. The individual officers and directors reached this conclusion for the following reasons:

Conserved our Additional Available Cash Resources. The RSUs held by our officers provide these individuals with the right to require us to pay the applicable state and federal taxes due upon the settlement and delivery of their vested RSU shares in exchange for the individual cancelling and returning to us that number of shares of common stock equal in value to the contractual tax payment obligation. By agreeing to cancel the RSUs, we were not required to utilize our available cash resources to pay the tax payments on behalf of our officers, and as a result, we were able to conserve our cash resources to support the continued implementation of our business plan.

Reduced Pressure on Our Stock Price. The RSUs held by our non-employee directors provide these individuals with the right to immediately sell into the public market that number of shares of common stock sufficient to cover the applicable state and federal taxes payable as a result of the settlement and delivery of their vested RSU shares. Our common stock has a limited daily trading volume, and the sale or the potential sale of a substantial number of shares of common stock by our officers and directors to cover their federal and state tax obligations would have adversely affected the market price of our common stock, which in turn, could have harmed our ability to raise funds to support our operations or require us to raise funds at terms and valuations that would be more dilutive to our existing stockholders.

Each of our officers and directors who are parties to the RSU Cancellation Agreement agreed to cancel their RSUs and the shares of common stock underlying the RSUs in their individual capacities as stockholders and equity award holders, and without any agreement or promise from us or our officers or directors to issue them equity, equity-based awards or cash compensation in the future in exchange for entering into the Agreement.

During the fiscal year ended July 31, 2017, \$87,000 of pre-vest expense was reversed as a result of the RSU cancellation.

#### Stock Issued for Services

During the fiscal year ended July 31, 2018, we issued 190,500 shares of common stock for accrued services valued at \$121,000.

#### Stock Option Plans

##### 2007 Equity Incentive Plan

In February 2016, we amended and restated our 2007 Equity Incentive Plan, the (“2007 Plan”), to, among other changes, increase the number of shares of common stock issuable under the 2007 Plan by 4,000,000 shares and extend the term of the 2007 Plan until February 4, 2026. The 2007 Plan provides for the grant of incentive and non-qualified stock options, as well as other share-based payment awards, to our employees, directors, consultants and advisors. These awards have up to a 10-year contractual life and are subject to various vesting periods, as determined by the Compensation Committee of the Board of Directors. As of July 31, 2018, there were approximately 940,000 shares available for issuance under the 2007 Plan.

##### 2017 Equity Incentive Plan

Approved by our shareholders in January 2018, the 2017 Equity Incentive Plan, the (“2017 Plan”), has a share reserve of 5,000,000 shares of common stock, which were registered under a Form S-8 filed with the SEC in February 2018. The 2017 Plan provides for the grant of incentive and non-qualified stock options, as well as other share-based payment awards, to our employees, directors, consultants and advisors. These awards have up to a 10-year contractual life and

are subject to various vesting periods, as determined by the Compensation Committee of the Board of Directors. As of July 31, 2018, there were approximately 2,815,000 shares available for issuance under the 2017 Plan.

*Stock Option Activity*

During the fiscal year ended July 31, 2018, we issued 2,245,000 stock options at various exercise prices to employees, directors, and consultants. The options vest between one and two years and carry a term between five and ten years.

During the fiscal year ended July 31, 2018, the Compensation Committee of the Board of Directors extended the expiration terms of 740,000 employee options by three years. We accounted for the option modification under ASC Topic 718 and recorded a one-time expense of \$203,000, which was expensed under the share-based compensation line item on the consolidated statements of operations.

During the fiscal year ended July 31, 2017, we issued 3,735,000 stock options at various exercise prices to employees, directors, advisory members and consultants. The options vest between one and four years and carry a term between five and ten years.

A summary of our stock option activity for the fiscal years ended July 31, 2018 and 2017 is as follows:

	Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at July 31, 2016	2,277,968	\$ 1.60	\$—
Granted	3,735,000	\$ 1.05	
Exercised	—	\$ —	
Cancelled	(253,125 )	\$ 1.42	
Outstanding at July 31, 2017	5,759,843	\$ 1.25	\$ 1,120,000
Granted	2,245,000	\$ 0.84	
Exercised	—	\$ —	
Cancelled	(378,750 )	\$ 1.96	
Outstanding at July 31, 2018	7,626,093	\$ 1.09	\$—

The weighted average expected term of options outstanding at July 31, 2018 was 5.47 years.

