

Agilent Aims to Ramp up Early-Stage CDx Development Deals

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NEW YORK – Despite its recent divestiture of Resolution Bioscience, an Agilent executive said the company plans to forge more partnerships with pharma firms early in drug development to facilitate early-stage biomarker development and testing during clinical trials, providing Agilent a robust companion diagnostics pipeline as promising therapies come to market.

"We've been very successful in the later-stage companion diagnostic development, but our goal is to move earlier in the assay development spectrum," said Paul Beresford, vice president and general manager of Agilent's Companion Diagnostics Division.

In the first half of 2024, the Santa Clara, California-based firm plans to open in its CLIA-accredited BioPharma Services Lab that will integrate immunohistochemistry development and testing. Beresford said Agilent plans to apply the capabilities from that Carpinteria, California-based lab and the firm's established reputation as a life sciences tools developer to take on an expanded role in drug development from feasibility studies through the launch of commercial companion diagnostics. That includes helping companies decide which biomarkers can be used to determine whether a candidate therapy is working and whether technologies such as mass spectrometry, flow cytometry, or next-generation sequencing would be the best choice to identify those biomarkers.

When those partners' therapies arrive on the market, Agilent will have a head start in developing the tests to guide their use.

Though Agilent recently shed its Resolution Bioscience subsidiary that developed companion diagnostics, Beresford said the firm remains invested in other aspects of the companion diagnostics space. Agilent [announced last month](#) it was selling the Resolution liquid biopsy business to Exact Sciences for undisclosed terms, granting a reprieve to the business Agilent had [planned to shutter](#) due to what it deemed a disappointing market for kitted next-generation sequencing-based companion diagnostics.

Despite that setback, Agilent has [continued bringing](#) companion diagnostics to market and has been [forging deals](#) to expand access to those tests.

During the past year, it has announced to deal in the CDx space including in January a [collaboration with Akoya](#) to combine Agilent's Dako Omnis autostaining instrument capabilities with Akoya's Phenolmager HT imaging platform for tissue biomarker analysis in companion diagnostic development. The firms said they plan to develop chromogenic and immunofluorescent assays for use by biopharma companies as they develop and validate biomarkers for precision cancer therapeutics.

Agilent also announced early in the year it had [inked a multiyear partnership](#) with PathAI to apply PathAI's algorithm development expertise and Agilent's workflow expertise toward development of companion diagnostics and other assays. Under the latter agreement, Agilent also will distribute

PathAI's AI Sight and AISight DX+ software and AIM PD-L1 NSCLC algorithm to anatomic pathology labs.

According to Beresford, pharma has been moving ahead rapidly to develop new antibody-drug conjugates (ADCs) that could be administered to a wider range of patients than stand-alone drugs, and immunohistochemistry assays will be key to identifying the right patients for those therapies. He cited as an example AstraZeneca and Daiichi Sankyo's Enhertu (trastuzumab deruxtecan) ADC for treatment of patients with HER2-low cancers, which provides a treatment option for patients who were ineligible for treatment with Herceptin (trastuzumab) alone.

"IHC technology, it's a little long in the tooth, but, ultimately, there's a lot of runway for this technology to be relevant clinically because it's a very important component of how people diagnose, prognose, and ultimately provide therapy to patients," he said. "And with the addition of things like multiplexing, digital imaging, or using artificial intelligence, you're able to extract additional information out of those slides that are stained for various markers."

Beresford noted that Agilent worked with Merck on the commercialization in more than 90 countries of Agilent's PD-L1 INH 22C3 companion diagnostic assay to help select patients for treatment with Merck's Keytruda (pembrolizumab). The assay is a companion diagnostic for use in lung, breast, cervical, esophageal, and head and neck cancers.

Agilent is also collaborating with several companies on companion diagnostics to guide treatments with ADCs, including Sanofi's experimental tusamitamab ravtansine ADC targeting the CEACAM5 glycoprotein that is expressed in non-small cell lung cancer, gastric cancers, and other malignancies. That drug is in Phase III clinical trials.

He declined to name other partners but said Agilent is also developing tests that could be used to help select patients for anti-HER2 ADCs for breast and gastric malignancies, among other potential therapies.

Beresford sees similarly high activity in immunotherapy-drug combinations. In addition to Agilent's PD-L1 IHC 22C3 pharmDx test, and he said the next wave of companion diagnostics development could involve identifying which patients will benefit from Keytruda in combination with immunomodulators or other targeted therapies.

Last week, Merck officials [described their plans](#) to develop new targeted therapy combinations and build on their pipeline of ADCs. That includes clinical trials of the TROP2-targeted ADC MK-2870 in combination with Keytruda in patients with solid tumors.

To be sure, other firms are also partnering with pharma companies in the CDx space. For example, Revvity has [made similar moves](#) toward expanding its partnerships in early-stage drug R&D, from biomarker discovery onward, as part of the firm's shift toward becoming a key partner for pharma companies. Company officials said those collaborations provide insights into what new treatments will emerge and where the company should focus its own diagnostics development pathways, and the recent divestment of the PerkinElmer applied, food, and enterprise services businesses this year has revitalized the firm's diagnostics and life sciences technologies.

Revvity Chief Scientific Officer Madhuri Hegde said in a statement that the company has a long history of partnering with pharma companies during the drug discovery process, and he cited as a recent example an announcement in May that it had [inked a licensing agreement](#) for AstraZeneca's use of Revvity's Pin-Point base editing system to develop cell therapies for the treatment of cancer and immune-mediated diseases. He said the firms that partner with Revvity in those early stages benefit from the continuity of the firm's services throughout the drug development lifecycle.

"We bring comprehensive capabilities and expertise that encompass target discovery, lead optimization, and clinical development," he said. "This includes IVD and development of companion diagnostics."

Roche subsidiary Foundation Medicine also has partnerships with pharma companies to develop companion diagnostics for therapies under development by [Merck KGaA](#) and investigational therapies by firms such as [Bristol Myers Squibb](#), [Boehringer Ingelheim](#), and [Relay Therapeutics](#).

Beresford said precision oncology is undergoing incredible innovation and Agilent aims to become a one-stop shop for early-stage research that will advance translational medicine and commercialization of the IVDs for those technologies. He said the company brings to that challenge a strong research tools portfolio including mass spec, cell analysis, flow cytometry, IHC, and next-generation sequencing.

"Agilent as a whole is really excited to have that opportunity to translate these new technologies, attach them to clinical data, and ultimately act as that translational medicine tool to help researchers as well as biopharma achieve their goals in translating those biomarkers into the commercial arena," he said.

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