



Sunquest Seeks to Grow Informatics Footprint in MDx Space With Recent Acquisitions

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NEW YORK (GenomeWeb) – With the acquisition of two informatics companies, GeneInsight and UniConnect, in the last year, laboratory software developer Sunquest is positioning itself as a provider of a complete software solution for molecular diagnostics and next-generation sequencing-based testing.

"Labs are really struggling to come up with a supporting IT platform that allows them to scale their operations, bring down costs, and to remove the complexity out of what is a really complex process," Chris Callahan, Sunquest's vice president in charge of GeneInsight, said. "Our strategy is to build a single platform on which all of this testing can be run and scaled so that this type of [testing] can become a standard of care."

Traditionally Sunquest's products have focused on anatomic and clinical pathology software products, "but now we are investing heavily in molecular pathology [because] we really feel it is an area of robust growth for our business in the future as the market itself expands," Nabil Hafez, Sunquest's senior director of product management, said.

Last April, Sunquest purchased GeneInsight from Partners Healthcare for an undisclosed amount. The deal followed a partnership between the two that dates back to 2014, which gave Sunquest 20 percent ownership of the company. Then in November, Sunquest added to its informatics portfolio by purchasing laboratory information management systems vendor UniConnect also for an undisclosed sum.

GeneInsight offers clinical genome interpretation and reporting capabilities for use in clinical and pathology laboratories. It includes tools such as VariantWire, which is a networking resource that allows laboratories to securely transfer genetic test results and integrate data with electronic health record systems. UniConnect markets software products built on UniFlow, a proprietary laboratory process management technology. Products built on the UniFlow platform include Precision Molecular Diagnostics, a software solution which is designed to support molecular diagnostic laboratories.

According to Callahan, the technologies are complementary solutions for both the wet and dry lab components of the diagnostics space. "By combining the two, you really have what you need to be able to scale and grow a molecular genetics testing program," he said. For example, by using GeneInsight, labs can compress the time required to interpret genetic tests by as much as 70 percent according to internal studies data.

Furthermore, researchers in these labs can do more of their own testing because they have the tools and the knowledgebases embedded in the software to do the interpretation in a more repeatable, standardized manner. "We give them the tools to do this stuff themselves and to keep [their] genetic testing in house," Callahan said. "That saves money and improves patient care because the turnaround times are better and the data is local."

GenelInsight, for example, is already integrated with the Epic electronic medical record system at Partners Healthcare, so patients who undergo genetic testing there can have those results integrated into their medical records. Besides Epic, Sunquest plans to integrate its solution with other EMR systems, Callahan said, and has begun discussions with Cerner, for example.

For its part UniConnect provides the requisite resources for managing lab workflows, including tracking materials, inventory, samples, and quality controls.

In addition, both solutions, as well as other Sunquest software, are registered as Class 1 devices with the US Food and Drug Administration. All of the firm's development centers are also listed with the FDA, Callahan added.

Sunquest currently sells both solutions separately, but it is working to integrate them into a single platform. Callahan said that while the firm is well on its way to doing so, it isn't finished. "We need to work on making sure that the solutions have the same interface, for example, and that the user-management aspects between the two are the same. But in terms of the data flow and the data modeling, that's work that we've already completed."

At least one client is already using the integrated solution internally — MedComp Dx, a spinoff of MedComp Sciences focused on providing genetic testing capabilities. MedComp Gx currently tests for inherited conditions with plans to add tumor testing in the near future. It initially tapped UniConnect's software to manage its real-time PCR testing activities, and when the company began developing an NGS platform last year, it tapped the GenelInsight platform to handle data and support its bioinformatics pipelines.

"We wanted a platform that could accommodate [quality control], had connectiveness to the broader scientific and diagnostics community, and was responsive to development," Paul Lang, geneticist and technical supervisor at MedCompGx, said, adding that he was especially impressed that GenelInsight was developed by people with expertise in regulatory requirements.

"When I interact with members of the team, I know that they understand what we have to accomplish from the diagnostic point of view [and] from the compliance point of view," he said.

Also with GenelInsight, "you can approach reporting and variant filtration from multiple paths, which means that if you have a diverse menu, there will be a solution to your problem ... and you can pivot fairly easily as opposed to having to take one approach and [force] it to work," Lang added.

Jason Walker, lead geneticist at MedComp Gx, expressed similar sentiments about the company's experience with UniConnect's Uniflow. He and his colleagues worked closely with UniConnect for three months developing an LIS for real-time PCR testing. "Their platform for molecular diagnostics was the most amenable to our workflow," he said.

