

THE WALL STREET TRANSCRIPT

Questioning Market Leaders For Long Term Investors

DNAPrint genomics, Inc. (DNAG)



RICHARD GABRIEL is President and Chief Executive Officer of DNAPrint genomics, Inc. He served as President and Chief Executive Officer of Calix Corp., parent company to Pharm-Eco Laboratories, Inc., from 1998 to 2001. He was instrumental in closing and managing more than \$135 million in contract revenue for Pharm-Eco Laboratories and successfully completed the formation of numerous joint ventures, limited liability companies and spinoffs that resulted in several public and private companies in the genetics/chemistry/pharmaceutical field. From 2001 until joining DNAPrint, Mr. Gabriel consulted for several startup companies while working as a partner at Genbiomics, LLC, and as head of Life Sciences Practice at Semaphore, Inc. Prior to the formation of his own consulting practice in 1985, he was a product manager for W.R. Grace. Mr. Gabriel obtained his MBA from Suffolk University's Executive MBA Program, Boston, Massachusetts, in 1985, and a BS in Chemistry from Ohio Dominican College, Columbus, Ohio, in 1978.

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(ACW612) TWST: Would you give us an overview of DNAPrint genomics?

Mr. Gabriel: The mission of the company from its very founding in 1999 has always been to leverage genomic expertise to develop drugs and to deliver them to patients in a more efficacious, safer way. That was always the goal for our Founder, Dr. Tony Frudakis.

Because we are a small company, out of necessity we've taken an indirect path to get where we are today. When we first went into business we wanted to start generating revenues as soon as possible, so we focused on developing a product for consumers. This was ANCESTRYbyDNA™, a kit that can determine family heritage and which part of the world your ancestors come from.

Then we turned to forensics, which enabled us to field-test and validate our technology under rigorous conditions. That led to the development of DNAWITNESS™ forensics technology for law enforcement, which enables investigators to identify potential suspects or "persons of interest" from DNA recovered at a crime scene.

In the meantime, Dr. Frudakis was communicating with the U.S. Food and Drug Administration (FDA) about the emerging field of pharmacogenomics. In fact, it has only been in the last couple of

years that pharmacogenomics has emerged as a viable technology. As I said previously, our company has taken a winding path, but we have evolved into a company focused on three areas: pharmacogenomics and the development of personalized drugs called theranostics; genealogy, which is basically our consumer ancestry product; and forensics for law enforcement. Pharmacogenomics is the company's biggest market opportunity and we've focused on developing pharmaceutical applications for our products and services. To facilitate these developments, we also created DNAPrint Pharmaceuticals, Inc., a wholly owned subsidiary.

TWST: So one thing led you down the path to the next.

Mr. Gabriel: Think about our company as having a factory. We have a machine that can pump through 5,000 DNA samples a day. It doesn't care whether the samples are for an ancestry product, a forensics product or a pharmaceutical product. It's blind to those applications. What we've done is change the application platform as we move from one market to the next. And we have matured along the way. The ancestry product is not as complicated as the forensics product and the forensics product is not as complicated as the pharmaceutical product.

TWST: It seems as if there is a great deal of opportunity in pharmacogenomics.

Mr. Gabriel: Yes, there is. We have licensed a product called erythropoietin (EPO), a drug for the treatment of anemia and renal failure, from Beth Israel Deaconess Hospital in Boston. We call it PT-401, which is proceeding into clinical development. Our goal is to develop a more powerful longer-lasting Super-EPO. Beth Israel Deaconess made an independent survey and estimated that the market potential for this drug is around \$2.5 billion. We expect to file a New Drug Application (NDA) by 2009 and a product launch somewhere around 2010.

Additionally, we recently licensed three new Ritalin™-like compounds targeting attention deficit hyperactivity disorder (ADHD), drug addiction and depression. The depression market is about \$7 billion, the drug addiction market is around \$500 million and the ADHD market, by last report, is around \$4.6 billion. We're targeting NDAs for these three new drugs in 2009, 2010 or 2011.

ally practicing personalized medicine. When the pharmaceutical companies came on, they had to standardize their production. Doctors have known for some time, however, that different patients respond differently to medications. We combined our DNA studies of human populations, which we piloted back in 1999 and 2000, so that we can focus on identifying the genealogy mixture within various groups. For example: perhaps your genes or metabolizing enzymes originated with one family member 500, 1,000 or 2,000 years ago. That gene has passed through your family, and that one gene could prevent a response to the drug TAXOL/Carboplatin. Now, if you're a woman with ovarian cancer, that's not good news, since TAXOL/Carboplatin is a proven therapy. So if we can identify women who are non-responders, a doctor could seek and recommend an alternative therapy. That could include radical surgery or it could be entering the patient into a clinical trial program of another new drug. Currently we are working with the H. Lee Moffitt Cancer Center in

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TWST: Are any of these already approved for use?

