

# [MisterMicroCap's Instablog](#)

| Write a new Instablog post

- **FDA ACTION AND SUBWAY WIN VALIDATE PURE'S "SDC" AS FRONT-LINE FOOD SAFETY SOLUTION** [[Edit](#) or [Delete](#)][0 comments](#)

Dec 22, 2014 4:05 PM | about stocks: [PURE](#)

## Summary

- The domestic food industry is 2 Trillion Dollars
- The USDA estimates the direct costs of food recalls at between 7 and 37 billion dollars per year.
- A food recall can be catastrophic to food manufacturers.
- The Grocery Manufacturers Association reports insurance is the third or fourth most expensive cost of food manufacturers and it frequently does not pay food recall claims.
- SUBWAY'S adoption of SDC and the FDA's approval to reopen a listeria stricken plant validate SDC as new food safety solution.

PURE Bioscience (OTCQB:[PURE](#)) [announced](#) an important [White Paper](#) released by Dr. James L. Marsden, PhD, a "Distinguished Professor" of Food Safety and Security at Kansas State University. The White Paper details the challenging remediation of a *Listeria* contamination in a food processing facility that forced a leading supplier of Hummus to layoff of all employees and close its plant. It all started when about 15,000 pounds of hummus were voluntarily recalled after the Texas Department of Health discovered *Listeria* in routine testing.

Decontamination of the plant was achieved in cooperation with the FDA and included PURE® Hard Surface and PURE® Hi-Foam and Multi-Purpose Cleaner, both containing the powerful, but safe [SDC](#) antimicrobial.

## SDC Technology

PURE Bioscience's patented technology involves a molecule named silver dihydrogen citrate. The molecule is an electrolytically generated source of stabilized ionic silver. It is colorless, odorless and non-caustic. *"SDC is like a Trojan horse,"* said Hank R. Lambert, PURE's CEO. *"When applied to a surface with pathogens or bacteria like raw food, the bacteria are attracted to the SDC because they view it as a food source. The silver ions then attack the DNA of the bacteria – which renders them incapable of replicating – and then they die."* Interestingly, the bacteria cannot build up a resistance to SDC, unlike ammonia or chlorine - which is used extensively in meat processing plants today.

The plant and equipment had been previously cleaned and sanitized using traditional treatments - however two pieces of processing equipment and a drain were found to still be positive for *Listeria*.

After completion of the remediation treatments that included the application of two PURE products, all 300 post-treatment samples tested negative for *Listeria* as analyzed by independent third party, Deibel Labs.

The successful test results were provided to the FDA and the agency released the equipment and plant for manufacturing of FDA regulated products - allowing the plant to be reopened.

SDC has been tested extensively in labs and on location trials, including in more than 600 SUBWAY® restaurants, and has been shown to be highly [effective](#) against *Listeria*, *Salmonella*, *E.coli*, *Campylobacter*, Norovirus and many more pathogens. The EPA has granted SDC its safest toxicity rating of Category IV, and SDC carries the desirable designation of GRAS, "Generally Recognized As Safe" when used as a surface biocide.

## High Cost of Food Recalls

The plant in the White Paper is not a rare case, and it is not a large case. But it did cause the manufacturer to lay off all its employees and close its doors leaving shareholders with nothing but the proverbial empty bag.

In 2009, the U.S. Agriculture Department's Economic Research Service [estimated](#) total food recall costs alone to be between \$6.6 - \$37.1 billion each year. In addition to the direct expense of a recall, declining sales due to poor consumer confidence, brand rehabilitation expenses and potential shareholder lawsuits may also contribute to long-term losses.

A food recall [study](#) conducted by the Grocery Manufacturers Association and Ernst & Young reported that insurance is the third or fourth most expensive cost of food manufacturers and processors. The study also reported that in spite of the high cost of insurance, it frequently does not pay for food recall claims.

The insurance giant, AON, [reports](#) a list of food recalls responsible for staggering losses sometimes exceeding 50 to 100 million dollars.

One of the more significant and widely publicized events of 2013 involved Rich Products Corporation. A diversified food processor based in New York, Rich's announced a voluntary recall of frozen meals and appetizers linked to an E coli 0121 outbreak in March of 2013. The initial recall of 196,000 pounds was expanded to 10.5 million pounds produced at the company's Georgia facility.

With exposure to very large risks from food recalls, and with insurance premiums priced so high, there is a clear need for a solution that will reduce that risk and insurance premiums. With evidence mounting in SDC's favor, PURE Bioscience may find SDC in fast-growing demand as food manufacturers and processors learn about this new solution.

