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Biofidelity attracts $23M series A investment to launch lung cancer test

By Catherine Longworth

Cancer diagnostics company Biofidelity Ltd. reported a $23 million series A+ investment round, led by Octopus Ventures with participation from SBI Investment Co. Ltd. and existing investors. Funds will be used for the commercial launch of the company's first commercial assay Asypre-Lung.

The oncology panel is designed to detect DNA mutations from tissue or liquid biopsy quicker than current approaches like gene sequencing. Once specific biomarkers are identified, physicians can individualize a patient's cancer treatment and monitoring. The company is initially targeting non-small-cell lung cancer where there are more than two dozen drugs available for different mutations.

"Aspyre provides oncologists with genomic biomarker data with extreme sensitivity and specificity, but in a way that overcomes the limitations of PCR and NGS," Biofidelity CEO Barnaby Balmforth told *BioWorld*. "It can scale to large numbers of genes and has the sensitivity needed for testing from blood or tissue, but has the simplicity, speed, low cost and ease of adoption of PCR.

The technology has been designed to run on existing PCR instrumentation, enabling the decentralization of biomarker testing and reduced result times. "Our mission is to ensure that all patients diagnosed with cancer have access to the genomic information they need to receive the best possible treatment," added Balmforth. "This financing is an important step towards making this vision a reality, enabling us to launch our revolutionary technology and to make comprehensive biomarker testing faster, more affordable and more accessible than ever before. We're delighted to have the backing of Octopus Ventures and SBI Investment, as well as strong support from our existing investors, as we embark on this next phase of our journey."

Founded in 2019, Biofidelity has expanded its operations from Cambridge, U.K., to include both a U.S. headquarters and clinical cancer diagnostic laboratory located in Research Triangle Park, N.C. In May 2020, the company raised $12 million from investors including Blueyard Capital, Longwall Ventures, and Agilent Technologies.

"It's hard to overemphasize both the uniqueness and transformational impact of Biofidelity's technology," said Octopus Ventures partner Luke Hakes. "We're proud to partner with this world-class team on its mission to increase the accessibility and affordability of biomarker testing, to democratize cancer diagnostics and unlock the full potential of precision medicine for all patients."

New legislation supporting biomarker tests

Biofidelity will initiate commercialization efforts for Aspyre-Lung in 2022 and could benefit from new U.S. legislation expanding access to biomarker testing. Last year, a new California bill was approved by Governor Gavin Newsom that will prohibit health insurance and health plans from requiring prior authorization for biomarker testing for an insured individual with advanced or metastatic stage III or IV cancer, as well as biomarker testing for cancer progression or recurrence in these individuals.

The bill defines a biomarker test as a diagnostic test of the cancer patient's biospecimen, such as tissue, blood or other bodily fluids, for DNA or RNA alterations to identify an individual with a subtype of cancer and guide patient treatment. The bill will go into effect from July 1, 2022.

The new legislation was welcomed by Biofidelity. "Every patient deserves to have the very best treatment options," said Balmforth.

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"This bill marks an important step forward in reducing the delays patients face in gaining access to the testing that makes those options available."

Treatment delays can often mean the difference between life and death for patients, added Biofidelity chief medical officer Wendy Levin. "Unfortunately, only about 50% of the patients in the U.S. diagnosed with cancer who are eligible for molecular testing are actually receiving biomarker tests. By eliminating the need for prior authorization, the new California legislation improves the likelihood that doctors will order the tests. When you have just been presented with a devastating diagnosis, even a week or two is a long time to wait. All patients deserve the opportunity to receive the best targeted treatment, and California's new legislation takes us one step closer to that goal."