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Roche Aims to Become End-to-End Oncology Solutions Provider With New Acquisitions

May 12, 2026 | Kelsy Ketchum

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NEW YORK – With two recent pending acquisitions under its belt in the cancer diagnostics space and its new sequencing instrument set to launch later this year, Roche is aiming to provide end-to-end solutions throughout oncology market, from early detection through therapy selection and monitoring, executives said during the firm's diagnostics day on Tuesday.

In addition, the company touted its multiple upcoming launches in the core lab, molecular lab, and point-of-care diagnostics arenas.

With the recently announced $1.05 billion acquisition of PathAI, Roche sees use cases for both its diagnostics and pharmaceutical businesses, said Roche CEO Thomas Schinecker. There is "strong synergy" with the company's existing advanced staining business, as well as an ability to use PathAI's tools for research, he said.

The PathAI technology is complementary to the firm's Ventana tissue-based pathology business and has "high levels of complementarity" to the pharma services businesses in pathology and at Foundation Medicine, Roche Diagnostics CEO Matt Sause said. Through PathAI, the company will be able to engage earlier with pharma companies to build companion diagnostic programs, and the new acquisition forms a "key part" of the company's oncology strategy, Sause said.

And with the $595 million acquisition of Saga Diagnostics announced last month, Roche subsidiary Foundation Medicine will gain a new tool in the disease monitoring market with the firm's Pathlight MRD technology. Foundation Medicine CEO Dan Malarek noted that the company is excited about Pathlight MRD due to its demonstrated ability to detect disease recurrence early and its existing Medicare approval for early-stage breast cancer across all subtypes.

Malarek noted that Saga has also launched an assay for colorectal cancer and has studies in ovarian cancer, and Foundation will "further invest in driving clinical evidence in other indications," including lung cancer.

The firm's new sequencing instrument, Axelios, will also play a role in Roche's transition to becoming a major oncology player, as it is already being used in early access at Foundation Medicine and at sites around the US and Europe. Sause added that Axelios is the "key to drive the future of molecular-based oncology testing."

While Sause declined to provide the firm's specific market share ambitions, he noted that the company expects Axelios to be an "accelerant on our growth" and expects to capture significant market share. In Sause's view, a successful launch would be placing 100 systems in the first year, and the company already has orders for the instrument across the globe.

Josh Lauer, Roche's global head of molecular lab, noted that sequencing will be "a very significant platform in clinical diagnostics," adding that Foundation Medicine has demonstrated the power of Axelios in minimal residual disease.

Foundation Medicine is implementing Axelios into its clinical workflows and plans to onboard the platform into its service sites across Europe. Axelios is "something we're extremely excited about" and provides the potential for better turnaround times and a lower cost base, Malarek said. Its capabilities "will also enhance our offerings to our biopharma partners and enable us to further differentiate," as well as allowing Foundation to "enhance our own internal developments in what we're able to provide in terms of services to our pharma partners," he added.

Roche also has a "strong position and optionality" in the early detection market through its commercialization and licensing partnership with Freenome to commercialize that firm's cancer screening products in certain markets, Sause said. Lauer added that Roche will work with Freenome to determine what Axelios can do in terms of multi-cancer early detection and enabling decentralized testing.

The firm has "built a unique set of assets that span the entire continuum of testing" in oncology, he added.

Beyond oncology

The company is also working to expand its core lab offerings, as core lab makes up the largest share of its diagnostics business. One of its recent instrument launches, the Cobas I 601 mass spectrometry instrument, is targeting an installed base of 100 instruments by the end of this year and has already launched 39 tests in countries that accept the CE mark, with the goal to launch four more by the end of 2026, said Palani Kumaresan, global head of Roche Diagnostics Solutions.

The US makes up the biggest market for the I 601 mass spec platform, which along with six steroid tests and a test for vitamin D, has received US Food and Drug Administration 510(k) approval. Kumaresan said the firm is actively working with the agency to bring the rest of its existing tests through the 510(k) market by the end of this year and into early next year.

The company is also working on the next wave of mass spec tests it plans to launch, targeting drugs of abuse testing.

Also in the core lab space, Roche is developing its Cobas Smart E instrument for low-volume laboratories, which Sause said will be "critical to enable our market capture" of the firm's upcoming tuberculosis IGRA test launch. Intended to be a successor to the firm's Cobas E 411 instrument, which Kumaresan said has a "very healthy installed base" of more than 18,000 instruments, the new platform will use the same reagent cartridge as Roche's other immunoassay platforms and will launch toward the end of 2026 in countries accepting the CE mark.

In the pathology lab business, the company is working on a next-generation advanced staining platform with Hitachi that will replace its existing Benchmark Ultra Plus system, Kumaresan noted.

Laura Apitz, head of pathology at Roche, added that the company is working on a self-collection solution for sexually transmitted infections and HPV testing that it intends to launch next year.

Within the near-patient care segment, Roche is aiming to launch the Cobas Sense platform, a benchtop analyzer intended for use in the emergency room. That instrument will launch in 2027 with a high-sensitivity troponin test, with plans to launch other cardiac tests in the future. The test has

demonstrated excellent correlation between the point-of-care version and laboratory-based tests and shown lab-like performance, said Ildiko Amann-Zalan, head of R&D for Roche Diagnostics Solutions.

The company is also investing heavily in its point-of-care LumiraDx business, with plans to launch an HbA1c test in 2027 and a lipid panel in 2028.

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