



## Producing and Selling Premium Biosciences Products



**Kevin D. Kuykendall- CEO**

Vivione Biosciences, Inc., (TSXV: VBI) formerly PACEPartners, Inc., is a TSX Venture Exchange listed biosciences company focused on the commercialization of its proprietary RAPID-B system, developed in collaboration with the Food and Drug Administration's National Center for Toxicological Research (NCTR).

RAPID-B is an integrated system of hardware, software and chemical reagents that quickly (15 minutes to 7 hours) and accurately identify, quantify and qualify bacteria and other pathogens in key food & water safety, clinical, industrial and oil & gas environments.

**Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine**

**CEOCFO: Mr. Kuykendall, what is the concept for Vivione Biosciences?**

**Mr. Kuykendall:** We are currently positioned to produce and sell premium biosciences products in key markets. Our core product is our RAPID-B diagnostic system aimed at key food safety, industrial and clinical microbiology segments.

**CEOCFO: What are you doing?**

**Mr. Kuykendall:** We are in the midst of the rollout of our RAPID-B diagnostic product and are very excited about it. This system is composed of hardware, software and wetware that can identify bacteria in food as well as in industrial and clinical applications. Today, depending on the application, it can often take several hours to several days to get results, sometimes with limitations and mixed results. However, we can get highly accurate results in a fraction of that time, anywhere from 15 minutes to seven hours. What really differentiates us is the quality level of the testing we can deliver in that short amount of time.

**CEOCFO: What is wetware?**

**Mr. Kuykendall:** The term 'Wetware' refers to our chemical reagent kits; it is the testing kits themselves. These reagents are really quite special; they are designed to specifically target only the bacteria (i.e. *E. coli* O157, STEC's, and *Salmonella*) we are interested in; **and** they can further tell us whether each individual bacteria is alive or dead.

**CEOCFO: What have you figured out to allow the rapid testing?**

**Mr. Kuykendall:** We use a flow cytometer, an instrument that utilizes a laser to analyze a sample, optically 'illuminating' every particle in a liquid sample. The resulting signal from each individual microscopic particle is then viewed in real time for a multitude of characteristics. Using our flow cytometer, we are able to see the size, shape and reflective index that, when coupled with specific targeting reagents like antibodies, allows us to pick out a specific bacteria amidst a multitude of debris (including other cells and bacteria) in the sample. By examining a multitude of characteristics for each cell, we can confidently identify individual bacteria cells in the sample. The RAPID-B system allows us to see a single cell of bacteria, and this sensitivity enables tremendous time savings when compared with competing systems looking for the signal from a multitude of bacteria. Our system simply needs enough bacteria within the analyzed sample volume to render results. Typically, we will still do some level of 'grow out' of bacteria within a sample to give greater confidence in results and to make sure the bacteria are indeed viable, but this is significantly less than other systems; thus allowing us to garner results in a much shorter timeframe.

**CEOCFO: Are there competing technologies or equipment, now?**

**Mr. Kuykendall:** Not at this point in the flow cytometry and RAPID-B-like systems. There are other rapid technologies, but again these either take longer to achieve results and/or cannot provide the accuracy of our system. We are the only ones today, to my knowledge, with this capability and we have comprehensive knowledge of the existing competitive landscape.

**CEOCFO: *Is your system being utilized today?***

**Mr. Kuykendall:** We teamed with the FDA seven years ago and in April 2013, the company went public on the Toronto Stock Exchange, and we are currently in the commercialization process. We officially launched last year and expect revenue and contracts in the second quarter of this year. We anticipate obtaining our AOAC and FSIS certifications in the second quarter of this year for our first *E. coli* O157 our non-O157 STEC applications, which are relevant within the beef market.

**CEOCFO: *What are the challenges in getting a new technology accepted?***

**Mr. Kuykendall:** Specifically food and some industrial users have been performing their diagnostic tests for over 40 years utilizing culture plate technology. Many of these users have an embedded capital cost and the “If it isn’t broken, why fix it?” mentality, even if there are better solutions available. However, I think what we are starting to see in the discussions and demonstrations to large corporations is we currently have several things in our favor. With all the recent food recalls and the Food Safety Modernization Act, there is a regulatory perspective that is pushing companies to be more proactive during processing of food products rather than testing the product at the end of the value chain. The public nature of recalls, I believe, will continue to reinforce the need for further change. From a bottom up perspective, many of the big-box stores such as Costco and Walmart are pushing back on the producers. Their position is that recalls are producer’s issue and therefore require the producers to increase diagnostics and test **before** the product is shipped to the retailer. There is a unique little squeeze play going on, one that will eventually incite change...and the public will be the beneficiary.

