

Revolutionary Prescription Writing and Ordering Portal based on a Patient's Genetic Profile allows Physicians to provide more Personalized Medications



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"The science is bold. It is using your genetic profile from 22 genes that are involved in the metabolism of many medications to accurately predict your response to more than 340 medications." - Paul Owen

CEOCFO: Mr. Owen, what is the concept behind OneOme, LLC™?

Mr. Owen: OneOme was established in late 2013, early 2014 in collaboration with three cofounder scientists from Mayo Clinic to develop a comprehensive, low-cost pharmacogenomic test and interactive tools that would allow providers to combine a patient's genetic profile as well as his or her current medications to identify the optimal drug therapy the first time.

CEOCFO: Why patients as opposed to doctors as a beginning?

Mr. Owen: That is a great question. It is actually for both. There is a tremendous amount of benefit for the patients. There are more than four billion prescriptions that were written in 2015, just within the United States alone. Scientific and clinical evidence shows that less than half of those work as intended for various reasons. How you metabolize drugs is one of the factors contributing to that response. The OneOme pharmacogenomic test may identify which inherited genetic variations you have to predict how you will or will not metabolize a drug. While this doesn't apply to all medications, it does allow providers to get much more precise in our prescription writing which benefits patients. By using pharmacogenomics, providers don't have to take a trial-and-error approach but can start to narrow down the process of finding the most effective medications that an individual should be on. The cost of adverse drug reactions (ADRs) to the health system is about one hundred and thirty-five billion dollars per year. ADRs are the fourth-leading cause of death in the United States. Pharmacogenomic testing can help to reduce the number of ADRs and the associated costs to the health care system. So for the providers, pharmacogenomics benefits them by reducing the overall cost to the health system and also increases patient satisfaction.

CEOCFO: Do most patients still feel that the doctor knows what he or she is doing and is taking this into account? Are people generally realizing that may not be the case?

Mr. Owen: With President Obama's 2015 State of the Union address about precision medicine and more information available about personalized or precision medicine, I think individuals are starting to realize that they can take more responsibility in their healthcare. It's not a lack of trust with their physicians, but rather, after patients learn about pharmacogenomics and its benefits, they often have a higher level of confidence the prescription is right for their genetics.

CEOCFO: Would you tell us how the OneOme RightMed™ works?

Mr. Owen: We have made every effort to make ordering our test very simple. It starts with your healthcare provider ordering the OneOme RightMed pharmacogenomic test. Once the order is placed, we send a simple cheek swab kit either to the provider's office where they can collect the patient's sample or directly to the patient's home. The patient swabs the

inside of his or her mouth for about ten seconds on each side, replaces it back in the tube and sends the kit back to our laboratory in a pre-labeled and pre-paid box. Within seven to 10 days from when we receive the sample, the ordering provider would be able to access the test results through our secure portal. This then allows the provider to look at the medications in multiple different ways within our portal, called RightMed Advisor, an interactive tool that allows users to search and select medications based on current medical indications such as cardiovascular or psychiatric conditions or medications. RightMed Advisor provides clinical guidance based on industry standards (CPIC, DWG), provides drug-gene interactions details, checks for drug-drug interactions, displays drug alternatives, and integrates with Surescripts for the previous 12 months of the patient's prescription history. The provider can save and print custom drug reports. A PDF report is also available for downloading that shows the drugs binned into three categories based on the patient's genetic makeup. Some drugs can be taken as directed (binned green) as the results indicate that the patient is expected to have no issues metabolizing those medications. A patient may also have red binned drugs, which should be prescribed with great caution and yellow binned drugs, which should be prescribed with caution. These are cases where the patient either metabolizes the medications too quickly or too slowly which can result in no effect or potentially an adverse effect. The report also breaks down the medications based on different indications such as cardiovascular disease, cancer, chronic pain, psychiatric conditions, etc., so the provider can quickly identify which medications are safe to use for the indication the patient has presented with.

