Personalis Files Patent Infringement Lawsuit Against Foresight Diagnostics

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MENLO PARK, Calif.--(BUSINESS WIRE)--Aug. 2, 2022--Personalis, Inc. (Nasdaq: PSNL), a leader in advanced genomics for cancer, announced today that it filed a lawsuit against Foresight Diagnostics Inc. for infringement of Personalis' U.S. Patent Nos. 10,450,611, 11,299,783, and 11,384,394. These patents are part of Personalis' intellectual property portfolio in the field of whole genome-enabled, tumor-informed molecular residual disease (MRD) testing.

Personalis' patent portfolio protects its pioneering work in whole genome sequencing to identify mutations that indicate the continued presence or recurrence of cancer with part-per-million sensitivity. Personalis is seeking both injunctive relief and monetary damages based upon Foresight's infringement of these patents.

"Personalis has been active in whole human genome sequencing from very early on. By 2013, when we first began filing the applications that led to the patents we are asserting against Foresight, Personalis had already received customer orders to sequence and analyze over 1,000 human genomes and had realized the power of utilizing whole genome sequencing alongside our advanced targeted sequencing methods," said Personalis CEO, John West.

Personalis launched its ultra-sensitive MRD solution, NeXT Personal ™, in late 2021. NeXT Personal leverages many elements of the asserted patents, including the use of whole genome sequencing to identify up to 1,800 variants that are specific to a patient's cancer, thereby achieving superior signal-to-noise in the detection of ctDNA in plasma samples. NeXT Personal is purpose-built to accurately detect MRD in patient samples with low overall ctDNA, which is particularly important for cancers that have low shedding or low mutational burden, such as breast and prostate cancers, or soon after resection.

"Personalis has invested hundreds of millions of dollars in research and development across a broad array of disciplines for over a decade, and we stand firm in our resolve to protect that investment and our leadership position in the field. NeXT Personal is our most recent product leveraging our pioneering work. We believe that it represents the most sensitive MRD approach for solid tumors and can be transformational in cancer, detecting residual disease and recurrence, and in actively fighting cancer after recurrence has been detected," Mr. West added.

About NeXT Personal

NeXT Personal is a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify MRD and recurrence in patients previously diagnosed with cancer. The assay is designed to deliver industry-leading MRD sensitivity down to the 1 part-per-million range, an approximately 10- to 100-fold improvement over other available technologies. It leverages whole genome sequencing of a patient's tumor to identify up to 1,800 specially selected somatic variants that are subsequently used to create a personalized liquid biopsy panel for each patient. This may enable earlier detection across a broader variety of cancers and stages, including typically challenging early-stage, low mutational burden, and low-shedding cancers. NeXT Personal is also designed to simultaneously detect and quantify clinically relevant mutations in ctDNA that may be used in the future to help guide therapy when cancer is detected. These include known targetable cancer mutations, drug resistance mutations, and new variants that can emerge and change over time, especially under therapeutic pressure.

About Personalis

Personalis, Inc. is a leader in advanced cancer genomics, enabling the next generation of precision cancer therapies and diagnostics. The Personalis NeXT Platform® is designed to adapt to the complex and evolving understanding of cancer, providing its biopharmaceutical customers and clinicians with information on all of the approximately 20,000 human genes, together with the immune system, from a single sample. To enable cancer sequencing, Personalis' Clinical Laboratory was built with a focus on clinical accuracy, quality, big data, scale, and efficiency. The laboratory is GxP-aligned as well as Clinical Laboratory Improvement Amendments of 1988-certified and College of American Pathologists-accredited. For more information, visit the Personalis website and follow Personalis on LinkedIn and Twitter.

Forward-Looking Statements

All statements in this press release that are not historical are "forward-looking statements" within the meaning of U.S. securities laws, including statements relating to attributes or advantages of the NeXT or NeXT Personal platforms, Personalis' business opportunities, leadership, plans, or expectations, legal proceedings to enforce patents, the presumed validity or enforceability of the company's patents or other intellectual property rights, the potential issuance of additional patents from the company's pending or future patent applications, or other future events. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from any anticipated results or expectations expressed or implied by such statements. Factors that could materially affect actual results can be found in Personalis' filings with the U.S. Securities and Exchange Commission, including Personalis' most recent reports on Forms 8-K, 10-K and 10-Q, the company's registration statement on Form S-3 filed on December 30, 2020, and the company's prospectus supplement filed on January 3, 2022, and include those listed under the caption "Risk Factors." Personalis disclaims any obligation to update such forward-looking statements.

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