QIAGEN Unveils Initiative to Create Next-Generation Sequencing Portfolio for use in Clinical Research and Molecular Diagnostics

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- **Aim to expand next-generation sequencing beyond current focus on life sciences research**
- **QIAGEN plans to offer sample-to-result workflows that integrate its sample preparation and assay products with a next-generation benchtop sequencer and new bioinformatics**
- **Initiative combines broad range of QIAGEN products with acquisition of sequencing specialist Intelligent Bio-Systems, Inc. and a new strategic collaboration with SAP AG**

QIAGEN N.V. (NASDAQ: QGEN; Frankfurt Prime Standard: QIA) today unveiled an advanced initiative to enter the field of next-generation sequencing (NGS) that aims to establish these technologies as routine processes used in new areas such as clinical research and molecular diagnostics.

QIAGEN is in the advanced stages of creating sample-to-result, efficient and cost-effective NGS workflow solutions. These will combine a broad range of QIAGEN products - including automated sample preparation solutions (nucleic acid extraction, DNA enrichment, library preparation and targeted gene analysis panels) - with a previously undisclosed next-generation benchtop sequencer in development with Intelligent Bio-Systems, Inc., a privately held company that QIAGEN has acquired. New bioinformatics, including solutions emerging from a new collaboration with SAP AG, will be incorporated into the workflows. A first sample-to-result NGS solution is expected to be launched next year, while details on specifications and launch plans are set to be released in early 2013.

"The rapid advances in next-generation sequencing have enabled life science researchers to unlock many secrets about the molecular building blocks of life. Our ambition is to create a new dimension of benefits for these technologies by offering workflow solutions for clinical use, particularly to develop new medicines and improve healthcare with advanced diagnostics," said Peer M. Schatz, CEO of QIAGEN N.V. "While next-generation sequencing is viewed today mainly as a research tool, our initiative is to expand beyond this and to offer applications designed to address the needs of customers in clinical research and molecular diagnostics."

Key elements of this initiative include:

- **Content:** The development of a broad portfolio of gene panels designed for NGS analysis based on QIAGEN's extensive offering of molecular content, including

GeneGlobe (http://www.geneglobe.com), an online portal that offers access to more than 60,000 well-defined and characterized molecular assays. In the first wave, QIAGEN plans to offer eight preconfigured gene panels for use in cancer, as well as enable customers to create customized panels for specific molecular pathways and diseases.

- **Sample technologies:** An extensive range of NGS sample preparation products is planned to be launched that are based on QIAGEN's global leadership position in sample technologies and enzymology.
- **NGS module:** A previously undisclosed NGS benchtop sequencer is in late stages of development with Intelligent Bio-Systems, Inc. (IBS), a privately held U.S. company that QIAGEN has acquired. This novel system can process multiple samples in parallel with highest flexibility and performance, and benefits from the use of proprietary sequencing by synthesis (SBS) technology exclusively licensed from Columbia University.

  Building on elements of previous IBS designs as well as on QIAGEN technologies, this new system - which is expected to enter beta testing with customers in 2012 - seeks to offer a new dimension of benefits and cost savings. Key features include new sample technologies and software as well as the ability to process up to 20 individual samples in parallel without a need for pooling and bar-coding, which can result in significant time and cost savings in clinical sequencing. Its design allows for flow cells and reagents to be loaded continuously while in operation, and also for up to 20 different assay types to be processed simultaneously and in random order. Many of these features - particularly the parallel processing of multiple samples and continuous loading of reagents and random samples - are considered essential for clinical sequencing. Two automation alternatives are being developed in combination with QIAGEN platforms to create workflow solutions from biological sample through to final result. One workflow integrates the NGS module into the QIAsymphony automation family, while a second is based on the QIAcube automated sample preparation system. Both workflows will offer extensive bioinformatics, including from the SAP collaboration. Financial terms of the IBS acquisition, which was completed during 2012, were not disclosed.