CEOFCO: *Would the doctor or the patient provide a list of the medications they are taking?*

Mr. Owen: Yes. We have two different ways to do that. The doctor would likely collect the medications that the individual is currently taking. However, in our ordering portal, through a company called Surescripts, we have the ability to also incorporate, if the patient consents, a list of all the medications that have been prescribed to the individual throughout the last 12 months. That can also be incorporated into their analysis and into the RightMed Advisor. Therefore, the physician can go in and look at drug-to-drug interactions, so if there is one medication that should not be taken with another medication they can see that easily and potentially prescribe a recommended alternative.

CEOFCO: *Is dosage important or would it not matter if a drug is not right?*

Mr. Owen: Yes, dosage does matter. For example, if you metabolize a drug slower or faster than normal, your physician may recommend a different dose of a particular medication. The FDA, PharmGKB and CPIC (Clinical Pharmacogenetics Implementation Consortium) have some really good and reliable dosing guidelines that we have incorporated into the test. If there is not a dosing guideline for a particular medication, we do not provide dosing recommendations, because we do not practice medicine; that is job of the provider as they have all of the information about that patient's health status and health history. We just want to give them the absolute best information that they can get for that individual when making a prescribing decision.

CEOFCO: *What is the science behind what you are doing and what was the challenge in creating RightMed?*

Mr. Owen: The science is bold. It is using your genetic profile from 22 genes that are involved in the metabolism of many medications to accurately predict your response to more than 340 medications. We feel as though the 22 genes that we have selected have the most scientific and clinical pharmacogenomic evidence to support inclusion in our test. Primarily, there are four organizations that we look at to curate our medications: the FDA, PharmGKB, CPIC, and the Dutch pharmacogenomic working group. There are four levels of scientific and clinical data used by these organizations to assess the strength of data supporting the association between the gene and the drug. Level 1 has published guidelines from CPIC and FDA labels and level 2 has published clinical evidence of high quality. Level 3 and 4 are not included in the OneOme test because we do not believe that they have enough clinical evidence to be used in a diagnostic test at this time. What we have done, from a OneOme perspective, is established a rigorous, uniform procedure for reviewing, implementing and retiring pharmacogenomic data into our proprietary database. Currently we have curated more than 340 medications included in our database. We are continually reviewing and updating our database as new information is available.

CEOFCO: *Would you give an example of what a doctor or patient might find and what action they should take?*

Mr. Owen: Using Clopidogrel (brand name: Plavix), a platelet aggregation inhibitor, as an example: Plavix is often prescribed for patients at risk for strokes, heart attacks, or other heart problems. Thirty percent of the population receive no benefit from the medication and have an increased risk of death resulting in an FDA-label requiring genetic testing be performed before prescribing. Warfarin is another example where you would want to ensure that you understand your ability to metabolize Warfarin, before you started taking it.

CEOFCO: *Let us take Warfarin for example. Would it just not be as effective? What would be happening, depending on the genotype?*

Mr. Owen: Warfarin, an anti-coagulant that has been prescribed to more than 40 million Americans, has a well-documented variability in response due to genetic variants. Knowing your genotype can assist your healthcare provider in

selecting the optimal starting dosage. Certain variants in two genes can result in great sensitivity to Warfarin, which could cause bleeding events or lack efficacy. The OneOme pharmacogenomic test can simply and easily provide this information at a low cost, potentially saving your life.

CEOCFO: *Are there other products on the market competing with what you have developed?*

Mr. Owen: There are a number of pharmacogenomic companies and tests out there. However, many of them are focused on only a one or a few indications, such as psychiatry. What we set out to do is not focus on a few indications but instead provide a comprehensive test that could provide valuable information to patients throughout the course of their lifetime. After talking to many providers and patients, we realize that an individual that may be treated for depression or some type of a psychiatric event often times has other clinical indications that they are addressing as well. Perhaps they could have diabetes or they could have hypertension or something else. Therefore, we cover 23 different clinical indications (including cardiovascular disease, cancer, chronic pain, psychiatric conditions, etc.) and to my knowledge there is not another pharmacogenomic company out there that has both the depth and the breadth of what we are covering to insure that you are looking at the whole individual, verses just one clinical indication or area at a time.

