



Consumer Genomics Startup Genos Research Plans to Let Customers Explore, Share Their Data

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This story has been updated to correct details about a letter Sure Genomics received from the FDA and to include a comment from the company.

NEW YORK (GenomeWeb) – As the number of consumer genomics firms grows, Genos Research of California is planning to appeal to a different subset of customers with a new genetic testing and research service model.

The startup is currently recruiting a number of beta testers, including members of the Harvard Personal Genome Project, who for \$399 will get their exome sequenced at 75X coverage by a CLIA-certified laboratory and gain access to software to visualize their data and explore medical implications of their genetic variants. Starting this fall, Genos also plans to enable customers to share their data with researchers and to receive compensation for doing so.

Genos, based in Northern California, is a spinoff of Complete Genomics' consumer division and was founded by two former executives of that company: Cliff Reid, until last year CEO of Complete Genomics, who serves as Genos' executive chairman, and Mark Blumling, former president of Complete's consumer division and now Genos' CEO. The company recently completed a private equity financing, details of which it will reveal at its commercial launch, which is planned for the fourth quarter.

Reid left Complete Genomics after its parent company, BGI of China, said last year that it was shifting its strategy, turning Complete into an R&D organization to support its products and services. "My last act as CEO of Complete Genomics was to spin the [consumer] division into a separate company," Reid told GenomeWeb, adding that consumer genomics had been a personal interest of his, as well as of former BGI CEO Jun Wang. For the last couple of years, the division had been exploring the consumer sequencing market, he said, working with Bay Area design company Frog Design, but had not launched any products.

Genos aims to build a large cohort of individuals with sequenced exomes and genomes and to make their data available to the research community for a fee. A big difference between Genos and other consumer genomics firms that allow customers to donate their data for research, Reid said, is that Genos customers have more control over how their genetic information is used in research studies.

"The model is that you own your genome," Reid said. "All we are doing is being like an app store for data. When a researcher is paying to access a genome, they are not paying us directly, they are paying the individual, and we are taking a percentage in order to maintain a secure website."

Researchers will likely find this model attractive, he said, because Genos expects to be able to offer them a "very large database" of genomic data, combined with self-reported phenotypic and health-related data, at "a very low price," though pricing details are not yet available. In some cases, researchers will also be able to recontact individuals to obtain additional information. On its website, Genos promises researchers an initial cohort of thousands of whole genomes or exomes, but Reid said this many customers have not yet signed up.

Consumers might be inclined go with Genos for three reasons, he said: First of all, the company will sequence their exome and provide them with a list of their genomic variants, along with a genome browser to go through them and look them up in the ClinVar database, which provides detailed information on clinically significant variants. Customers can also download their variants as a VCF file.

"Individuals can go put on their scientist cap and go learn about their genome in the scientific literature," Reid said. "Sometimes that information is self-contradictory, and we're still at the early stages of researching the meaning of all of the variants in the genome, but there is a large body of literature already available."

Genos does not provide an interpretation of the variant data, stating on its website that its services are "not intended for diagnostic or prognostic use," and has no clearance from the US Food and Drug Administration or other agencies for its test. However, it does offer customers the option to contact a genetic counselor who, for a \$150 fee for a 1-hour session, can go over their genomic data and answer health-related questions.

Also, even though the firm's exome sequencing service is not a diagnostic test, it is physician ordered, meaning that a customer's online request is reviewed by a physician, who must sign off on it before the test kit is mailed out. Reid said the FDA recommended this approach to the company after initial conversations they had where he and his colleagues presented their business model.

Consumers also need to sign an informed consent form to learn about Genos' safety and privacy policies and to understand "the positive or negative consequences of learning about your genetic makeup," according to the website, even though the service is currently not considered a research study. The company also promises prospective research customers that all data they license will be consented for the purposes of their study.

The second incentive for individuals to sign up with Genos is that it provides an easy way for them to obtain their genome data and make it available, along with self-reported health information, to the academic research community at a low cost. "This is a way of being a philanthropist for \$400," Reid said.

Thirdly, customers can become entrepreneurs by licensing their own genome data for a fee, in particular to pharmaceutical and biotech companies who want to use the data to develop new products, he said. The size of the fee has not been determined yet.

"By having your genome sequenced, you can use it in these three roles, as a scientist, as a philanthropist, and as an entrepreneur," Reid said.

In this process, Genos will serve as a middleman between consumers and researchers, and as the data host.

After receiving a kit, customers ship their saliva sample to Genos, which will handle it in its CLIA-certified laboratory. Sequencing will be outsourced to CLIA-certified partner laboratories, using whatever sequencing platforms these have established. The lower cost of exome sequencing compared to genome sequencing was one consideration in starting with an exome test, Reid said, although longer term, the company plans to switch to whole-genome sequencing.

All data will be stored in the cloud by Amazon Web Services, which Reid said is HIPPA compliant and provides "extremely good" security, and Genos is currently determining how it will make the data available to researchers who license it.

Genos also allows individuals who already had their exomes or genomes sequenced through the PGP, and possibly elsewhere, to upload their data to Genos for free, so they can make it available to researchers through the company. "Our business is not to make money sequencing people, our business is to make money enabling researchers and individuals to connect and transact with each other," he explained.

Once it launches commercially, Genos will compete with a growing roster of consumer genomics firm that are vying for different segments of the market. Among the largest are 23andMe and Ancestry.com, which both currently rely on SNP-based genotyping and offer consumers ancestry information and, in the case of 23andMe, "fun genomics," such as predicted earwax type, as well as certain disease carrier status information.

More recently, Veritas Genomics, cofounded by Harvard Medical School researcher George Church, launched a \$999 whole-genome sequencing and interpretation service, called myGenome, that must be ordered through a customer's doctor.

Also, last year Sure Genomics announced a \$2,500 whole-genome sequencing service for consumers but earlier this year, the company received a letter from the FDA asking about clearance for its SureDNA test. Like Genos, Sure Genomics' test uses the Oragene Dx saliva sample collection device, which has FDA clearance for IVD use, but the FDA said in its letter that the SureDNA test "appears to meet the definition of a device" and therefore might need clearance. A company spokesperson told GenomeWeb this week that SureGenomics is "in active communication with the FDA to show compliance as we gear up for public availability in the late summer."

Another startup planning to offer whole-genome sequencing to consumers is Guardiome, which emphasizes customers' privacy and will not store their data for them, delivering it on a desktop storage device.

Finally, Illumina formed a consumer genomics company called Helix last summer that plans to launch its first product later this year. Illumina already offers consumers genome sequencing and interpretation services through its "Understand Your Genome" seminars.

How Genos and its business model will fare remains to be seen. "We're going to run a lot of experiments in the marketplace, reach out to different groups of individuals, and just find out where this approach to consumer sequencing resonates," Reid said. "That clearly won't be

with everyone, but we think this trio of being a scientist, a philanthropist, and an entrepreneur is likely to appeal to certainly some people, and we are going to find out exactly who they are."