  "We are very excited to join forces with QIAGEN, which is an ideal partner to bring our new ultra-low cost sequencing technologies to the market as part of a complete workflow that will expand our product's use into new areas," said Steven J. Gordon, Ph.D., CEO and founder of Intelligent Bio-Systems. "We can deliver greater value to our customers from our novel technologies by leveraging QIAGEN's leadership in sample preparation, advanced gene panels and global reach along with the bioinformatics expected to emerge from the collaboration with SAP. Our goal is to better address the demands of clinical and core lab customers for complete solutions, since many have been struggling to adapt existing sequencing platforms to their workflows."
- **Bioinformatics:** SAP and QIAGEN are collaborating on bioinformatics efforts aimed at significantly reducing the time required for the analysis of sequencing data. The basis for the collaboration will be to apply the breakthrough SAP HANA® platform in next-generation sequencing interpretation. Reducing this time period is seen as an important factor in driving greater use of sequencing technologies in new areas and reducing overall operating costs.

"Rapid and accurate sequencing, assembly and interpretation of genomes represents a great challenge of our times in healthcare," said Dr. Vishal Sikka, member, Executive Board, SAP AG. "SAP HANA brings a dramatic acceleration to the data analysis challenges at the heart of genomics. We at SAP are very excited to collaborate with QIAGEN on this extraordinary opportunity to transform the biological sciences and help improve people's lives."

QIAGEN intends to offer this new product portfolio across all of its customer classes, with priority focus on clinical research in Academia and Pharma as well as in some Molecular Diagnostics franchises, including select areas of Personalized Healthcare.

The next-generation sequencing market, which up to this point has been driven primarily by life sciences research, is estimated to be more than $1 billion a year and growing rapidly as the use of these technologies expands into new areas.

QIAGEN is a pioneer in enabling the use of biomarker data to guide treatment decisions through companion diagnostics based on real-time PCR technologies as well as a portfolio of sequencing-based diagnostic assays based on its Pyrosequencing® technology. Together with its portfolio of next-generation sequencing technologies, QIAGEN can offer customers workflows that include the widest range of sample technologies to collect and process nucleic acid samples as well as leading assay and data analysis technologies for use across its customer classes in Academia, Pharma, Applied Testing and Molecular Diagnostics.

The adoption of next-generation sequencing in clinical research and molecular diagnostics is still hampered by workflow challenges, particularly time required for data analysis as well as regulatory uncertainties and sequencing costs. The various features in this initiative seek to address these challenges, and could lead to NGS technologies being adopted in certain areas such as exploratory diagnostics, the diagnosis of complex diseases and treatment of cancer patients. NGS technologies are also expected to complement established routine molecular technologies such as real-time PCR.

QIAGEN currently anticipates the investments planned to create this new NGS portfolio to be dilutive to adjusted EPS (earnings per share) by approximately $0.01 for full-year results in 2012 and by approximately $0.02 in 2013, but to be accretive to full-year results in 2014.

About QIAGEN:

QIAGEN N.V., a Netherlands holding company, is the leading global provider of Sample & Assay Technologies that are used to transform biological materials into valuable molecular information. Sample technologies are used to isolate and process DNA, RNA and proteins from biological samples such as blood or tissue. Assay technologies are then used to make these isolated biomolecules visible and ready for interpretation. QIAGEN markets more than 500 products around the world, selling both consumable kits and automation systems to customers through four customer classes: Molecular Diagnostics (human healthcare), Applied Testing (forensics, veterinary testing and food safety), Pharma (pharmaceutical and biotechnology companies) and Academia (life sciences research). As of March 31, 2012, QIAGEN employed

approximately 3,900 people in more than 35 locations worldwide. Further information can be found at http://www.qiagen.com/.

About Intelligent Bio-Systems, Inc.:

Intelligent Bio-Systems, Inc. was founded in 2005 by Dr. Steven Gordon and Dr. Jingyue Ju to commercialize advanced sequencing technologies and patents from Columbia University. Next-generation sequencing refers to methods of analyzing DNA that began to emerge in the 1990s to improve upon earlier sequencing approaches that were time-consuming and laborious. Intelligent Bio-Systems' newer generation of sequencing by synthesis (SBS) technology incorporates proprietary advances in DNA sequence readout and DNA sample preparation, enabling low-cost, high throughput sequencing with high-quality data, making it attractive for customers.

https://www.prnewswire.com/news-releases/qiagen-unveils-initiative-to-create-next-generation-sequencing-portfolio-for-use-in-clinical-research-and-molecular-diagnostics-160283625.html