CEOCFO: *What has changed at OneOme since you became Chief Executive Officer?*

Mr. Owen: A number of different things. We are a technology company as well as a diagnostic company. I joined the organization in August of 2015 and since then we have built out a CAP (College of American Pathologists) accredited CLIA (Clinical Laboratory Improvement Amendments) lab to offer our 22 gene panel. We have built out a number of different products that allow the provider to have the information right at the bedside, which is very important to us. We have a clinical decision support tool that is interactive and can be built into an institution's EMR (electronic medical record). We have built haplotype and pharmacogenomic engines that allow us to look at, not just a drug to a single gene interaction, but the interaction that multiple genes (or enzymes) have on a drug's metabolism. This is an important process because there are many drugs that are metabolized by multiple genes. We utilize a combinatorial analysis of a patient's genes versus a single-gene analysis. This approach tells us how variations in multiple genes interact and affect the way a patient may respond to medications. We launched the product in July of this past year and we have signed contracts with a number of large health systems. We are in the process of getting them up and going and ordering tests from us. We are also in the process of working with a number of technology companies on building our decision support tool, so providers can have easier access to the information through their electronic medical records.

CEOCFO: *How are you able to get attention in a healthcare system that is so overloaded with ideas?*

Mr. Owen: The receptivity, both domestically and internationally, has been extremely strong! People are very intrigued! One of the things that we chose to do after I joined the organization last year was to go with an aggressive pricing model. We are very passionate about keeping our costs low, because we want to be accessible to all patients, regardless of whether they have healthcare benefits or whether the test would be reimbursed or not. After much market analysis, we decided that there would probably be a point where individuals would pay out of the pocket if they had to in order to get this product. Therefore, we came out with this product for \$249 dollars. The receptivity at the health system level has been quite strong, including at the senior leadership level of these institutions. They understand it, because they stay awake at night worrying about generating revenue and reducing costs, and this product helps them achieve that goal. If you look into any of the clinical literature about the health economics of pharmacogenomics there is a tremendous story, particularly when the test is only \$249 dollars. Doctors routinely order one-time, one-use tests every day with costs that far exceed the cost of our test. The great thing about our test, is that it provides on-going value to the patient throughout the course of their lifetime and we continually update our medication database so providers always have access to the latest information when making a prescribing decision.

CEOCFO: *Is it reimbursable or is that yet to come?*

Mr. Owen: Yes, there are specific genes that are reimbursable. It entirely ends up being about the indications that the patient is being tested for and what the payer is willing to reimburse for. Therefore, there is some pretty good data out there that certain genes are reimbursed under the right clinical indication. There are some genes like many of the cytochrome P450 genes that are often tested for that are reimbursed quite well. We also know that from a patient's perspective he or she can use his or her Health Savings Accounts (HSAs) to cover these.

CEOCFO: *Are you funded for your next steps? Are you looking for investments or partnerships?*

Mr. Owen: We are well funded at this moment. We were co-founded between Invenshure, a health care incubator Minneapolis-based company, and Mayo Clinic who both funded our Series A financing. We are in the process of doing strategic raises for a Series B.

CEOCFO: *Why is OneOme, LLC so important?*

Mr. Owen: OneOme allows you to take more control of your overall health. If you look at the statistics, 47.3 percent of the United States population has had one or more drugs prescribed to them in the last thirty days. What I really find surprising

is that almost 21 percent of the United States population has had **three** or more drugs prescribed to them in the last thirty days. I think the important factor is that many, many individuals are affected by medications throughout their lives and this test can help determine which medications will work best for them. Plus, since your genes do not change throughout the years you will be able to utilize the test results for different medications throughout your lifetime. We have worked very, very hard to make this affordable and as scientifically strong and clinically valid as possible for patients and providers to make informed prescription decisions.

