

With a Technology that moves Breath Analysis from the Research Lab to the Clinical setting through an Easy-to-Use Portable Device, Picomole Instruments Inc. represents a Major Advance in the Field of Breath Analysis



**Industries
Instrumentation
(Private)**



Dr. John Cormier
CEO

Company Profile:

Picomole's technology represents a major advance in the field of breath analysis, which has the potential to impact health care on a global scale. Picomole's technology permits easy analysis of hundreds of volatile compounds found in exhaled breath samples at parts-per-billion levels and below within minutes. The key differentiator in Picomole's technology is its ability to move breath analysis from research labs to clinical settings through an easy-to-use, portable device.

Interview conducted by:
Lynn Fosse, Senior Editor
CEO CFO Magazine

CEO CFO: Dr. Cormier, would you tell us the focus at Picomole Instruments?

Dr. Cormier: The focus of our company is to build excellent tools for breath analysis. Pioneers in breath analysis have blazed a trail over the past 40 years and shown the vast potential of the diagnostic technique. Along the way, these researchers have struggled with some daunting hurdles largely due to the limitations of the technologies that were available to them. We saw this unsatisfactory situation as our opportunity to make a difference. We developed technologies for breath analysis that just work, which is key in this market. The medical community wants hassle-free turnkey diagnostic solutions that are robust and user-friendly.

CEO CFO: What have you figured out that others have not?

Dr. Cormier: Well for starters, we use a completely different underlying scientific principle to do the gas analysis. Our approach is based on infrared laser spectroscopy, whereas conventional gas analysis technologies in use in analytical chemistry labs are based on mass spectrometry. We started from the first principles of the underlying science and developed a different approach that was completely novel. This has enabled us to build practical devices that work, that achieve the level of performance that is needed for this type of analytical technology to be commercially viable. In terms of the sensitivity, the broad coverage, the ability to detect and quantify

molecules of many different kinds, the speed of the analysis and being able to get results in minutes, and ease-of-use so that people do not need extensive training to use it - all these things are key enablers to the success of breath analysis as a whole, and to our company in particular.

CEO CFO: When someone breathes into your machine, what is happening?

Dr. Cormier: The first step is to record, with very high precision, the infrared spectrum of the breath sample that was collected. Once it has recorded an accurate infrared spectrum, analysis algorithms de-convolve the spectrum into the underlying components, the different volatile compounds that are found in the sample. Most of the air you exhale consists of nitrogen, oxygen, argon, carbon dioxide, and water vapor. None of that stuff is very interesting from a diagnostic standpoint. It's a bit like an onion that you have to peel away layer-by-layer. The volatile compounds that are interesting to us, the biomarkers for different diseases, are present at very low levels: parts per million, parts per billion and parts per trillion levels. That is where we have to look in order to find the biomarkers. They really are like needles in a haystack, so you need a very sensitive technology in order to be able to detect the infrared signatures that they produce. The last step, which is currently under development, is to have the machine look for patterns of biomarkers that indicate the presence of a disease. The goal is to present reliable test results without requiring the operator to have any knowledge of how the technology it-

self actually works, and that's something we know we can achieve.

CEO CFO: What is the level of accuracy or does it depend on what is being tested?

Dr. Cormier: The field of breath analysis is now at a point where it needs accurate technologies in order to progress further. We decided to pursue the development of infrared-based technologies for breath analysis, because of the ease-of-use, the sensitivity, and the accuracy of the technique. The existing technologies for breath analysis are mostly all built around principles of mass spectrometry, and have a number of limitations that are well documented. For example, instruments built using mass spectrometry have trouble differentiating isomers, and this is a problem in clinical diagnostics because different isomers may have completely different physiological origins. Picomole's technology has no difficulty in correctly identifying isomers, because the infrared signals don't look the same. Our technology is also fully quantitative, meaning that it doesn't just report the presence of a compound in a sample, it reports how much of the compound is present.

CEO CFO: What do doctors expect?

Dr. Cormier: We are setting out to show that there are clear unambiguous differences in the breath profiles of individuals known to have certain diseases versus healthy controls. When you can establish that, it then becomes the basis of a diagnostic test. We are in the development phase right now but we have unpublished data that show that our technology is capable of detecting diseases in a non-invasive and pain-free way.

CEO CFO: Where did the impetus for trying this method originate?