Additionally, I do believe that for the first time, the food industry is also poised to realize significant cost reductions via real time diagnostic capability. The normal manufacturing cycle consists of two shifts for production and then one shift down to clean. Once cleaned, producers swab their machines for testing and 24 to 48 hours later, they receive the results. Meanwhile, the production cycle has restarted prior to receiving any results, thus creating a potential two to three day “waste” of production if the results show high bacteria counts. There are countless examples of mass amounts of inventory destruction due to the testing delay, damage to a company’s brand, and/or at times, irreparable harm to the public. I think Vivione is a large part of this compelling paradigm shift. Companies can now start using the diagnostic data almost immediately to make changes, whether it is in their antimicrobials, lines, inventory hold times, and/or product release times. The RAPID B system provides them the capability to use data as a strategic advantage instead of a measurement of previous problems.

**“We are an early stage company with a tremendous amount of validity – seven years in development with the FDA, patents, licenses and a solid articulated strategy on how to address the marketplace.” - Kevin D. Kuykendall**

**CEOCFO: *One might say that given the number of recalls, the system is broken!***

**Mr. Kuykendall:** It definitely is. The North American food manufacturers do a phenomenal job in cleaning and testing products; however, many of the current processes and procedures use many antimicrobials resulting in increased costs. Some of the larger Fortune 100 companies spend seven figures on microbial costs. If someone could offer a tool that decreases the amount and cost of antimicrobials as well as increases the efficiencies and economies of scale of the machines, THEN you can see the “repair” needed to the current broken system.

When I talk about Vivione with various CEOs and CFOs, I never talk about the technology. Instead, I tell them, “Let me explain what I think you can get from this system and how you can reduce the cost of antimicrobials”. If a CEO/CFO currently spends \$60 million to \$70 million dollars a year on antimicrobials, and implementation of the Vivione system saves two to three percent on those costs, all parties will be satisfied—particularly knowing that food manufacturers work off single-digit margins. In addition to the cost savings by using Vivione’s system, inventory control is another area of potential improvement. Many companies have to wait two to three days to release product due to the risk of recall from bacteria. However, if our RAPID B system can deliver results in hours versus days, many companies will be able to turn inventory much faster resulting in less storage requirements and costs. When I talk to these executives, it is mainly about the economic benefits of our system and how we help mitigate the risk of product recalls.

**CEOCFO: *Are there regulatory bodies or insurance companies that should be mandating or strongly suggesting the use of your system?***

**Mr. Kuykendall:** Most regulatory bodies do not mandate technology but rather set standards that may only be achievable by using a specific manufacturer’s equipment. Vivione feels confident in our system versus our competitors. Having said that, I think the regulatory bodies and the new Food Safety Modernization Act is good step for creating guidance and rules that enhance food safety. The FDA and USDA have done a good job talking with industry producers about their current processes and about emerging technologies; however, remain cautious to not get ahead of the technologies and create a regulatory environment that no one can meet from a technology standpoint. We think our technology is well positioned for the enactment of the Food Safety Modernization Act - FSMA.

**CEOCFO: *What are your plans globally?***

**Mr. Kuykendall:** Our focus right now is getting our United States food certifications – specifically AOAC. Once achieved, we plan to deploy our equipment into Canada and Europe through the MFLP and AFNOR certification programs. By 2015, Vivione hopes to have a large footprint in the food sector in North America as well as Europe. Additionally, at the end of the second quarter of 2014, we are introducing a new diagnostic capability, which will apply to industrial applications.

More specifically, we will be introducing pharmaceutical sterility tests, and testing capabilities in the oil and gas sector; specifically identifying bacteria (known as SRBs or sulfate reducing bacteria) that, if left untreated, can “gum up” a well causing significant pipe damage. Today, the technologies to correctly identify and quantify these bacteria are very inadequate; thus, forcing many operators to use high quantities of expensive and environmentally damaging biocides in order to protect operations.

Due to our ability to see a single cell, we are moving into the development of new clinical applications, which will quickly identify Staphylococcus in a hospital or clinical environments. We have completed the proof-of concept phase in several new tests recently conducted. In addition, Vivione has an active tuberculosis test that produces results in less than 30 minutes and we have signed a cooperative research and development agreement with the FDA to develop a test for prion, the causative agent for mad cow disease. Today, human diagnosis is rendered post-mortem by looking at the brain tissue and furthermore, the diagnosis of animals thought to be carrying the disease is done via the sacrifice of entire herds. Due to this, there is a critical need to have a diagnostic tool for the identification of disease in live animals as well as the applicability of such a test to the management of the blood supply, transplant organs etc. We feel confident that we will be able to offer a RAPID-B prion test within the next year.