Moving forward, Callahan said Sunquest will continue to monitor the market and plan their business activities around its movements. "Molecular and genetic testing is the future for our customers and for diagnostics in the US," he said. "We see both an opportunity because there's growth, but we see a need for it because of the complexity and the lack of mature systems in this place. This is exactly what information technology is meant to do, and these are the kinds of problems that software can help solve."

In terms of bringing the combined solution to market, the company is targeting two kinds of customers, including existing customers of its anatomic and pathology software solutions.

"There's the traditional Sunquest enterprise customer who uses Sunquest's LIS products in their institute or the hospital, and we want to make sure that once they are ready for the molecular component, we can support them with a comprehensive solution for both the LIS component and the analysis component," Hafez said. "With GeneInsight and UniConnect, when that enterprise customer is ready to bring on the molecular ... there'll be another Sunquest product that they can bring on."

Sunquest will also target laboratories that focus strictly on clinical genetics and NGS, "to provide that one comprehensive solution that can do everything for them both on the wet lab, as well as the analysis piece," Hafez said.

Sunquest will keep its eye on the next-generation sequencing-based testing market, as well. "Molecular testing has obviously been around a lot longer and it's a little bit further along the adoption curve than NGS-based testing, but it is absolutely a growth area for our customers and for the market, in general," Callahan said. He expects that GeneInsight will be a key solution for customers in this particular domain, particularly because it was specifically developed for genetic testing in clinical contexts rather than a repurposed research use solution.

"When we bought the company a year ago, it was a very robust mature technology [that had] been around since 2005, but [it] only had four customers," he said. "Today we have over 18 [and] we are planning to significantly increase our customer base this year."

In terms of NGS, the company sees interest in its solutions from two main sources. There are children's hospitals, which are interested in setting up genetic testing programs to test for inherited diseases; and cancer centers, which are interested in solutions to support somatic tumor profiling internally.

Particularly for cancer centers, "there's a really easy [return on investment] case for us to make," Callahan said. "[We can] go to them and say 'Using our solutions and our embedded knowledgebases, you can do this testing yourself, you don't have to send this out to any of a number of other labs and pay them \$5,000 to test.'"

Moving forward, Sunquest will continue to expand its software portfolio. As things stand, Callahan estimated that the company has about 80 percent of the capabilities in place needed to support the MDx market. One of the challenges is that this is an early-stage market that can change rapidly.

"We have to be honest with ourselves and say we don't know what we don't know," he said. "We need to continue to be open to the market's continued evolution."

Hafez expressed similar sentiments in his comments. "We think we have the core capabilities, but we are always on the lookout for promising new technologies or new companies that would help enhance our solutions or unlock new capabilities in the space."

One area that Callahan anticipates seeing some movement in the near future is in sequencing-data analysis. "Today we can solve for the bioinformatics part of the workflow in a number of ways ... but I would guess that sometime in the next two to three years, we would need to somehow standardize that and have that be out of the box," he said.

The company also anticipates increasing competition from pure play software companies and from instrument vendors that have beefed up their informatics pipelines in recent years and can couple these solutions to sequencers, making it easy for customers to move from sample to interpretation and reporting in fewer steps.

However Callahan said he isn't worried. There are companies that offer solutions for the individual markets, such as Illumina's GenoLogics, and Core Informatics, which develop and sell LIMS. There are also companies that offer bioinformatics solutions specifically for analyzing data associated with inherited diseases and cancer, such as Agilent's Cartagenia; Fabric Genomics, formerly called Omicia; GenomOncology; and PierianDx.

Some of these companies have also, in recent years, merged with other informatics companies to beef up their pipelines. For example, PierianDx recently bought Tute Genomics and Fabric Genomics bought Spiral Genetics earlier this year. While interest runs high in the space, "there's not anyone out there that has the breath and comprehensiveness of what we do," Callahan said. In terms of the instrument vendors, "I expect them to be competition to us at some point in the future [although] they are not there today ... But it's clearly their strategy and they are investing monies to that end."

Hafez also highlighted the company's ability to combine traditional clinical anatomy and pathology results with the results of molecular testing. "Over time, we are seeing hospitals increasingly talk to us about integrated diagnostics ... not a lot of companies out there can do that, so that's one strength [that] we can bring."

While Callahan acknowledged that vendors have the advantage of being able to couple their software with instruments, some clients may not want to be locked in to a single technology.

"I think there will be some clients out there that are just an Illumina shop [for example], but that will be the exception to the rule," he said.

The company is also looking to grow its customer base in the US and abroad. As part of those efforts, "we have looked into the approvals [required] ... We have work to do in the EU, but elsewhere we've found that our FDA listing suffices," Callahan said.

He added that the company recently secured a deal with an unnamed customer based in Japan.