

InfanDx AG Revises Strategy and Broadens Diagnostics Pipeline for Child Health

- *After promising top-line data for metabolic biomarkers, in-depth data analysis revealed BANON study results not generalizable to HIE patients in clinical routine.*
- *Development of HypoxE® test based purely on metabolic biomarkers discontinued accordingly.*
- *Shareholders unanimously approve expansion of business strategy into new areas of pediatric health care.*

Cologne/Berlin, Germany, and Boston, MA, USA, March 28, 2023 – InfanDx AG, a privately held company focusing on the development and commercialization of novel diagnostic solutions for child health, today announced a strategic repositioning of the Company by broadening its pipeline of innovative solutions for child health.

The repositioning follows the discontinuation of the development of a metabolic biomarker-based test for the early detection of Hypoxic-Ischemic Encephalopathy (HIE). While top-line results from a blinded biomarker validation study, BANON, published in October 2022 looked promising, in-depth analysis of study data after de-blinding raised serious doubts about the generalizability of the study data to the intended use population of the HypoxE® Test.

“Clinical studies are models of clinical reality,” said Dr. Gunter Weiss, COO of InfanDx. “In our detailed analysis of the BANON dataset we saw certain subgroup effects that were specific to the study cohort and therefore not reflective of a broader target population of the test we intended to develop. When we modeled the performance of our metabolic biomarker panels in a data subset that was more reflective of the targeted intended use population, we had to conclude that the performance was insufficient for an HIE test to gain acceptance in the medical community. In an approach driven by our understanding of disease biology, we are now looking at other biomarker classes to address the pressing issue of the early detection of HIE.”

In parallel to exploring alternative diagnostic solutions for the reliable early detection of HIE, the Company will pursue further novel opportunities in prenatal testing and infant health with the intention of creating a high-value portfolio that balances biological, technological, and market risks. Due to ongoing partnering discussions and intellectual property related activities, the Company has not disclosed any further details on such opportunities.

To ensure sufficient financial runway for the implementation of the new strategy while retaining relevant key talent, the Company was restructured immediately following the decision to discontinue the development of the HypoxE® Test based on metabolic biomarkers as originally planned. It is now well funded to achieve key milestones in pursuing each of the portfolio opportunities. Based on such achievements the management expects the Company to be in a position to raise further funding by year-end 2023 or early 2024.

The change in strategy was unanimously approved by all of the Company’s shareholders at a recent Extraordinary Shareholder Meeting.

“With the realization that our metabolic biomarker data did not meet expectations, we were able to rapidly adapt to the situation and further strengthen our pipeline in pediatric care by adding two promising development projects to our portfolio,” commented Dr. Achim Plum, CEO of InfanDx. “This wouldn’t have been possible without the tremendous trust and support we received from our Supervisory Board and shareholders who are fully committed to walk with us on our journey as a new

InfanDx. I would also like to thank the team at InfanDx - those colleagues we had to part with in the restructuring for their enormous efforts in executing our original plan, and those colleagues that stayed for their trust, excellence, and professionalism in the transition to our new strategy."

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About InfanDx

InfanDx AG is a privately held company focusing on the development and commercialization of novel diagnostic solutions for child health.

Lead by a team of seasoned industry experts, the Company pursues the development of a portfolio of high-value diagnostics opportunities in pre-natal testing, neonatal acute and critical care, and infant health.

The Company is headquartered in Cologne, Germany, with a branch office in Berlin, Germany, and a wholly owned subsidiary in Boston, MA, USA.

For more information, please visit: <http://www.infandx.com/>

Meet the Management at DBT 2023

For questions and comments, please meet the InfanDx Management today, March 28, 2023, at

German Biotechnology Days 2023 (DBT 2023)
RheinMain CongressCenter
Friedrich-Ebert-Allee 1
65185 Wiesbaden
Germany

<https://www.biotechnologietage.de/en/>

For meeting requests, please use the conference networking portal or contact Mrs. Nathaly Schaefer (see below).

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