Mr. Gabriel: No, they're in preclinical development. But the drug addiction compound has actually been selected by the National Institute of Drug Abuse (NIDA) for further study. NIDA is looking very carefully to see if it can help people who have a craving for alcohol and other drugs. So it's being advanced by NIDA within their clinical development group and we'll be working with them on that project.

TWST: As you license these products, what is it that DNAPrint brings to the equation?

Mr. Gabriel: There are many patients who are non-responders to certain drugs. Perhaps you remember the blockbuster theory of drug development. You have to sort of back-peddle a little bit and remember where the pharmaceutical industry was before the end of World War II. Though it's a large industry today, it is not really a mature industry by business standards. The pill industry really came about as a more efficient way of delivering medications to doctors and patients. Before that, all the formulations were delivered by the pharmacist. They were compounded in the pharmacy — that's where tablets were made and formulations were made — so drugs were sort of tailored for the individuals, and pharmacists were actu-

Tampa on a diagnostic test called OVANOME™, that matches ovarian cancer patients with the most suitable form and dose of chemotherapy based on the patient's DNA.

In most cases, the favorable response average to a drug is 60%-80%. If you're among the 20% of patients who don't respond, this is critical information that your doctor needs to know. We can eliminate the risks of non-responders by looking at their DNA through a simple test. This way, your doctor can make the decision about personalized treatment and a test/drug combination without relying on the pharmaceutical industry's one-pill-fits-all treatment strategy.

TWST: Is the FDA moving in that direction?

Mr. Gabriel: The FDA already has approved Herceptin®, an antibody for the treatment of metastatic breast cancer along with a non-genetic-based diagnostic test. Researchers have found that women who have the HER-2 gene and are identified by this test respond to the medication. So the FDA has been a leader in this area.

Pharmacogenomics have profound benefits for people with attention deficit disorder, drug addiction, cancer, people on kidney dialysis. So it is extremely important, as far as the FDA is concerned, to improve the efficacy of drugs.

There was a recent article in *The Wall Street Journal* about a former FDA reviewer who for the last few years has been concerned about the fact that a particular drug causes certain patients to become hypoglycemic, pass out and faint. As a result, a patient could die in an automobile accident. He has tried to get the FDA to monitor the situation. If you had a test where you could pick out those patients who become hypoglycemic, then you would say to them: "This is not a good drug for you to take." Then an alternative therapy could be sought.

Our goal is a drug that is 95%-99% efficacious. Using a theranostic product, every time the patient passes a DNA sampling test, the doctor knows that patient is going to respond — and the patient knows, too. It brings a lot of mental-emotional well-being to a difficult situation.

As for the big pharmaceutical companies, I don't think you can expect them to risk marginalizing revenues by narrowing their market by focusing on specific populations. That's not the case with the FDA.

TWST: Is the public ready for this?

Mr. Gabriel: Absolutely. I've talked to many, many people, and the idea that genetic technology is some sort of discriminatory device is unfounded. Personalized medicine doesn't have anything to do with discrimination. It's trying to provide the best medicine to people who need it and who can respond to it. And my feeling is that people are ready for that.

TWST: Let's turn to genealogy and your product for consumers.

Mr. Gabriel: Actually, we have four. Our legacy product, of course, is ANCESTRYbyDNA, which determines which of the four major bio-geographical ancestry groups a person belongs — Sub-Saharan African, Indo European, East Asian or Native American — as well as the relative percentages. Our EURO-DNA product further breaks down ancestry into Northern European, Southeast European (Mediterranean), Middle Eastern and South Asian sub groups.

We recently acquired Trace Genetics, a company in Richmond, California. Trace brings two new complementary technologies to our autosomal ANCESTRYbyDNA testing for determining the percentage of a person's ancestry — y-chromosome testing for tracing ancestry by following the paternal line and mitochondrial (mtDNA) x-chromosome testing for the maternal line.

TWST: What is it that you can provide law enforcement in the forensics area?

Mr. Gabriel: In the case of the Louisiana serial killer, there were two or three eyewitnesses who said that they saw a Caucasian male in a white pickup truck near one of the crime scenes. So over a period of about 18 months, approximately 2,000 white Caucasian males were questioned by police and volunteered to have their DNA analyzed. After all of this work there were no matches. Meanwhile, the rate of women being murdered was accelerating. The killer's DNA recovered from a crime scene did not turn up in the FBI database system. Finally, the authorities sent us a sample and after 48 hours we called them back and told them they were looking for the wrong person. The DNA showed

that the killer had 85% sub-Saharan African and 15% Native American ancestry — clearly not a Caucasian. The authorities immediately changed the focus of their investigation and ultimately captured a man who was a perfect match to the crime scene DNA. In addition, one of the most difficult things in forensics is identifying eye color. We have now developed a product for the forensics community called RETINOME™, which has the ability to determine eye color, either light (blue or green) or dark (brown, hazel or black), from a DNA sample.