Dr. Cormier: It is the great unknown because there was no prior basis to look at and say well if they did it then so could we. I think that is part of what the great adventure of science is all about, trying the untried, to see

what happens. From my background in atmospheric physics, I knew that scientists have been able to understand the composition of planetary atmospheres using infrared-based technologies. Compounds are present in the earth's atmosphere at very low levels, and we have this knowledge because of infrared-based instrumentation. I had strong reasons to believe that if we were to develop infrared instrumentation specifically designed for the challenges of breath analysis, we would be successful. The recent demonstrations of our technology have validated seven years of work by our scientists and engineers.

CEO CFO: Where are you in the development process?

Dr. Cormier: We have working devices now. We are looking for biomarkers for diseases. The peer re-

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viewed scientific literature from the past forty years has exciting hints that there are biomarkers for many different diseases. However, there is also considerable frustration with the scientific literature because of the apparent lack of robustness and reproducibility of some of the published results. That, probably more than anything has hindered the acceptance of breath analysis by the medical community. We looked at that and after a careful meta-analysis of the published data, concluded that the reasons why the data were less than satisfactory, was probably in large part due to the underlying technologies that were themselves being pushed beyond their capability. We believe that if we use our infrared-based system on those same problems, the outcome would be more robust sets of biomarkers. We've just started down this

path, but the early signs are very encouraging.

CEO CFO: Looking at your website, it seems there are many different diseases and conditions that you anticipate being able to detect!

Dr. Cormier: Our cues for this come from the peer reviewed scientific literature. It seems that just about every major field of medicine has potential breath analysis applications. There are very exciting suggestions that have come out in recent years of just how deep this can go into many different areas of cancer even cardiovascular disease and of course metabolic disorders, but even things that I wouldn't have expected, like mental illness.

CEO CFO: Is the medical community starting to pay attention?

Dr. Cormier: We have not found it difficult to interest the medical community in what we do. There is something about breath analysis that just seems to fascinate everyone, and the medical community is hungry for innovation. Everyone is concerned by the current state of healthcare with costs ballooning out of control, but there is a lack of diagnostic tests that are affordable, fast and can be

administered by front line healthcare personnel. The feedback we have received from doctors is that our breath analysis technology could be a very effective solution to that problem.

CEO CFO: Development is always an expensive situation. How far will your current funding take Picomole Instruments?

Dr. Cormier: We receive funding from private investors and non-dilutive funding from a number of government sources. It's always the case that you wish you had more because you could go much faster, but our team has achieved amazing things with the funding we've received. We have a working device now, and so we get noticed a lot more than we would have two years ago. When people come into our lab to

demo the technology, you can feel the excitement. We're currently leveraging that excitement to close deals with investors, and we expect that we will soon have sufficient gas in the tank to complete the development process and bring our first product to market.

CEO CFO: What are your people doing day-to-day at the facility?

Dr. Cormier: We have scientists and engineers that are actively engaged in research on many different fronts. The physical side of it with the hardware and the optics and the software that controls things is obviously a major part of what we work on. We also have research going on related to metabolomics and understanding the biochemical origins of the breath biomarkers. One of the areas of research that I'm proud to say we don't overlook relates to how we create a positive user experience with our technology. We ask ourselves: Is it going to be something that our customers are going to look at, touch, experience and just immediately feel that they need. That is something that we have seen in the consumer electronics in-

dustry and companies like Apple have an excellent track record at that. With a rapidly growing point-of-care segment to the diagnostics market, we see a focus on enhancing the user experience as a key differentiator. Doctors are very busy and need turn-key solutions that "just work," which is how they put it in their own words. Our innovative breath analysis technology inherently caters to this need. This contrasts with many of our competitors, that seem to be content to market complex instruments that require considerable knowledge and skill to operate. This slows down acceptance by the medical community because there is too much that they still have to do, too much interfacing and too much understanding of the technology before they can actually get to a point where they can use it. We are designing instrumentation that customers will order, receive, unpack, plug-in and use. This whole sequence takes a year or more with currently available gas analysis technologies that require a dedicated site with expensive infrastructure, installation and equipment modifications before you

can even begin to perform breath analysis. Our goal is to deliver instrumentation for breath analysis that you can unpack, plug-in and use, in one hour or less.

CEO CFO: Why should people pay attention to Picomole Instruments today?

Dr. Cormier: We are disrupters in a market that desperately needs disruption, and that's always exciting to follow. We believe we have insights and direction on how the technologies that we have developed can be positioned to make a profound difference in healthcare. As I said, healthcare is ripe for innovation, but this is not just a scientific objective. Our focus is on building a business that translates innovation into attractive returns on investment for our shareholders. By addressing the needs of the clinical diagnostic market with a user-friendly, fast and cost-effective platform for non-invasive breath testing, I believe there will be opportunities for our company that can only be dreamed about today.



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