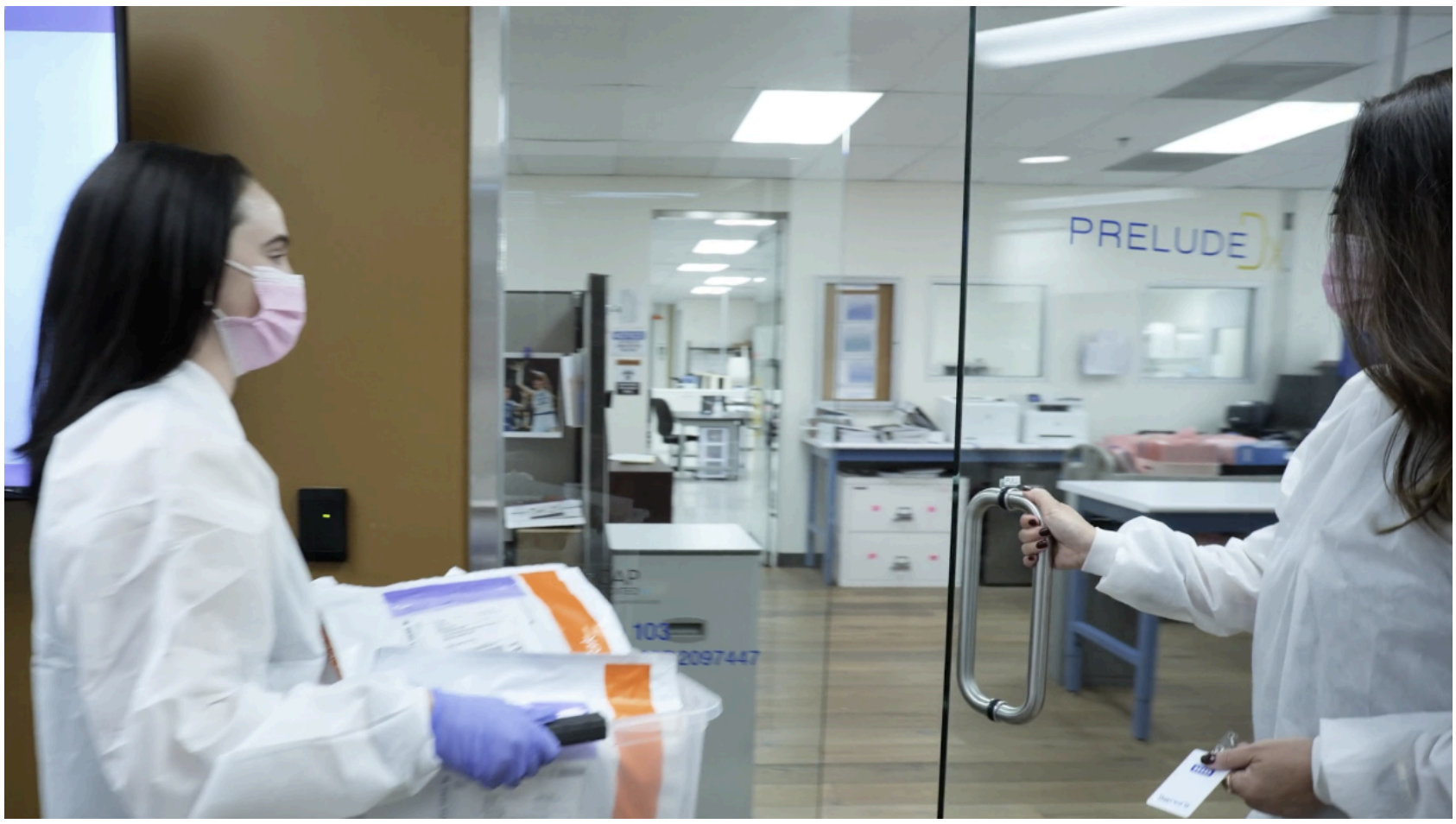
HEALTH CARE

# PreludeDx Nears $40M with New Breast Cancer Test

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*PreludeDX counts 100 employees at its Laguna Hills office*

LAGUNA HILLS — PreludeDx is on track to generate $40 million in revenue this year as it seeks reimbursement for its next-generation risk assessment test for early-stage breast cancer.

In April, the FDA granted breakthrough device designation for AidaBreast, the Laguna Hills-based firm's new test designed to assess a woman's 10-year breast cancer recurrence risk and predict whether radiation therapy is likely to improve her outcome. The test is designed to help some women avoid unnecessary treatment and its side effects.

