Zacks Small-Cap Research

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Pure Bioscience, Inc. (PURE-OTC)

PURE: FCN resubmitted, strong revenue growth is expected in fiscal 2015 and beyond—maintaining Buy rating

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	10/16/2013
Current Price (09/17/15)	$0.71
Twelve- Month Target Price	**$3.00**

OUTLOOK

PURE develops and markets SDC-based antimicrobial products that provide non-toxic solutions to numerous global health challenges. SDC is a novel, patented platform technology with superior efficacy and low toxicity and can be used in diverse markets including food safety, personal care, preservatives, industrials, agriculture and pharmaceuticals.

After recent massive management change, PURE is refocusing on the food safety industry. We expect growth will accelerate in fiscal 2015 and beyond. We maintain Buy rating for PURE shares.

SUMMARY DATA

52-Week High	**$1.18**
52-Week Low	**$0.45**
One-Year Return (%)	**-30.39**
Beta	**0.07**
Average Daily Volume (sh)	**26,846**
Shares Outstanding (mil)	**41**
Market Capitalization ($mil)	**$29**
Short Interest Ratio (days)	**3.92**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**36.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Products**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2014	0.12 A	0.04 A	0.26 A	0.13 A	0.55 A
2015	0.12 A	0.27 A	0.11 A	0.30 E	0.80 E
2016					3.50 E
2017					12.50 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2014	-$0.06 A	-$0.03 A	-$0.07 A	-$0.09 A	-$0.26 A
2015	-$0.05 A	-$0.04 A	-$0.05 A	-$0.04 E	-$0.18 E
2016					-$0.10 E
					-$0.01 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

PURE Resubmit FCN to FDA for SDC Use in Raw Poultry Processing and Produce Processing

In September and June 2015, PURE resubmitted a Food Contact Notification (FCN) to the US FDA for Silver Dihydrogen Citrate (SDC) as an online reprocessing (OLR) antimicrobial for raw poultry processing and produce processing respectively.

Background Information

In Nov 2014, PURE withdrew the FCN it submitted to the FDA in July 2014 for the use of SDC in **raw poultry processing** and in January 2015, the company withdrew its FCN to the FDA for **produce processing.**

The withdrawal is based on a deficiency letter the company received from the FDA stating that the agency has developed new data 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 absent new data or additional information that adequately addresses its new toxicity concerns.

New Development

PURE has been discussing with the FDA after the withdrawal regarding PURE's new test data. The Company's resubmission follows constructive discussions with the FDA regarding results of new SDC testing:

- Demonstrating materially significant reduction in Salmonella contamination in poultry,
- Demonstrating materially significant reductions in Salmonella, Listeria and E. coli in produce;
- While achieving silver residue levels that are approaching non-detectable; and
- Below existing FDA guidelines.

The company believes that its FCN resubmission has adequately addressed the FDA's prior issues regarding the FCN based on the positive results from the new SDC testing. This builds upon prior SDC test results indicating the ability to reduce Salmonella below detectable levels.

Huge Market Opportunity for SDC as a Food Contact Processing Aid

Food contamination, especially by Salmonella, is a global health issue. Salmonella is responsible for an estimated 1.2 million food borne illnesses each year. In testing, the USDA has found that at least 25% of chicken parts in the food supply chain were contaminated with Salmonella.

In order to address the issue, the USDA has initiated a Salmonella Action Plan, which is the top Department priority, aiming to significantly reduce the number of Salmonella-related food borne illnesses in the US. This USDA initiative drives increased scrutiny to poultry inspection and processing practices.

Processing aids or interventions commonly used in the US food industry today are highly toxic chemistries. In addition, pathogens can become increasingly resistant and render current interventions less efficacious. As a result, poultry processors need new, highly effective antimicrobial interventions that can provide a heightened level of control over Salmonella that current interventions are not achieving. The demonstrated ability of SDC to reduce Salmonella to levels below the detection limit (when applied during the on-line reprocessing of raw poultry products) has the potential to play an important role in the solution.

