

Bringing to market Diagnostic Technology that Detects the Presence of Harmful Pathogens in the Food Supply, Invisible Sentinel is addressing the World's Food Safety Challenges and well positioned to be a Game Changer with their First-in-Class Veriflow Technology

**Life Science
Food Safety**

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**Benjamin Pascal
CEO**

BIO:

Benjamin Pascal co-founded Invisible Sentinel in late 2006, and has worked diligently to increase value; advancing the Company's interests both domestically and abroad. As CEO, Mr. Pascal draws from first-hand experience in the successful development and launch of new clinical devices in the medical device industry, including the coordination of a multi-disciplinary

team for the development of B. Braun Medical's first antimicrobial medical device—for which he was listed as an inventor on a corresponding patent. He was recruited by B. Braun to take part in the company's Rotational Development Program. As the first American selected, he was nominated to submit for the Global Innovator of the Year from a field of more than 20,000 employees. Previously, Mr. Pascal gained experience at the National Institute for Medical Research in London where he participated in designing a functional cellular vaccine against malaria. He has been on market launch teams and has manufacturing and validation experience with bio-products not unlike Invisible Sentinel's technology. Mr. Pascal graduated with honors from The George Washington University with concentrations in Biology and Political Science and completed his MBA at Lehigh University.

About Invisible Sentinel:

Invisible Sentinel is a leading-edge rapid diagnostics company innovating next generation technologies to address the world's food safety challenges.

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

CEOCFO: Mr. Pascal, what is Invisible Sentinel?

Mr. Pascal: Invisible Sentinel is a diagnostics company that my partner Nick Siciliano and I founded in 2006. We manufacture a first-in-class regulatory approved diagnostic technology

that detects the presence of harmful pathogens in the food supply including Salmonella, E.coli, Campylobacter, and Listeria. Our technology represents an ultra-sensitive new class of technology that allows food processors, farmers and third-party labs to test the food that they are sending out before it hits the consumer tables.

CEOCFO: What is being used today and what is it that you have figured out that is different and better?

Mr. Pascal: There is a major push in the food industry to move towards molecular detection or being able to detect genes that are indicative of contamination or toxins in the food supply. The major technology that is out there today is something known as RT-PCR and it is a very sensitive device but it is also very expensive, requires a skilled scientist, requires multiple sample processing steps, and often provides results that are difficult to interpret. Our development team built a completely new class of diagnostic that allows for molecular detection but in the context of what we call a flow-based immunoassay, similar to a pregnancy test in terms of the read-out: One or two lines, but now those lines are genes that are indicative of contamination.

CEOCFO: What is measured and how are you able to measure it?

Mr. Pascal: The sampling requirements determined by government agencies including the USDA play a role in plans to reduce pathogens. For example, in the poultry market whole chickens are sampled. The chickens are rinsed in a media and that liquid is

sampled and applied onto our test. If a pathogen of interest is present, two lines can be viewed on the test. One control line, and one test line indicating a positive hit for the selected adulterant.

CEO CFO: Where are you in the process?

Mr. Pascal: We just received our regulatory approval on our Veriflow Technology in October. We fitted out our manufacturing facilities over the course of 2012 and are pursuing ISO 13485 certification on the operation. We are bringing on sales and marketing staff. Additionally, we have put agreements in place with our initial beta sites, which will begin using our technology, so the technology is going out now and will be in the hands of poultry processors in Georgia, third-party testing labs in the Chicago area and other large meat processors across the United States.

CEO CFO: Are the people that should know about you aware?

Mr. Pascal: We have done a good job especially in the Philadelphia region but now we really have expanded our presence both in the United States and internationally. We've generated a great deal of interest in Australia and Europe. The technology is clearly differentiated from our competitors and this has helped to create more visibility for the Company. I think it is going to be quite exciting now that it is in the hands of customers.

CEO CFO: What specifically are you selling?

Mr. Pascal: We sell diagnostic kits. Our first product is for a bacteria known as Campylobacter, which is primary found in poultry. We sell kits that have 25 tests in a kit and all of the accessories and laboratory consumables that are required for sampling and testing. The kits are sold to manufacturers, processors, and third party testing laboratories of food.

CEO CFO: How does the cost factor relate to the cost of testing now?

Mr. Pascal: We price very similar to what our competitors do, the reason being that the margins in the food industry are very slim. The industry is consequently even more sensitive to price or a price premium than you would typically see in the clinical market.

CEO CFO: What are the next items you are going to be testing for and how do you decide the order on which you develop tests?