"If you don't use these tools, you're going to get the treatment wrong potentially about half of the time," Dan Forche, chief executive and president of PreludeDx, told the Business Journal during a tour of the company's Laguna Hills facility.

It marks the second breakthrough designation for Prelude.

The company's first test, DCISionRT, was made to detect Stage 0 non-invasive breast cancer that's contained in the milk duct and hasn't spread to surrounding tissue. It received breakthrough designation in 2024.

Both tests fit into the company's mission to help reduce overtreatment with radiation therapy.

"Would you take a drug if it wasn't going to benefit you? No, you would not," he said. "It's the same thing here. Why would you get radiation if you didn't have to?"

Founded in 2009, Prelude is a portfolio company of Fjord Ventures, a venture capital firm and startup accelerator founded by Olav Bergheim. Fjord's other portfolio companies include Sonendo Inc. and Adagio Medical Holdings Inc.

## AidaBreast Triples Addressable Market

"The only thing we do is breast cancer," Forche said.

Breast cancer is the second most common cancer among U.S. women after skin cancer. Last year, more than 316,000 women were projected to be diagnosed with invasive breast cancer and about 60,000 with noninvasive disease.

AidaBreast triples Prelude's market size beyond the roughly $500 million addressable market for DCISionRT, according to Forche.

Women with early-stage breast cancer are typically treated with breast-conserving surgery followed by radiation therapy to destroy remaining cancer cells and lower the risk of recurrence.

The challenge, Forche said, is that many patients receive radiation unnecessarily.

Studies show that only 15% of women benefit from radiation therapy, which can cause burns and infections in the short term and longer-term complications such as changes in breast texture and lymphedema, according to Prelude Chief Scientific Officer Troy Bremer.

"There are too many consequences, and the challenge has been to find out for whom it's needed in," Bremer said.

## Test Used by UCI, City of Hope, St. Joseph

The FDA's breakthrough device program is designed to accelerate development and review of promising technologies.

AidaBreast and DCISion RT are currently available as laboratory-developed tests (LDTs).

About 2,600 physicians nationwide have ordered DCISion RT, according to Forche.

Locally, the test is used by UCI, City of Hope and Providence St. Joseph Hospital in Orange.

Prelude has provided DCISionRT in Australia through a partner since 2019 and also has a presence in parts of Europe and South America, though the company's primary focus remains the U.S. market.

Last year, a federal court in Texas overturned a controversial rule that gave the FDA authority to regulate LDTs as medical devices, stating they are services

under Clinical Laboratory Improvement Amendments (CLIA), overseen by the Centers for Medicare & Medicaid Services.

Despite this, Forche said that Prelude continues to work with the FDA.

“The right way to approach this, given that it is an LDT, is making sure you synchronize between the two sides of CLIA and the FDA,” Bremer said. “It’s just not done very often for LDTs.”

Licensed Biomarkers from UCSF

Prelude had about five employees when Forche joined the company from Irvine-based Pathnostics.

Today, the company has grown to 100 employees.

“We’ve seen that growth, but it takes time,” Forche said. “It doesn’t happen overnight.”

Prelude’s initial three biomarkers were licensed from the University of California, San Francisco (UCSF).

Bremer said the underlying discovery was made by a professor and patented by the university.

He first learned of the biomarkers around 2006 through the late Dr. Susan Love, known for her pioneering work in breast cancer research.

“I had been interested in early-stage disease, and she knew I was looking for biomarkers,” Bremer said.

It took eight years from licensing the technology to develop a commercially viable test.

Both assays generate a score from zero to 10, with anything below three considered lower risk. Women in this group have about a 5% risk of recurrence over 10 years without radiation therapy.

Traditionally, doctors determined risk based on broad characteristics such as age and tumor size, according to Bremer.

“What we’re doing is personalizing information for them based on their tumor biology,” he said.

DCISionRT analyzes seven protein biomarkers within the tumor that act like “fingerprints,” revealing how fast it grows, how sensitive it is to hormones and more.

“These biomarkers by themselves don’t really help you very much, but together they tell a story,” Bremer said.

AidaBreast expands that approach with a panel of 20 proteins.

The test maps where proteins are located within the tumor environment and measures RNA expression from 329 genes, using AI to generate an individualized risk assessment.

Currently, the company is focused on radiation therapy assessment, with plans to eventually add endocrine therapy and chemotherapy response to its pipeline.

“Our goal is to really own early stage,” Forche said. “If we can treat women early, they don’t have to be a stage III or IV patient where it’s metastatic.”