Illumina Submits Companion Dx to FDA; China Business Flourishes Despite Disappointing Quarter

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Premium

NEW YORK (GenomeWeb) – Illumina has submitted a companion diagnostic test it developed in conjunction with pharmaceutical company Amgen to the US Food and Drug Administration for pre-market approval, the company said this week.

The submission is just one example of the company's continued move into the oncology market, Illumina CEO and President Francis deSouza said during a conference call discussing the firm's third quarter 2016 results.

Illumina reported lower-than-expected total revenues in the quarter and struggled with sales of its HiSeq instruments. However, its microarray and oncology business segments continued to improve and sales to China boomed, making China its second largest market outside the US. In addition, deSouza noted that whole-genome sequencing is a rapidly growing application enabled by the lower price point offered by the HiSeq X Ten.

Oncology

Illumina's oncology business grew 24 percent in the third quarter this year, deSouza said. The firm submitted its NGS-based companion diagnostic test that it developed with Amgen for its colorectal cancer drug Vectibix(panitumumab) to the FDA, and it is on track to launch its TruSight Tumor 170 assay initially for research use only in the fourth quarter this year, deSouza said. The TST170 panel follows the launch of the TST15 panel, which is available for both research and investigational use.

Illumina is also developing a universal CDx with AstraZeneca, Janssen Biotech, and Sanofi, but deSouza did not provide an update on that work.

Interestingly, deSouza said that reimbursement for oncology tests has been encouraging, which seems to counter what molecular diagnostic companies have said in regards to reimbursement. For instance,

while Foundation Medicine reported that the number of tests it ran in the second quarter 2016 increased, the average reimbursement rate has declined to around $3,000 per test from a high of $3,600 per test at the end of 2014.

DeSouza, however, noted that the use of NGS oncology panels is growing among Illumina's customer base. And, he said there have been "encouraging signs for reimbursement."

Earlier this month, for instance, the Centers for Medicare and Medicaid Services issued final pricing determinations for several tests, including NGS-based tests for hereditary breast cancer, increasing its final determination to $925 per test from a previously proposed rate of $623 per test.

"We're not seeing headwind from reimbursement," deSouza said.

DeSouza did not provide an update on Illumina's spinoff company Grail, which is developing a circulating tumor assay for early cancer detection. But, he said, the team is "making good progress on defining the assay" and expects to release data in the second half of 2017.

China

Continuing on a trend from last quarter, sales to Chinese customers continued to increase, driven by the country's Precision Medicine Initiative, as well as rapid adoption of NGS in the clinic. Revenue from Chinese customers increased by more than 85 percent in Q3 2016.

The Chinese market is growing faster than expected, deSouza said, and is now Illumina's "number two country market in the world." In particular, deSouza noted that Chinese customers have been purchasing the HiSeq X systems either because they have been tapped to be a service provider for the Chinese PMI or in anticipation of being a service provider for that project. Meanwhile, the NextSeq system has been popular among Chinese clinical customers, particular for those running noninvasive prenatal screening tests.

HiSeq woes

The launch of Illumina's HiSeq X Ten system in 2014 has helped drive the human whole-genome sequencing market. Whole-genome sequencing now makes up 15 percent of all high-throughput sequencing runs, deSouza said, up from just 2 percent of NGS runs two years ago.

Nevertheless, sales of the HiSeq family of instruments, in particular, the HiSeq 2500 and 4000 systems, declined this quarter. In addition, funding changes, capital constraints, and lab readiness contributed to fewer HiSeq X units shipping than expected.

DeSouza said that while Illumina had around 90 HiSeq X units in its backlog, 60 of which it expected to ship in the second half of this year, it was now removing 35 units from that backlog.

However, he said in the US there are projects in place that will require more than 100,000 genomes to be sequenced in the coming years. He also noted that France plans to establish a population sequencing project, and as such he continues to "believe that sequencing sample growth remains robust."

Not everyone was convinced, however, and thought that Illumina's HiSeq sales decline was instead an indication that the market was saturated.

Joseph Munda, an analyst with First Analysis, wrote in a research note following the earnings call that Illumina's assertion that overcapacity was not a problem was "difficult to swallow," and said that based on conversations with customers, "overcapacity is a problem." Munda added that many "multi-instrument research customers we spoke with seemed more interested in purchasing a long-read sequencing technology," like those being developed by Pacific Biosciences and Oxford Nanopore, "than another Illumina sequencer."

Isaac Ro with Goldman Sachs also noted that "saturation in core academic markets" could be a key issue in 2017, adding that "improvements to usability and applications" would be needed to double the firm's installed base of approximately 10,000 instruments.

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