At July 31, 2018, options to purchase 4,017,343 shares of common stock were exercisable. These options had a weighted-average exercise price of \$1.18, an aggregate intrinsic value of zero, and a weighted average expected term of 4.02 years. The weighted average grant date fair value for options granted during the years ended July 31, 2018 and 2017, was \$0.44 and \$0.67, respectively. The total unrecognized compensation cost related to unvested stock option grants as of July 31, 2018 was approximately \$1,533,000 and the weighted average period over which these grants are expected to vest is 2.43 years.

For the fiscal year ended July 31, 2018 and 2017, share-based compensation expense for stock options was \$1,525,000 and \$968,000 respectively.

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

**For the years ended**

**July 31,**

2018

2017

Edgar Filing: PURE BIOSCIENCE, INC. - Form 10-K

Volatility	71.18	%	81.00	%
Risk-free interest rate	2.32	%	1.70	%
Dividend yield	0.0	%	0.0	%
Expected life	3.69 years		4.66 years	

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

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

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

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

## 9. Related Party Transactions

On June 28, 2018, we raised \$500,000 to support our continued operations by issuing a one-year promissory note to Tom Y. Lee, a member of the Company's Board of Directors and our largest stockholder. The note accrues interest at 6.5% per annum, compounded annually. As of July 31, 2018, \$500,000 of principal and \$3,000 of accrued and unpaid interest remained payable (See Note 12 to these consolidated financial statements).

On December 11, 2013, the Company entered into a five-year strategic collaboration agreement with St. Louis-based Intercon Chemical Company (ICC). The agreement consists of a multi-prong approach to accelerate the commercialization of PURE's unique and proprietary SDC-based products. The strategic collaboration agreement provides:

ICC licenses from PURE its patents and technology know-how for the exclusive manufacture of our SDC-based products.

ICC will invest in plant improvements to allow for expanded SDC production.

ICC's R&D team will collaborate on SDC product line development.

ICC licenses the distribution rights for SDC-based products into its core businesses of institutional cleaning and sanitation products.

ICC will also develop a new initiative focused on US hospital, healthcare and medical facilities.

PURE earns royalty income on SDC-products sold by ICC and its affiliates.

During the years ended July 31, 2018 and 2017, our net product sales to ICC was \$8,000 and \$33,000, respectively. As of July 31, 2018, \$86,000 was payable to ICC for the production of SDC based products with no accounts receivable due to the Company. As of July 31, 2017, \$75,000 was payable to ICC for the production of SDC based products and \$6,000 of accounts receivable was due to the Company.

The president of ICC is a shareholder of the Company.





## 10. Sales Concentration

Net product sales were \$1,774,000 and \$1,831,000 for the years ended July 31, 2018 and 2017, respectively. For the year ended July 31, 2018, three individual customers accounted for 20%, 16% and 11%, of our net product sales, respectively. No other individual customer accounted for 10% or more of our net product sales. For the year ended July 31, 2017, two individual customers accounted for 33% and 19%, of our net product sales, respectively. No other individual customer accounted for 10% or more of our net product sales. For the years ended July 31, 2018 and 2017, all net product sales occurred in the United States.

## 11. Income Taxes

We file federal and state consolidated tax returns with our subsidiaries. Our income tax provision for the years ended July 31, 2018 and 2017 was \$1,650; the minimum state franchise taxes we pay regardless of income or loss.

At July 31, 2018, we had federal and state tax net operating loss carry-forwards of approximately \$105.2 million and \$60.5 million, respectively. At July 31, 2017, we had federal and state tax net operating loss carry-forwards of approximately \$100.3 million and \$74.7 million, respectively. Utilization of the net operating loss carry-forwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code as well as similar state provisions. These ownership changes may limit the amount of net operating loss carry-forwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 of the Internal Revenue Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Since our formation, we have raised capital through the issuance of capital stock on several occasions (both before and after our initial public offering in 1996) which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future upon subsequent disposition. While we do not believe that we have 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 begin expiring in the year ended July 31, 2019 and, unless previously utilized, will completely expire in the year ending July 31, 2038. Our state tax loss carry-forwards began to expire in the year ending July 31, 2029, and will completely expire in the year ending July 31, 2038.

