



Illumina Plans to Launch NovaSeq Accessory; Sees Reimbursement Progress for NIPT

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Premium

SAN FRANCISCO (GenomeWeb) – Illumina said that it plans to launch an accessory device for its newly launched NovaSeq instrument that will enable customers to run different types of sequencing applications on different lanes of the flow cells.

During a conference call discussing the firm's [first quarter 2017 results](#) this week, CEO Francis deSouza said that the company planned to launch the accessory and consumables in the fourth quarter of 2017, shortly after the launch of its S4 flow cell.

Also during the call, deSouza said that the firm has seen reimbursement rates pick up for both noninvasive prenatal testing as well as exome sequencing for undiagnosed rare diseases, and continues to see strong demand from China customers driven in part by the China Precision Medicine Initiative and China Food and Drug Administration approvals of NIPT.

The new NovaSeq accessory product will enable customers to use less input DNA as well as to run multiple types of sequencing experiments in one run. In addition, deSouza said it would help alleviate the issue of index switching that [some customers](#) have experienced on the HiSeq 4000.

DeSouza said that the firm decided to develop the accessory product based on feedback from customers, who wanted to "address each lane of the flow cell independently." The device, associated consumables, and workflow will "allow customers to load different projects, libraries, and applications in each lane," deSouza said.

In a research note, Amanda Murphy, an analyst with investment bank William Blair, wrote that the new product could "ultimately catalyze further orders" of the NovaSeq "from labs with relatively higher diversity in sequencing applications." She added that the bank has received feedback from some core labs that the current configuration of the NovaSeq — having to pool different libraries and applications on the flow cell — has "given pause" to some labs considering the instrument.

"Users are concerned about the complexities introduced by variations between user library types and insert sizes, for example," she wrote. "Moreover, without pooling libraries across multiple applications, many of these labs would have difficulty accessing the advertised economics of the NovaSeq." As such, she said that the accessory product could help drive further adoption.

With regards to the index switching issues that customers reported experiencing with the HiSeq 4000, deSouza said that he did not expect that to be an issue with the NovaSeq. In addition, he said that aside

from a few customers who have had highly elevated levels of index switching, for most customers, the problem affects a very small number of reads and "hasn't had an impact on results for most applications." He said that the company is now working with customers who have had problems.

Clinical markets

Illumina continued to make progress in growing its two major clinical markets: reproductive health and oncology.

Illumina said that it expects reimbursement for NIPT in the US to continue to increase among both private payors and Medicaid. DeSouza said that the Coalition for Access to Prenatal Screening, a group of five genetic testing firms that includes Illumina, Natera, Counsyl, Progenity, and the Laboratory Corporation of America's Integrated Genetics, has made progress in talking to state Medicaid programs about the updated [fee schedule](#) for NIPT. In Q1, the coalition contacted most state Medicaid offices, and more than 20 percent are now in the process of reviewing fee schedules and four are already in the process of increasing them, deSouza said.

Outside of the US, the firm recently launched VeriSeq NIPT as a CE-IVD marked test in Europe. Both the Netherlands and Denmark now cover NIPT and a coverage decision for NIPT is expected soon in France, deSouza noted.

Shipments in the oncology space grew by 20 percent, driven by commercial molecular diagnostic customers as well as the growing liquid biopsy segment, deSouza said.

Aside from its core clinical markets of reproductive health and oncology, Illumina recently began efforts to drive adoption of exome sequencing for patients with rare, undiagnosed diseases. "This market is progressing well," deSouza said, and to date around 50 million lives are covered under contract by payors who will reimburse an exome test for pediatric patients with a suspected genetic condition.

Chinese customers have played a big role in growing Illumina's clinical markets in particular, and sales to Chinese customers represent roughly 10 percent of Illumina's business, deSouza said. "It's a market we're excited about," he added.

The China Precision Medicine Initiative has driven much of the demand, and deSouza said that projects under that initiative are now being funded and moving forward, which he expects to continue to drive demand. "We remain bullish on the Chinese market opportunity," he said.

Outside of the Chinese PMI, commercial labs in China continue to make progress in developing the NextSeq for clinical use, particularly NIPT applications. Berry Genomics has been running its NIPT assay on a version of the NextSeq that received China Food and Drug Administration [approval](#) in 2015. Recently, Beijing-based Annoroad received CFDA approval for its version, the NextSeq 550AR, as well as its assay for NIPT. Illumina has been [collaborating with Annoroad](#) to develop NGS-based clinical tests since 2015.

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