### **SDC As Hard Surface Disinfectant**

PURE has proven SDC's value in food safety as a contact surface decontaminant and has [announced](#) that 27,000 SUBWAY® Restaurants have all been cleared by their corporate headquarters to buy SDC. With SUBWAY® adopting SDC as their new standard for antimicrobial protection, other QSR's are expected to line up for SDC. This could also lead the way for future sales to build in other high-traffic areas like super markets, hospitals, schools, airports, cruise ships, and hotels where disease-causing pathogens present a very large problem.

### **SDC As A Direct Food Contact Decontamination Solution**

The CDC [estimates](#) that each year roughly 1 in 6 Americans (or 48 million people) get sick from foodborne illnesses, 128,000 are hospitalized, and 3,000 die.

July 14, 2014 PURE [announced](#) it had filed an FCN, Food Contact Notification, with the FDA requesting approval to use SDC on poultry to reduce *Salmonella*. The Company reported an impressive *Salmonella* kill rate with non-detectable levels of the pathogen when combined with industry standard immersion chilling.

The USDA's *Salmonella* Action Plan, a top Department priority, aims to significantly reduce the number of *Salmonella*-related food borne illnesses in the U.S. The USDA initiative drives increased scrutiny to poultry inspection and processing practices. Poultry processors need new, highly effective antimicrobial interventions that can provide a heightened level of control over *Salmonella* that current interventions are not achieving.

Nov 10, 2014, PURE shares suffered a setback when the Company [announced](#) that it had withdrawn the Food Contact Notification it submitted to the FDA for the use of SDC in raw poultry processing. The Company decided to withdraw its FCN, without prejudice, following its receipt of a Deficiency Letter from the FDA stating that the agency has developed new silver-related data (unrelated to SDC) that is currently under review. That data calls into question the long established safety levels of the cumulative dietary intake of silver in the US resulting from the food contact uses the agency had previously approved. As a result, the FDA indicated that it would not approve PURE's FCN until it establishes new safety levels and PURE can demonstrate that it meets the new requirements, if any.

The FDA has not yet publicly released this new data. Going forward, the Company intends to work with the FDA and the food processing industry to collect or develop the additional data and information that may be necessary to address the FDA's current safety concerns. The Company cannot provide an exact timeline of when it will be able to resubmit an FCN for the use of SDC as a direct food contact processing aid for treating raw poultry because the FDA has not established the new standards that it may require going forward.

Timing is uncertain, but it is known that an FCN filing is a relatively short process typically requiring about four months for the FDA to respond. As soon as the safety data for SDC is confirmed, PURE intends to file FCN's for poultry, beef, pork and produce that represent a billion-dollar opportunity for PURE.

In the meantime, PURE is not standing still and has already initiated testing using additional processes and protocols

that the Company believes will demonstrate further reduced residual silver levels.

## Financial and Risk Factors

Revenues for the first fiscal quarter of 2015 were \$117,000, comparable with revenues of \$115,000 for the first fiscal quarter of 2014. Total operating costs and expenses, excluding share-based compensation, other share-based expenses, and restructuring costs, for the first fiscal quarter of 2015 and 2014, were \$1.4 million and \$1.2 million, respectively. The fiscal first quarter 2015 net loss was (\$1.9 million) compared with (\$3.8 million) for fiscal first quarter 2014. Pro forma net loss, adjusted for significant items, for fiscal first quarter 2014 and fiscal first quarter 2013 was (\$1.3 million) and (\$1.1 million), respectively.

Cash and cash equivalents, reported as of October 31, 2014, was \$5.3 million. Total adjusted liabilities, excluding restructuring liabilities, were \$686,000, a net reduction of \$833,000, or 55%, compared with Fiscal Year 2014 adjusted total liabilities of \$1,519,000.

On September 3, 2014, PURE [filed its 8K](#) with the SEC stating it had raised \$7.9 million, from Franchise Brands, LLC owned by the same owner as the owner of SUBWAY®, and from a group of private investors. This cash infusion combined with revenues is expected to provide PURE with adequate cash for the next year allowing the opportunity for revenues to grow. There is the risk that PURE will fail to execute further anticipated sales of SDC, but that seems unlikely with the start they already have with QSR's. PURE shares are selling close to the lows for the past year and with \$5 million in bank, with 27,000 SUBWAY® stores cleared to buy SDC, and with Zack's just [reiterating](#) their "Strong Buy" recommendation and \$3.00 price target in the next 12 months, shares appear to be a bargain.

**Disclosure:** The author has no positions in any stocks mentioned, but may initiate a long position in PURE over the next 72 hours.

Themes: [Food safety](#), [restaurants](#), [food manufacturers](#), [food processors](#) Stocks: [PURE](#)

- Share this Instablog with a colleague

0



### Comments (0)

Be the first to comment

**Instablogs** are Seeking Alpha's free blogging platform customized for finance, with instant set up and exposure to millions of readers interested in the financial markets. [Publish your own instablog](#) in minutes.