

Genetic Information for Prescription Guidance through Pharmacogenomics

Interview with: *Adel Mikhail, Ph.D. – CEO, GnomeDX*

CEOCFO: *Dr. Mikhail, would you tell us the idea behind GnomeDX?*

Dr. Mikhail: The idea of GnomeDX is to be able to provide genetic information that will guide physicians in prescribing the right medicine for the right patient at the right dose.

CEOCFO: *Which products have you developed to allow that to happen?*

Dr. Mikhail: We sequence a group of genes that are responsible for metabolizing 180 different drugs. Based on the individual genetic sequence of patients, the physicians can prescribe the correct dose. Today, physicians effectively do a trial and error process to identify the right medicine for the right patient and that is not a very effective approach in terms of the adverse drug response that are occurring as well as inefficacy of drugs.

CEOCFO: *What are you able to do better, faster, cheaper and more effectively, or is there room for many people in this space?*

Dr. Mikhail: Pharmacogenomics is just coming to fruition. The number of patients that need this type of service is immense. The market is enormous, the price has come down significantly that it will make economic sense in the healthcare system.

CEOCFO: *Are all in agreement that this is the way to go?*

Dr. Mikhail: That is correct! For the most part people who are informed about the power of pharmacogenomics and personalized medicine understand that it is coming and there is nothing to stop it. There are a few naysayers in the particulars of personalized medicine but generally speaking, they understand that this is the way of the future.

CEOCFO: *How are you approaching the vast potential clientele?*

Dr. Mikhail: We are approaching it on multiple fronts. We are approaching physicians directly who appreciate the fact that prescriptions need to be better guided based on metabolic and genetic information. We are discussing with healthcare providers who understand the pain of paying for medicines that do not work repeatedly. We are approaching healthcare systems that understand that ADRs is the fourth leading cause of death and a huge cost on the healthcare system. About \$136 billion a year is wasted on medication that either does not work or causes an adverse response. Now because the cost of these tests is so economical and the cost of healthcare is so high, people are motivated to identify the best approach to treating patients.

CEOCFO: *Are patients asking for this as well and do you work to educate the public?*

Dr. Mikhail: We have patients asking for this. We only do it through physicians and not direct to consumers. As the public becomes better informed, they can identify better medications at better doses. They certainly are coming to us and we advise them to discuss it with the physician to prescribe the tests.



CEOCFO: *Are there particular conditions or diseases that you are able to test?*

Dr. Mikhail: The most valuable tests in pharmacogenomics are related to cardiovascular disease. As you know, it is the number-one killer. Even drugs as popular as Coumadin and Plavix

are the responsible for a significant amount of ADRs today and ironically they are the most validated. The NIH has guidance on clopidogrel (Plavix) and warfarin (Coumadin) that recommends genetic testing to make sure that the patient is therapeutic on it. For instance, the number needed to test for Plavix to prevent one major cardiovascular event that is either a death, an MI or a stent thrombosis, is eight. By testing eight patients you can save one from another cardiac event. That is compelling both for patients and the healthcare system. We just have to get everybody to acknowledge and implement, which is hard in the medical community.

CEOCFO: You are also a biotechnology development company and you are doing some research on some chronic diseases. Would you tell us about that?

Dr. Mikhail: We are actually developing our own panels around different genes that are responsible for drug metabolism and response to drugs. Those will come out as we validate them.

CEOCFO: What is the original intent to have two sides to the company or did the research develop over time?

Dr. Mikhail: Initially, we actually were more of a research company than we were a clinical company. We just got tired of everybody talking about personalized medicine and nobody doing anything about it. Small companies have one major advantage and that is they can move fast. The rhetoric of personalized medicine in the medical community is high but when you actually ask how many patients are being tested, the number is miniscule. I would never go to a hospital without my pharmacogenomic profile. You have to be crazy to do that.

CEOCFO: What do you and your team understand about the industry and about medicine that perhaps others do not?

Dr. Mikhail: I think because we are a small company we know we can be much more responsive to the industry. We do not have to go through a large decision-making process to bring products or services to market. We do understand, since we run clinical trials, that you have particular biomarkers or particular genetic markers that stratify patients. The more stratified the patient population is, the more likely you can tailor certain therapeutic drugs or treatments to. We are all different and the history of medicine has never identified until the past ten years ago that we are all different. We were being treated as a one-size fits all. I think the fact is that people are beginning to appreciate that one size does not fit all. Every family who has had a member take a drug and experience an adverse response understands that. I am not sure if we have any particular insights, we just want to do the right thing and bring it to market as quickly as possible.

“About \$136 billion a year is wasted on medication that either does not work or causes an adverse response.”- Adel Mikhail, Ph.D.

CEOCFO: When you are talking to potential clients, physicians or hospitals, do they understand the commitment or philosophy of your company?

Dr. Mikhail: You can imagine there is a stratification of the medical world as well in terms of people who completely appreciate this type of technology and those who find it intrusive. I would say 90% of the medical community that we talk to appreciates it. That does not mean they are going to implement it immediately but they can appreciate the technology and the fact that it is going in that direction. Having said that, there is a lot of complexity around implementation, about reimbursements, about how to interpret the data but we help them with that in an easy way in terms of the interpretation.

CEOCFO: Is it a matter of getting the right code for the test?

Dr. Mikhail: It is a matter of giving the right guidance and if this patient has this genetic profile, here is a recommendation. We make it very easy. The implementation of that data into their EMRs which physicians are now required to implement, is a bit of a challenge but we will get there.

CEOCFO: Are you confident that the focus on cost-cutting and more responsibility for outcomes will help push forward the testing?

Dr. Mikhail: That is exactly how this is going to get implemented. The motivation now is the ACA. There is no fee for services like the old days, it is more fee for outcome. If you can prevent an adverse response you are going to get paid as a healthcare provider a significant amount more than not. Now that they are motivated, I cannot imagine any other technology at this price that could save healthcare costs.

CEOCFO: Do you have funding for the next steps you would like to take, are you seeking investment or partnerships?

Dr. Mikhail: We are always seeking partnerships. We are self-funded and we are secure in that fashion.

CEOCFO: Why is GnomeDX an important company?

Dr. Mikhail: I think GnomeDX brings the technology to the patients and the healthcare system that is cost effective and important for their healthcare outcome. It is the best dollar you can spend with the best outcome.

For more information visit: www.gnomedx.com

Contact: Madison Bush 614-431-6414 madison@gnomedx.com