Produce is also a leading source of foodborne illness in the US. The Centers for Disease Control and Prevention (CDC) estimates that produce was responsible for 46% of foodborne illnesses and 23% of foodborne illness-related deaths in the US between 1998 and 2008. Leafy greens were identified as the primary source of foodborne illness.

We believe that SDC is a significant improvement over current processing chemicals and provides important advantages because SDC does not induce bacterial resistance and is:

- More effective in reducing or eliminating pathogens
- Easier to handle and dilute
- Non-corrosive to processing equipment
- Non-toxic - does not create noxious fumes

If approved for food contact processing aid, SDC will have the opportunity to target the $1+ billion dollar market and command a big chunk of the market share based on its superior efficacy and safety.

The initial customers for SDC will be big players in the food processing market including Tyson, Pilgrim's Pride, Perdue, Foster Farms, Wayne Farms, Koch Foods, Taylor Farms, Ready Pac, Dole, Fresh Express, and F and S Produce.

Given the immediate market need and the proven superior efficacy of SDC against Salmonella, we believe that SDC can achieve significant market penetration upon receipt of FDA and USDA approvals.

The Approval Process

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

On Sept. 17, 2015, PURE announced that it has received an Acknowledgement Letter from the US FDA stating that its FCN for SDC as a raw poultry processing aid is complete and setting an effective date of December 2015 (after PURE submitted additional information to support its FCN).

The next step in the regulatory approval process is to obtain USDA approval. With the receipt of the FDA's Acknowledgement Letter, PURE is now eligible to initiate this next step. Accordingly, after its receipt of the Acknowledgement Letter from the FDA, PURE immediately submitted its FCN to the Food Safety and Inspection Service of the USDA to commence the USDA review and approval process. As part of the USDA process, PURE is preparing to conduct in-plant process validation and optimization trials with the authorization of the USDA. At the completion of the trials, PURE expects the USDA to issue a "Letter of No Objection" and list SDC as an approved on line reprocessing poultry processing aid.

PURE is targeting the launch of SDC as a poultry processing aid in the **first quarter of 2016.**

PURE Exited Fiscal Third Quarter With a Strong Balance Sheet

On June 11, PURE reported financial results for fiscal third quarter ended April 30, 2015.

Revenues for the fiscal 3Q15 were $109,000 compared with $261,000 for fiscal 3Q14, a decline of 58%. This was mainly due to uneven orders (a few times a year) by some customers.

But we are pleased to see that the revenue mix attributable to food safety solutions increased over prior fiscal quarters to approximately 50% of total revenues in fiscal Q3 2015, a sequential increase from less than 10% of total revenues from fiscal 2Q15.

Total operating costs and expenses, excluding cost of goods sold, share-based compensation, other share-based expenses, and restructuring costs, for the fiscal 3Q15 and 3Q14, were $1.4 million and $1.6 million, respectively.

Net loss for fiscal 3Q15 was $2.1 million ($0.05 per share) compared with $2.1 million ($0.07 per share) for fiscal 3Q14.

Adjusted net loss for fiscal 3Q15 and fiscal 3Q14 was $1.3 million and $1.3 million, respectively.

PURE exited the fiscal third quarter with a relatively strong balance sheet. As of April 30, 2015, cash and cash equivalents was $2.5 million. There was no long-term debt sitting on the balance sheet.

Management has been working diligently to strengthen PURE's balance sheet since they took office. Specific measures included raising new funds and reducing non-core operating activities.

By reducing its non-core operating activities, PURE should be able to reduce its burn rate significantly in the next few quarters.

Update on Business Development and Operations

PURE continues to make progress in **three business segments**.

Food Processors/Manufacturers

The company is actively evaluating and/or testing in more than 35 companies (up from 20+ last quarter), and is initiating discussions with other established distributors in this market.

