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Pacific Biosciences to Launch First Application-Specific Sequencing Kit, For COVID-19 Surveillance

By Andrew P. Han

NEW YORK – Pacific Biosciences said this week that it is about to launch a kit and end-to-end workflow for sequencing the SARS-CoV-2 virus.

The application-specific assay will be the first of its kind for PacBio, which sees this type of product as a way to get an even larger share of money committed towards sequencing as well as drive adoption of its long-read platforms.

"One of our core strategies to accelerate the adoption of HiFi sequencing has been to develop end-to-end kitted solutions to make PacBio sequencing accessible to more labs and to simplify customer workflows," PacBio CEO Christian Henry told investors on a conference call on Tuesday following the release of the firm's third quarter financial results. Labs, especially in the US, have already been using PacBio's platform for COVID-19 surveillance, he said, but the company gets "such a small fraction of each sample, in terms of dollars, because we don't have a kitted solution."

Early-access experiments performed by Melissa Smith at the University of Louisville showed that the kit reduced hands-on time by as much as 80 percent, compared to PacBio's previous PCR-based protocol, developed with LabCorp, while also eliminating the transfer of samples between plates. "It's an extremely robust protocol," Smith said. "We see far more continuous genomes with the new kit, when pooled in a variety of fashions."

"We're excited to have the launch come so we can get our hands on a lot more reagents," she said.

The kit also reduces reagent usage and the amount of pipetting — an important factor, due to the widespread difficulty of obtaining certain pipette tips. Those global supply chain issues, which have already affected other sequencing providers, are starting to have an impact on PacBio as well. The company expects to see a 1 to 2 percent negative effect on gross margins over the coming quarters due to supply chain-related price increases and is anticipating competition for semiconductor chips in the second half of 2022.

Other global issues are looming, too. "There's macro factors that are completely outside of our control between the US and China that maybe I start to lose sleep over a little bit, " Henry said. "But based on what we control and what we can see and what customers are actually doing with our technology, we're quite encouraged, and we think the opportunity is still in front of us."

"We believe there remains a material amount of uncertainty in fourth quarter performance given potential international and supply chain issues," Canaccord Genuity Analyst Kyle Mikson wrote in a note to investors.

Henry also disclosed a collaboration with the Coriell Institute to produce a new high molecular weight DNA reference product, built around the company's recent acquisition of sample prep firm Circulomics and an outline of data from the firm's collaboration with Children's Mercy Research Institute.

PacBio posted record revenues of $34.9 million in the third quarter, but COVID-19 surveillance revenue is "still kind of hovering in the few million dollars a quarter [range,]" Henry said. "So I wouldn't say it was a significant contributor to the overperformance of the quarter."

Growth in the core business was the driving force and the company is on pace to break its record for most placements in a year. Nine orders in the quarter were from customers new to PacBio. The company also for the first time provided a breakdown of which applications drove revenues: Human germline sequencing accounted for approximately 33 percent, plant and animal genomics another 33 percent, microbiology and infectious disease 20 percent, and oncology and emerging applications 14 percent.

PacBio's HiFi sequencing, a protocol that boosts accuracy by distilling the highest quality circular consensus reads, continues to develop. The firm has collaborated with both Google Health and graphics processing unit maker and AI computing firm NVIDIA on software that reduces errors in HiFi reads by up to 40 percent.

Also, collaborator Children's Mercy Research Institute has now completed more than 600 HiFi genomes and has uncovered structural variants, single nucleotide variants, and repeat expansions related to disease that were not found with previous sequencing methods. "Specifically, HiFi whole-genome sequencing uncovered over four times more rare coding structural variants than short-read WGS and found variants and genes of unknown significance in over half of the undiagnosed cases," Henry said.

But the PacBio officials spent the most time talking about their new assay kit lineup.

"This is important for us to prove," PacBio Chief Operating Officer Mark Van Oene said. "To prove ourselves that we could kit a product," which includes sample preparation and back-end bioinformatics.

The sample prep step for the COVID-19 surveillance kit introduces target enrichment by using so-called molecular inversion probes, which Van Oene said reduces hands-on time. "If you compare that to the ARTIC PCR approach or other approaches that are on the market, you're going to see this really seamlessly plugs into existing automation and laboratory technicians just embrace this."

He and other officials said they would reveal more details at product launch but added that they're also preparing a kitted microbial genome assembly application for the Sequel IIe system. "This update doubles the current multiplexing capacity while continuing to deliver the industry's leading standard for reference quality microbial genomes," Henry said.

The company isn't stopping there. Gene therapy, CRISPR, synthetic biology, and even RNA isoform sequencing are all application areas that researchers are exploring with HiFi sequencing, and the company will follow suit by developing kits for them. "We can do it at a scale, now, that makes it very competitive and very compelling," Henry said. " I would look for us to be developing core kits around that, making those applications simple and easy to use, so customers around the world can get access to them."