TWST: Looking at the various pieces on your ancestral DNA, potentially, how big is that market, and how do you approach it?

Mr. Gabriel: That market is actually growing. We've seen certain market indicators that it's somewhere around \$100 million. That's not necessarily big, but we've sampled probably anywhere from 20,000-30,000 individuals, so it offers us a broad base of tests.

In the forensics area, we have a photo database that goes along with the product, and we estimate that market to be \$500-\$600 million a year. This is a new application that provides a "fuzzy" photograph based on DNA.

There are two functions of a crime lab: one is to gather the evidence and analyze it; the other one is to match DNA. Ours is a detective's product. It's used to help investigators focus the investigation so they can collect the DNA and then match it. We provide matching DNA analysis as well. We use that internally to track our DNA, so we validate our DNA using that technology. And as I said, that's a \$600 million plus market.

TWST: Looking out over the next 18 and 24 months, what are the milestones that investors should look at?

Mr. Gabriel: Considering what our pipeline is in diagnostics and drugs and also in the consumer and forensic areas, the company has the potential to generate revenues through some standard revenue generators. We look at the consumer market and the forensic market as means of generating revenue, though our longer-term investment is in the pharmaceutical area. But consumers are pretty excited about our products, and we've seen an increase in sales there, and we would really look at those two market applications as revenue opportunities. Therefore, we intend to work toward increasing awareness of our products in the consumer and forensic markets.

TWST: How are you going to go about that?

Mr. Gabriel: Through marketing and advertising. We try to stay in the public eye as much as possible. We're not very shy about being in the press — and there has been a considerable amount of press coverage of our company and our products over the years.

As far as the pharmaceutical area is concerned, we're compiling our data on OVANOME and a couple of other diagnostics as well, and we're going to be talking to the FDA sometime toward the end of the this year about what the next steps ought to be. After that, we will be working with some of our collaborators — for instance, the Moffitt Cancer Center. We are developing projects with Moffitt to look at the ovarian cancer patient populations in more detail and to provide analysis to the physicians as the patients are coming

through — and we expect to generate revenue from that. We've completed the background research and data mining and we believe the diagnostic value will be recognized — and paid for — by patients.

TWST: How about reimbursement from healthcare providers?

Mr. Gabriel: We're not ready to talk to healthcare providers at this point. They haven't quite made up their minds that they think this is a good thing. They speak all the language, but convincing an HMO that they need to approve your test is an arduous task.

Instead, we're going to go directly to the patient and directly to the doctor. We think there's a market niche there. We're going to exploit that niche for as long as we possibly can, and then, once we've built enough patient data we'll approach Blue Cross/Blue Shield and the HMOs and present the data to them. But it's far too premature to even start talking to them.

TWST: What has the response been to what you're doing?

Mr. Gabriel: Moffitt is the best example. When we started off with just the ovarian cancer project, physicians tended to be skeptical. But once we started delivering the data back to them, their attitude changed and now we have 10 projects and we sense a level of enthusiasm for what we are doing. As a matter of fact, we have to turn away projects now because it's time for us to move these projects from research and development into market, and that's what we're focusing on. We have lots of people who are interested in evaluating our technology. We have just recently completed an evaluation for one of the big Fortune 50 companies. We ran a 60-patient profile for them, and they loved the results, so we're going back and talking to them about doing more development work.

TWST: In a case like that where you're doing it for the company, why would the employees want to participate and let the company see their personal data?

Mr. Gabriel: In many respects, DNA is no different from a fingerprint or an eye scan or a photograph. It's just a different form of identifying individual, unique characteristics. We expect the courts to uphold the law in accordance with DNA. What people fear is the unknown. DNA is so new to most people that they don't understand it.

TWST: Do you have the financial wherewithal to support all this?

Mr. Gabriel: I believe we do. We're going to be going out and talking to private investors, VC's as well as others, to invest in our company — including our new subsidiary, DNAPrint Pharmaceuticals, Inc., which is exclusively focused on pharmaceuticals and diagnostics. We're in the process of putting that business plan together.

TWST: What are the two or three reasons you'd give potential investors to take a look at the company at this point?

Mr. Gabriel: What I would encourage them to do is to look at the pipeline of products and services and look at the fact that we have built a solid technical company. We're platform independent. We have focused in on three very promising areas of sales growth and we are expanding our company.

We have continual sales increases, and we've had them every quarter. This quarter is better than last quarter and this year is better than last year. I think there's a bright future for this company because it was at the right place at the right time. Products derived from pharmacogenomics, the forensic application of our genetic platform and, for the consumer, understanding their past, have promise because they can enrich people's lives. I think the future of the company is very bright.

TWST: Thank you.

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Forward-Looking Statements

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