PURE is diversifying its revenue in this channel with over a dozen national customers (poultry, meats, produce, bakery, pet food, tortillas). The company's distributors are also actively expanding adoption in their established customer base of more than 600 food processing plants.

Restaurants

PURE continues to build market reach into quick service restaurants (QSRs) and casual dining restaurant chains.

Hard Surface has been validated by SUBWAY® Restaurants, and the product has recently been approved for use in SUBWAY®'s nearly 27,000 franchised stores in the US. PURE continues to extend the launch of phased U.S. national sales rollout with SUBWAY®Restaurants.

So far, 15 total new distribution points gained in the SUBWAY® network, providing initial market reach into 4,900 stores, or 17% of SUBWAY's® U.S. system. PURE also gained commitments from major California and Mid-Atlantic markets to bring PURE into their distribution network, representing potential for an additional market reach of 2,200 stores (8% of system).

In addition to Subway, PURE is expanding its reach into other quick service restaurants (QSRs) and casual dining restaurants.

PURE is now conducting late phase testing with two casual dining restaurant chains, each managing more than 1,600 restaurants.

Evaluation with additional casual dining and QSR chains is on-going.

Cruise Lines

PURE and Intercon Chemical Company, the exclusively licensed manufacturer of SDC-based products, continue to collaborate on Intercon's direct sales initiative for the commercial adoption of PURE Hard Surface disinfectant in the cruise line industry.

Intercon has shipped PURE Hard Surface disinfectant into a major international cruise line for on-ship pilot commercial testing for its U.S.-based fleet. Intercon intends to commence on-ship testing of PURE Hard Surface disinfectant with two additional cruise lines during calendar 2015.

This new business segment is an important technology validation of SDC. Also, PURE could derive modest **royalty income** from sales made by Intercon to the cruise line industry.

We Expect Strong Revenue Growth in Fiscal 2015 and Beyond

PURE is now active in three market segments -- Restaurants (testing and sales), food manufacturing/processing (testing and sales), and cruise lines (testing). Management has set the calendar 2015 goals:

- Secure customer adoption in food safety with 2+ national restaurant chains and 10+ national food processors;
- Leverage outsourcing of operations and supply chain;
- Subject to updated feedback from the FDA, secure FDA and USDA authorization for use of SDC as a direct food contact/processing aid for poultry, produce, beef and pork; and
- Continue to out-license PURE distribution and SDC applications to non-core markets.

Based on the Company's current marketing plan and recent developments, **we expect** that strong revenue growth will be achieved in calendar 2015 and beyond.

We remind investors that PURE recently completed the restructuring, and is reborn as a new company with refocused strategy on food safety. We think the new management team has built significant momentum on its refocused business strategy to commercialize its SDC-based technology as a **food safety solution**.

During the second half of fiscal 2014, the new management team generated significant momentum in advancing its business strategy to commercialize its SDC-based technology as a food safety solution. PURE extended commercial market test launch of PURE® Hard Surface Disinfectant to over 650 Subway stores and is selling this product in all of its 27,000 stores. Customer feedback on both SDC product performance and ease of use are very positive. The phased U.S. national rollout is under way.

With new management and new strategy, we believe revenue will grow significantly in fiscal 2015 and beyond. Specifically, we estimate total revenue for fiscal 2015 will reach $0.8 million, representing an increase of 45% over fiscal 2014. The Company will become profitable in fiscal 2018 based on total revenue of $22.5 million according to our financial model. Earnings per share will reach $0.24 by fiscal 2020 based on revenue of $38.5 million.

We Maintain Our Buy Rating on PURE Shares

We maintain our Buy rating on PURE shares and reiterate our 12-month price target of $3.00 per share.

Our call is based on the recent progress the company has achieved and positive developments within the company as well as the attractive valuation.