Significant components of our deferred tax assets are as follows:

	July 31,	
	2018	2017
Net operating loss carry-forward	\$26,170,000	\$30,970,000
Stock options and warrants	2,590,000	3,250,000
Other temporary differences	(130,000 )	(140,000 )
Total deferred tax assets	28,630,000	34,080,000
Valuation allowance for deferred tax assets	(28,630,000)	(34,080,000)
Net deferred tax assets	\$—	\$—

F-21

During the year ended July 31, 2018, we had a net decrease in deferred tax assets of \$5,450,000. This change is a result of current year activity as well as a change in the federal tax rates. The change as a result of current year activity is an increase in deferred tax assets of \$7,653,000. This increase was offset by a \$13,103,000 decrease due to a remeasurement of the deferred tax assets based on new tax rates established through the Tax Cuts and Jobs Act passed December 22, 2017. The remeasurement is a provisional estimate under Staff Accounting Bulletin (“SAB”) 118 that could be revised based on any additional guidance issued by the U.S. Treasury Department, the U.S. Internal Revenue Service, and other standard-setting bodies. This new law did not have a significant impact on our consolidated financial statements for the year ended July 31, 2018 because we maintain a valuation allowance on the entirety of our deferred tax assets. However, the reduction of the U.S. federal corporate tax rate from 35% to 21% resulted in a remeasurement of the deferred tax asset reflected in the tax rate reconciliation table below, as well as, the deferred tax assets table listed above.

Given the significant impact of the Tax Cuts and Jobs Act, the SEC staff issued SAB 118 which provides guidance on accounting for uncertainties of the effects of the Tax Act. Specifically, SAB 118 allows companies to record a provisional estimate of the impact of the Tax Act during a one year “measurement period”. We have recognized the provisional tax impact related to the revaluation of deferred tax assets and liabilities and included these amounts in our consolidated financial statements for the year ended July 31, 2018. The ultimate impact may differ from these provisional amounts, due to, among other things, additional analysis, changes in interpretations and assumptions we have made, and additional regulatory guidance that may be issued.

A reconciliation of income taxes computed using the statutory income tax rate, compared to the effective tax rate, is as follows:

	<b>2018</b>		<b>2017</b>
Federal tax benefit at the expected statutory rate	26.4	%	34.0
State income tax, net of federal tax benefit	32.5		0.8
Expired net operating loss carryforwards	(20.0	)	(6.6
Other	(2.9	)	(7.7
Rate change adjustment	(175.4)		—
Change in state tax rates	—		(4.2
Permanent items	—		(3.3
Valuation allowance	139.4		(13.0)
Income tax benefit - effective rate	0.0	%	0.0

Following authoritative guidance, we recognize the tax benefit from a tax position if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position.

Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense; however we have had no accrued interest or penalties at either July 31, 2018 or July 31, 2017. We are subject to income taxes in the United States and in various states, and our historical tax years remain subject to future examination by the U.S. and state tax authorities. During the years ended July 31, 2018 and 2017, we did not record any activity related to our unrecognized tax benefits.

The Company and its subsidiaries are subject to federal income tax as well as income tax of multiple state jurisdictions. With few exceptions, the Company is no longer subject to income tax examination by tax authorities in major jurisdictions for tax years prior to 2012. However, to the extent allowed by law, the taxing authorities may have the right to examine prior periods where net operating losses were generated and carried forward, and make adjustments up to the amount of the carryforwards. The Company is not currently under examination by the IRS or state taxing authorities.

## 12. Subsequent Events

### Private Placement Financing

On August 16, 2018, we completed a closing (the “Closing”) of a private placement financing to accredited investors. We raised approximately \$1.5 million in the Closing and issued an aggregate of 3,333,964 shares of our common stock at a purchase price of \$0.45 per share, including the conversion of approximately \$0.5 million held in the form of a promissory note as of July 31, 2018. The shares issued in the private placement financing were issued pursuant to a securities purchase agreement entered into with the investors. Mr. Tom Y. Lee, a member of the Company’s Board of Directors invested approximately \$1.0 million through his affiliates, including approximately \$0.5 million of cash and the cancellation of existing indebtedness in the amount of approximately \$0.5 million that was held in the form of a promissory note payable as of July 31, 2018.

The net proceeds to us from the Closing (including the cancellation of indebtedness), after deducting fees and other offering expenses, are approximately \$1.49 million. We expect to use the net proceeds for general corporate purposes, including our research and development efforts, and for general administrative expenses and working capital.

The issuance and sale of the Shares was not registered under the Securities Act of 1933, as amended (the “Securities Act”), and these Shares may not be offered or sold in the United States absent registration under or exemption from the Securities Act and any applicable state securities laws. The Shares were issued and sold in reliance upon an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act. The Investors represented to the Company that each was an “accredited investor” within the meaning of Rule 501 of Regulation D under the Securities Act, and that each was receiving the Shares for investment for its own account and without a view to distribute them.