Vivione is also looking at clinical applications whereby we will revolutionize rapid microbiology by brining bacterial quantification to a very sensitive system. We believe there are significant opportunities in the lower respiratory infection and sepsis disease areas and working on a novel approach to rapid drug-susceptibility testing to aid therapy in infectious disease.

The key message here is that Vivione is translating knowledge gained in food safety to other applications. We are able to use the same instruments and software, with different reagents to offer tests for other relevant pathogens across the breadth of the food, industrial and clinical market spaces. I tell everybody this is a razor/razor blade like approach. We really just need one razor, and then will provide different razor blades depending on the application, whether it is food, industrial or clinical. This will allow Vivione to leverage our equipment and really focus on the development of the reagent kits; not developing multiple platforms of equipment. This is a key difference between our platform and platforms offered by other companies.

**CEOCFO: *Do you have your staff ramped up for the commercialization? Would you be adding to the team?***

**Mr. Kuykendall:** Yes, on both accounts. We recently announced we have now hired a new chief science officer who has 20 years’ experience in the food business and in food certification as well as a new chief medical officer who has years of experience in developing agents and equipment in the clinical side. With these two key hires, we are beginning to fill out the commercialization team. This year, we will add three or four more lab associates to increase our internal testing and development. We will couple that with collaboration agreements in the first half of this year alongside some very large international organizations who will act as our third party developers and help us on our certification programs.

**CEOCFO: *Do you have funds in place for the next steps?***

**Mr. Kuykendall:** Yes. As I said earlier, we took the company public last year, so we are well funded to execute our business plan.

**CEOCFO: *What have you learned in your past ventures with early stage and startup companies that has been most helpful as Vivione is developing and what do you draw on as you go forward?***

**Mr. Kuykendall:** I have learned three things over the years. One is that your product must provide an advantage to the consumer, whether that is economic or technological. The product must be fully developed and relative to the consumer. With the RAPID B system, we have done an excellent job articulating its advantages to our consumer. Second, the key to successful companies relies heavily on the core team. Vivione has a strong position, having assembled very high-powered, qualified individuals, with over 100 years of combined experience in food, clinical as well as startup companies. Third, adequate funding is crucial to executing the plan. Living hand-to-mouth does not allow you to build the company and execute any type of strategy. I think taking the company public not only gave us the needed funds available for us to build this properly, but it gave us a mechanism to raise the next round of funding when we need it. From a liquidity standpoint, it is a very good tool to raise your next round of money.

**CEOCFO: Put it all together for our readers. Why Vivione?**

**Mr. Kuykendall:** Right now, we are relevant. When you consider these food recalls, Vivione is a very good company if you are a producer. We also feel the technology's applications in rapid clinical (specifically infectious disease) testing has game-changing potential in helping physicians address the growing, and very concerning antibiotic resistant issues. If you are an investor, we are an early stage company with a tremendous amount of validity – seven years in development with the FDA, patents, licenses and a solid, articulated strategy on how to address the marketplace. The food, industrial and clinical industries are multi-billion dollar diagnostics markets and there is an enormous opportunity for Vivione in this environment and we are ready to play a major role over the coming years. In short, there is nothing like Vivione in the marketplace today.

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**BIO:** Mr. Kuykendall has served as a director and CEO of Vivione since November 2011. Mr. Kuykendall was a founding member and CEO of both Health2o Products, LLC (2008-2013) and White Energy, LLC (2005-2008). Over the past 10 years, Mr. Kuykendall has raised and/or participated in raising early stage funding for various ventures. At White Energy, Mr. Kuykendall was instrumental in raising \$490 million dollars in funding; creating an ethanol operation that was the fourth largest producer in the world. At Health2o, Mr. Kuykendall's fundraising experience helped to create and operate a company in the nutraceutical beverage industry. Health2o launched its first product in late 2009 and its new-patented formula underwent double blind human clinical studies. Prior to 2005, Mr. Kuykendall spent 17 years in the telecommunications business where he worked for MCI Communications and later owned his own telephone company in Africa. Mr. Kuykendall played professional baseball for the Cleveland Indians after graduating from Western Oregon University, Monmouth Oregon in 1986 with a Bachelor of Science in Business Administration.

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