PURE is a technology-based bioscience company that provides solutions to numerous global health challenges. PURE's proprietary high efficacy/low toxicity **SDC-based antimicrobials** represent innovative advances in diverse markets and lead today's global trend toward industry and consumer use of **"green" products**. Patented SDC is an electrolytically generated source of stabilized ionic silver, which formulates well with other compounds. As a platform technology, SDC is distinguished from competitors in the marketplace because of its **superior efficacy**, **reduced toxicity** and the **inability of bacteria to form a resistance** to it.

PURE's SDC is the first new disinfectant registered with EPA in over 30 years. SDC's competitive advantages in efficacy and safety make it outstanding among its competitors and represent a **paradigm shift** in the disinfectant/sanitizer market place.

Another key feature of SDC is that SDC-based products have broad applicability in diverse markets. The Company's current focus is to expand distribution of currently approved **disinfectant/sanitizer** products to consumers in the **food safety industry**.

Recent corporate governance change led to a new management, which is experienced, disciplined and results—oriented. New board will play key incremental role providing strategic insight to accelerate near term market penetration.

In terms of valuation, currently, the Company trades around $0.70 per share with a market cap of $30 million based on 41 million shares outstanding. We think this is a deep discount based on the company's fundamentals. According to our model, revenue will grow at 117% CAGR in the next fiscal 5 years. PURE will become profitable in fiscal 2018 with an EPS of 0.10 based on total revenue of $22.5 million. EPS will grow to $0.24 per share in fiscal 2020 based on total revenue of $38.5 million. With this in mind, we think PURE shares should be traded at a P/E ratio of 30 x. Applying this P/E multiple with our estimated EPS of $0.24 per share in fiscal 2020, discounted at 20% for 5 years, we come up with a target price of $3.00. This values PURE at $120 million in market cap, which we think is still conservative.

But keep in mind the risks. Although its lead product PURE Hard Surface is increasingly gaining recognition, sales may take longer time to gain traction since PURE is still in its early stage of commercialization of its SDC technology. Sales so far have not been impressive. SDC technology is quite new to most customers in the disinfectant market, and the costs for SDC are also higher than those for most existing technologies. Therefore, rollout of the SDC platform will take time.

Cash burn is another concern. Current cash will only provide funding for the next 12 months and the Company may need to tap the capital market again. Equity financing will dilute existing shareholder base. A financing deal with a strategic partner should be positive to the Company's long term growth.

