

Effective Capture Technology for DNA Sample Analysis



John Steel - CEO

About Diomics, Inc

Diomics is focused on life sciences, specifically diagnostics, forensics, integrated DNA analysis and genetic solutions. Our proprietary Diomat™ technology platform has the ability to efficiently pick up biologic materials from a variety of surfaces and release the majority of the DNA from the sample into the solution. The versatile characteristics of Diomat™ lend itself to a variety of product formats, including swabs, films, and fibers. Today based in Carlsbad, California, Diomics has developed numerous products, tools and services for the molecular diagnostic and forensic industries.

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

CEOCFO: Mr. Steel, what is the concept behind Diomics?

Mr. Steel: The concept behind the company is to develop a better technology to capture and release DNA. Currently, vials of blood, urine, or other biologic samples need to be analyzed for DNA. These samples are either collected through a cotton swab, other swabs, or a blood draw. When you get into smaller touch samples in forensics and diagnostics where a small sample site is extremely relevant, the current methodologies are not adequate. The goal of Diomics is to develop a better collection or capture technology that can release DNA for use in devices to analyze the genome for use in forensics and to determine human, animal, and plant identity. The collection step has been sorely lacking in terms of improvements over the last several decades, while the machinery and the analysis dynamics have improved almost weekly.

CEOCFO: What were the challenges in creating a better means of capture?

Mr. Steel: The traditional challenge has been the things that typically gather blood and saliva are very difficult in releasing those materials. For example, cotton and many of the commercial devices are known as hydrophilic. It's like a sponge; it can soak things up but not release much. At the same time you want the material to be hydrophobic, which means it releases the material or the DNA that it has collected. The technology that Diomics has developed efficiently captures and releases the DNA.

CEOCFO: How are you able to do so? What is actually happening?

Mr. Steel: We started off with a different project at the University of Arizona, where we were looking for materials that were hydrophilic. We needed materials to either dissolve or release enough of the relevant material to develop a unique device. Our scientists were able to figure out a way to make a material that could capture water and biologic material. They determined various technological aspects to also make it hydrophobic. They basically started with a polymer and manipulated it in such a way that it achieved both of those properties. They were able to dial in the properties that we needed for forensics and diagnostics applications.

CEOCFO: Where is the X-Swab™ today?

Mr. Steel: We have commercial activity under way for the X-Swab™. Our first orders were from municipalities, government agencies, and police departments that wanted to get as much DNA as possible off of samples of any size. We started filling those orders about six months ago. Then we started receiving bigger orders. We had to move into a larger production facility. We started off very slow, but now we are ramping up production on the X-Swab™. We also have another configuration for diagnostic applications, which is a little bigger than the X-Swab™, but has the same key properties. We are out of the development phase and into the market phase, and talking to various large and medium sized companies about OEM arrangements and/or alliances at present.

CEOCFO: What has changed since the product has been in use?

Mr. Steel: We have been able to automate the production line so that we can increase output. We have been able to dial in certain hydrophilic and hydrophobic properties, with modifications to the technology and methods. We get requests to

make a product that is more hydrophilic and less hydrophobic, and in many instances hold the DNA a little longer. We have also developed films and fibers using the same technology for other uses related to security and forensics.

CEO CFO: How does the pricing compare with the traditional products?

Mr. Steel: The cotton swabs are generally free. You can buy them at any drug store. The problem is that it is not really germane for use to prove a suspect's innocence. There are other commercial swabs. The scientists at the University of Texas compared our X-Swab™ to the state of the art technology. In the head to head comparison X-Swab™ demonstrated almost eight to nine times higher yield in releasing DNA from blood samples and three to four times from saliva samples. In terms of cost X-Swab™ is priced higher than the cotton swabs and about thirty to forty percent more than some of the other commercially available swabs. In the context of forensics and diagnostic cases that are depending upon these results, the benefits far outweigh the cost.

CEO CFO: You mentioned a new facility for the quick ramp up. How do you handle the challenges of the rapid growth and the rapid opportunities without losing focus?

Mr. Steel: There are many challenges during a rapid growth phase of a company. We prepared by establishing certain functions and making key hires. First, we wanted to develop the intellectual property, so we put a legal team in place who understood patent laws to handle our patent filings. I am happy to report that in the last two months we have had two separate patents issued. In preparation to transition from small scale to large scale manufacturing, we hired two individuals experienced with manufacturing and scale up of operations. Then we hired more chemists and biologists with skills to augment our existing technologies. We want to make sure we can replicate what we have here in other locations. We are in active discussions with five major global companies to partner on the manufacturing and distribution. We intend to leverage our technology, intellectual property, and personnel to establish key partnerships globally where we can adapt existing infrastructure to augment what we do.

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- John Steel

CEO CFO: This is not your first time around the block. What have you learned in previous experiences that have been most helpful at Diomics?

Mr. Steel: There were many challenges in some of my other ventures, particularly in endocrinology and cancer. You can come up with an idea but you have to test it from many different angles, and repeatedly. Then you might get two or three years down the road and things don't quite work out. What I like about Diomics is that we get immediate results. We can tweak things and within forty-eight hours get data back to give us “go, no go” decisions. The good news is that today the swab, films, and the other configurations that we have developed are about good science applications. We have been extremely successful.

CEO CFO: What should people remember when they read the Diomics story?

Mr. Steel: A study published in the journal *Forensic Science International Genetics* demonstrated that X-Swab™ yielded significantly more DNA compared to competing technologies for blood and saliva samples, particularly for low quantity samples. We are proud of what we've been able to accomplish and look forward to continued success.

BIO: Mr. Steel has held leadership positions in numerous biotechnology companies. Most recently Mr. Steel was the founder and chairman of Islet Sciences Inc. The company is publicly traded and develops DNA-based diagnostics, small molecules for diabetes and related disorders, and an artificial pancreas. Mr. Steel is a contributor to numerous global healthcare patents. Mr. Steel is a graduate of Dartmouth College and earned an MBA from USC.

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