Mr. Pascal: We have three additional products right now that are ready to go to their regulatory submission, which include Listeria, pathogenic

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- Benjamin Pascal

E.coli and Salmonella. We will be rolling out these products over the course of 2013. The technology is a molecular test, so we have the capability to test for other important food safety indicators including GMO or genetically modified organisms, which is a rapidly growing market, and allergen testing. Importantly, it is easy for us to make the transition into the clinical market, veterinarian market or animal husbandry, and the bioterrorism and bio warfare market as well.

CEO CFO: You mentioned pathogenic E.coli, so are there more than one type of E.coli?

Mr. Pascal: There are thousands of strains of E.coli and there are only a select few that produce toxins and will actually cause life-threatening condi-

tions. Our test only detects those strains classified as pathogenic.

CEO CFO: Right now Invisible Sentinel has won a number of awards, so are awards helpful in reaching your potential audience or are they just nice to have?

Mr. Pascal: Philadelphia has a supportive biotech and life sciences community and we have been honored to receive several awards as our Company has continued to grow. The Philadelphia Business Journal, University City Science Center, PACT, and Pennsylvania Bio are sponsors of several of these awards and have been very supportive of growth Companies like Invisible Sentinel. The

awards bring great publicity in the community, which is invaluable for a start-up, but they also serve as a good forum for getting Companies like Invisible Sentinel on the radar of investors and shareholders and other interested parties. We are humbled and honored to have been successful in winning some of these awards.

CEO CFO: Is there much competition in your industry and looking for innovative ways to test?

Mr. Pascal: The food safety market is very interesting.

When we first started the company there were several directions we could go and an initial focus was to bring the technology to the healthcare industry for hospital-acquired infections. Food was the market that we ultimately entered into because it has become absolutely white hot due to legislation including the Food Safety Modernization Act. This is the most sweeping piece of legislation in over 70 years, signed into law last year, in terms of food safety. It was right timing for us to enter the food market. This legislation and other similar regulatory rules that have been instituted force the market to go molecular, something they didn't have to do in the past. In terms of competition, there are several large competitors including 3M, Dupont, Neogen, and

bioMerieux. We are clearly differentiated from their technology. We do not require capital investments or a scientist on the staff, which increases overhead. We have very easy-to-read results; we can get your facilities up and running very quickly and empower you. You are now able to do molecular testing rather than having to outsource it or make large capital and infrastructure investments in your organization. It's a competitive advantage, in that where our competitors all compete with RT-PCR, we are the first clear alternative to RT-PCR and are just as fast if not faster than the technology that exists in the market right now. One of the important factors, often discussed in diagnostics revolves around false positives and false negatives. Besides ease of use and speed, no false positives or false negatives were reported during our independent laboratory evaluation required for regulatory approval. This means that Veriflow technology is highly specific as well.

CEO CFO: What is the regulatory process as compared to something that would be used for people?

Mr. Pascal: The regulatory process is different for food diagnostics. Food diagnostics must be licensed and certified by a group called the AOAC (The Association of Analytical Communities). They are a global regulatory agency, so when you receive the

license and the AOAC mark on your product it is recognized by many countries across the world. We have to apply for each pathogen for that regulatory approval. The approval by the AOAC is recognized by FDA and USDA in the United States.

CEO CFO: Does Invisible Sentinel have adequate funding to get through the next steps?

Mr. Pascal: We recently opened a new round of financing and in less than a month have oversubscribed the round. All four of our previous financings were successful, as management delivered on milestones set by shareholders on every occasion. I think it says a lot about management in that we have built a culture of always delivering on goals for our shareholders. The round will allow us to commercialize the technology, to service our beta sites, to receive additional regulatory approvals and move us through 2013.

CEO CFO: You have considerable history in bringing products to market in the medical life science industry, what have you learned from past ventures that is most applicable for you here?

Mr. Pascal: This is our first venture, so Invisible Sentinel is my first time at the gate if you will. I spent four and a half years in R&D for a great medical device organization called B.Braun

Medical and then my partner and I teamed up, developing the technology in the evenings. We took the plunge and started Invisible Sentinel. We have been very fortunate to have grown the Company to where it is today, and 2013 should be an exciting year as we enter the marketplace with our new diagnostic systems.

CEO CFO: Why should the business and investment community pay attention to Invisible Sentinel?

Mr. Pascal: Everyone understands. The food that comes to our tables is something we want to make sure is as safe as possible. The food industry for a long time has had a need for new technologies and better methods for testing for pathogens—Easier to use and faster methods. I think that we are well positioned to be a game changer with our first-in-class Veriflow technology. Management has done a good job at driving this technology through the regulatory process and hitting on goals for our shareholders. We have strengthened our board of directors, we have fitted out manufacturing, we built out our R&D facilities, and are beginning to ship product to our customers. For us, it is an exciting time and I think we are going to make a big splash in the market and be on everyone's radars.



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