PROJECTED INCOME STATEMENT

	2014A (Jul)					2015E (Jul)					2016 (Jul)	2017 (Jul)	2018 (Jul)	2019 (Jul)	2020 (Jul)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3A	Q4E	FYE	FYE	FYE	FYE	FYE	FYE
Total Revenues	**$0.12**	**$0.04**	**$0.26**	**$0.13**	**$0.55**	**$0.12**	**$0.27**	**$0.11**	**$0.30**	**$0.80**	**$3.50**	**$12.50**	**$22.50**	**$30.00**	**$38.50**
YOY Growth	*4.5%*	*-84.4%*	*1.2%*	*-29.6%*	*-32.9%*	*1.7%*	*565.9%*	*-58.2%*	*125.6%*	*45.3%*	*338.0%*	*257.1%*	*80.0%*	*33.3%*	*28.3%*
CoGS	0.04	0.02	0.09	0.20	0.34	0.05	0.11	0.07	0.09	0.24	0.70	2.50	4.50	6.00	7.70
Gross Income	**$0.08**	**$0.02**	**$0.17**	**($0.07)**	**$0.21**	**$0.07**	**$0.16**	**$0.04**	**$0.21**	**$0.56**	**$2.80**	**$10.00**	**$18.00**	**$24.00**	**$30.80**
Gross Margin	*68.7%*	*51.2%*	*65.9%*	*-49.6%*	*37.5%*	*61.5%*	*59.3%*	*40.4%*	*70.0%*	*70.0%*	*80.0%*	*80.0%*	*80.0%*	*80.0%*	*80.0%*
R&D	$0.23	$0.29	$0.25	$0.26	$1.03	$0.18	$0.22	$0.17	$0.20	$0.76	$1.00	$1.20	$1.30	$1.45	$1.50
% R&D	*203.5%*	*704.9%*	*95.0%*	*196.2%*	*187.6%*	*150.4%*	*78.8%*	*156.9%*	*66.7%*	*95.4%*	*28.6%*	*9.6%*	*5.8%*	*4.8%*	*3.9%*
SG&A	$0.99	$1.24	$1.34	$1.48	$5.06	$1.19	$1.20	$1.21	$1.22	$4.82	$6.50	$9.50	$11.00	$12.50	$13.50
% SG&A	*863.5%*	*3031.7%*	*512.6%*	*1114.3%*	*919.3%*	*1018.8%*	*439.9%*	*1107.3%*	*406.7%*	*603.3%*	*185.7%*	*76.0%*	*48.9%*	*41.7%*	*35.1%*
Other	$2.68	$1.71	$0.77	$0.86	$6.02	$0.63	$0.48	$0.77	$0.50	$2.38	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($3.8)**	**($3.2)**	**($2.2)**	**($2.7)**	**($11.9)**	**($1.9)**	**($1.7)**	**($2.1)**	**($1.7)**	**($7.4)**	**($4.7)**	**($0.7)**	**$5.7**	**$10.1**	**$15.8**
Operating Margin	-	-	-	-	-	-	-	-	-	-	*-134.3%*	*-5.6%*	*25.3%*	*33.5%*	*41.0%*
Other Net	($0.0)	$0.7	$0.1	($0.0)	$0.9	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($3.8)**	**($2.5)**	**($2.0)**	**($2.7)**	**($11.1)**	**($1.9)**	**($1.7)**	**($2.1)**	**($1.7)**	**($7.4)**	**($4.7)**	**($0.7)**	**$5.7**	**$10.1**	**$15.8**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($3.8)**	**($2.5)**	**($2.0)**	**($2.7)**	**($11.1)**	**($1.9)**	**($1.7)**	**($2.1)**	**($1.7)**	**($7.4)**	**($4.7)**	**($0.7)**	**$5.7**	**$10.1**	**$15.8**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*-85.1%*	*-914.3%*	*76.3%*	*57.2%*
Net Margin	-	-	-	-	-	-	-	-	-	-	*-134.3%*	*-5.6%*	*25.3%*	*33.5%*	*41.0%*
Shares Out	*20.7*	*25.0*	*27.9*	*28.9*	*25.6*	*37.0*	*39.9*	*40.8*	*42.5*	*40.1*	*45.0*	*50.0*	*55.0*	*60.0*	*65.0*
Reported EPS	**($0.19)**	**($0.10)**	**($0.07)**	**($0.09)**	**($0.43)**	**($0.05)**	**($0.04)**	**($0.05)**	**($0.04)**	**($0.18)**	**($0.10)**	**($0.01)**	**$0.10**	**$0.17**	**$0.24**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	*-840.3%*	*61.6%*	*45.1%*
One time charge	*$2.68*	*$1.71*	*$0.00*	*$0.00*	*$4.39*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($1.2)**	**($0.8)**	**($2.0)**	**($2.7)**	**($6.7)**	**($1.9)**	**($1.7)**	**($2.1)**	**($1.7)**	**($7.4)**	**($4.7)**	**($0.7)**	**$5.7**	**$10.1**	**$15.8**
Non GAAP EPS	**($0.06)**	**($0.03)**	**($0.07)**	**($0.09)**	**($0.26)**	**($0.05)**	**($0.04)**	**($0.05)**	**($0.04)**	**($0.18)**	**($0.10)**	**($0.01)**	**$0.10**	**$0.17**	**$0.24**

Source: Company filing and Zacks estimates

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 15.8%, Hold/Neutral- 78.3%, Sell/Underperform – 5.7%. Data is as of midnight on the business day immediately prior to this publication.