**June 9, 2026**
**Announcement no. 12**

**BioPorto initiates U.S. Adult Validation Study following U.S. Food and Drug Administration (FDA) feedback**

COPENHAGEN, DENMARK, June 9, 2026 – BioPorto A/S ("BioPorto" or "Company") (CPH: BIOPOR) today announces its intention to initiate the ProNephro AKI™ U.S. Adult Urine NGAL Validation Study. The initiation follows the constructive feedback from the U.S. Food and Drug Administration ("FDA") on the Company's pre-submission request filed on March 31, 2026, and will impact cost of study and timing.

CEO Carsten Buhl commented: *"FDA's feedback represents an important milestone for BioPorto. It reinforces our regulatory strategy and advances our pathway toward entering the U.S. adult Acute Kidney Injury market, which represents a significant commercial opportunity for the Company. The FDA feedback provided key regulatory alignment on the proposed clinical validation study design, establishing a strong foundation for the Company's planned 510(k)."*

BioPorto aligned with FDA on the need for a larger U.S. Adult Urine NGAL Validation Study to support robust performance claims for the adult population in connection with the planned 510(k) submission. The Cut-off Study enrolled approximately 500 patients whereas the Validation Study is now being planned to enroll approximately 900 patients, which the Company believes will provide a strong statistical foundation for the intended adult population claims.

As a result of the increased study size the FDA clearance is now expected mid-2028. The larger sample size results in additional study costs of approximately DKK 20 million, corresponding to an increase of approximately 70%.

These additional costs and the extended timeline led to the following update of the Company's financial aspirations for 2028:

| **Aspirations towards 2028** | | |
|---|---|---|
| **(DKK million)** | **Announced Aspirations** | **Updated Aspirations** |
| **Total Revenue 2028** | 135-185 | 135-185 |
| **Adj EBITDA margin 2028** | At least 15% | At least 15% |
| **Cash Flow Positive** | First half 2028 | Second half 2028 |

The increased study size moves timing for achieving cash flow positive to second half of 2028. The Company expects to bridge the additional cash flow requirements through a mix of operational efficiencies and other options, for example credit facilities.

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**Forward looking statement disclaimer**

Certain statements in this news release are not historical facts and may be forward-looking statements. Forward-looking statements include statements regarding the intent, belief or current expectations with respect to the Company's expectations, intentions and projections regarding its future performance including the Company's Guidance for 2026; currency exchange rate fluctuations; anticipated events or trends and other matters that are not historical facts, including with respect to implementation of manufacturing and quality systems, commercialization of NGAL tests, and the development of future products and new indications; concerns that may arise from additional data, analysis or results obtained during clinical trials; and, the Company's ability to successfully market both new and existing products. These forward-looking statements, which may use words such as "aim", "anticipate", "believe", "intend", "estimate", "expect" and words of similar meaning, include all matters that are not historical facts. These forward-looking statements involve risks, and uncertainties that could cause the actual results of operations, financial condition, liquidity, dividend policy and the development of the industry in which the Company's business operates to differ materially from the impression created by the forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Given these risks and uncertainties, prospective investors are cautioned not to place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date of such statements and, except as required by applicable law, the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Factors that may impact BioPorto's success are more fully disclosed in BioPorto's periodic financial filings, including its Annual Report for 2024, particularly under the heading "Risk Factors".

**About BioPorto**

BioPorto is an in vitro diagnostics company focused on saving lives and improving the quality of life with actionable biomarkers – tools designed to help clinicians make changes in patient management. The Company uses its expertise in antibodies and assay development, as well as its platform for assay development, to create a pipeline of novel and compelling products that focus on conditions where there is significant unmet medical need, and where the Company's tests can help improve clinical and economic outcomes for patients, providers, and the healthcare ecosystem.

The Company's flagship products are based on the NGAL biomarker and designed to aid in the risk assessment and diagnosis of Acute Kidney Injury, a common clinical syndrome that can have severe consequences, including significant morbidity and mortality, if not identified and treated early. With the aid of NGAL levels, physicians can identify patients potentially at risk of AKI more rapidly than is possible with current standard of care measurements, enabling earlier intervention and more tailored patient management strategies. The Company markets NGAL tests under applicable registrations including CE mark in several countries worldwide.

BioPorto has facilities in Copenhagen, Denmark and Boston, MA, USA. The shares of BioPorto A/S are listed on the Nasdaq Copenhagen stock exchange. For more information visit www.bioporto.com.