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Announcement no. 03

BioPorto announces preliminary results for 2023 and provides strategic update for the period 2024-2026

COPENHAGEN, DENMARK and BOSTON, MA, February 22, 2024, (GLOBE NEWSWIRE) – BioPorto A/S (BioPorto or the Company) (CPH:BIOPOR), today announced its preliminary results for 2023 and described its strategy and expectations for 2024-2026 and beyond.

Securing FDA clearance and meeting financial targets in 2023

In December 2023, BioPorto passed a major milestone when it received US Food and Drug Administration (FDA) 510(k) clearance for its NGAL test, ProNephro AKI™ (NGAL), for pediatric and young adult use (ages 3 months through 21 years) on the Roche cobas® c 501 analyzer. ProNephro AKI (NGAL) is designed to help doctors identify intensive care unit (ICU) patients at risk of developing or having persistent, moderate-to-severe acute kidney injury (AKI) earlier than the current standard of care, serum creatinine, with an aim to allow prompt intervention and save lives.

In addition to achieving the important FDA clearance, BioPorto increased revenues from The NGAL Test™ for research use only (RUO) in the US, and for general use in Europe, Canada, Israel, South Korea and other markets where the test is CE marked. BioPorto also maintained tight control over expenses.

Preliminary calendar year 2023 results show total revenue of DKK 31 million (USD 4.5 million), a 7% increase over the prior year. Preliminary adjusted EBITDA was DKK (56) million (USD (8.1) million). As of December 31, 2023, the Company had cash and cash equivalents of DKK 66 million (USD 9.8 million).

The 2023 preliminary revenue and adjusted EBITDA are in line with the guidance provided on November 1, 2023, of revenues in the range DKK 30-33 million and an adjusted EBITDA loss of approximately DKK (56) to DKK (59) million. BioPorto' s 2023 annual report will be published by April 4, 2024, in accordance with the Company's financial calendar.

Expanding use of ProNephro AKI (NGAL) for pediatric and young adults will boost revenue growth

ProNephro AKI (NGAL) for pediatric and young adult use targets an estimated global total addressable market of USD 150-200 million annually[1]. With the FDA clearance for US marketing of the test for this patient population successfully received in December 2023, BioPorto will in 2024 have a strong focus on preparing and executing its US commercial launch of ProNephro AKI for clinical testing of pediatric and young adult patients through its distribution agreement with Roche Diagnostics GmbH (Roche) on the Roche cobas® c 501 analyzer.

The primary target accounts and customers for BioPorto' s commercial activities are nephrologists, cardiologists, intensivists and laboratory directors at large pediatric hospitals and centers.

The commercial sales effort will include efforts to boost awareness of the test via Key Opinion Leaders (KOLs) responsible for describing the advantages and potential of the test at events, peer-to-peer educations etc., and BioPorto medical science liaison (MSLs) who can discuss the use of the

[1] Estimate based on S2N Data, BIS Data and management expectations.

test and provide tools to guide implementation. Along with the Company's dedicated sales team with in vitro diagnostics experience, they will work to expand market awareness and demand for the test by demonstrating the life- and cost savings value and hence build demand on top of the already strong relationships established by BioPorto with leading hospitals, clinics and physicians. BioPorto expects to gradually expand its US commercial organization to support the increasing activity over the next 3 years.

In addition to the increased marketing and sales activities, BioPorto has initiated dialogue with KDIGO, the leading global organization developing and implementing evidence-based clinical practice guidelines in kidney disease, to pursue including ProNephro AKI (NGAL), which is the first AKI biomarker test cleared for pediatric and young adult use in the US, in KDIGO's highly important guidelines for AKI.

During the period of 2024 through 2026, the primary sales focus in the US will be driving use of ProNephro AKI (NGAL) for testing pediatric and young adult patients at risk of AKI. In parallel, use of ProNephro AKI (NGAL) in CE-market countries outside of the US which has currently focused on adult use, will expand to also focusing on the pediatric and young adult testing market utilizing a similar marketing approach to the US and leveraging existing partnerships.

An important element in BioPorto's commercialization plan is to secure expansion of the instruments FDA cleared for ProNephro AKI (NGAL) use in order to enable more laboratories to implement the test and hence increase the serviceable market. Executing on this strategy, in February 2024 BioPorto expanded the global cooperation agreement with Roche which was for use on the cobas c 501 and c 502 analyzers to also include the cobas c 503 analyser. In 2025 and 2026, BioPorto plans to engage in more strategic distribution partnerships with additional leading instrument manufacturers to enable use of ProNephro AKI (NGAL) on their platforms, following completion of the necessary technical and clinical requirements.

Looking towards 2026, revenue from sales of the ProNephro AKI (NGAL) for pediatric and young adult use is expected to be the strongest revenue growth driver for the company.

Growing revenues and initiating an FDA clearance process for NGAL Adult

The total addressable market for adult use of the NGAL test is estimated at USD 2.8 billion annually.[2] Approximately 40% of the market is in the US.

The CE marked NGAL Test is currently marketed for clinical use in Europe, Canada, South Korea and other markets. The test is also available for research use in the US. BioPorto has initiated activities to seek FDA clearance for use of the test with adult patients. If successful, this clearance would not only open the largest single market in the world but could also drive for further adoption in other countries.

Following the successful pursuit of FDA clearance for ProNephro AKI (NGAL) in pediatric and young adult patients, BioPorto believes it has the experience and skills to obtain similar clearance for adults. BioPorto is designing clinical trials for this purpose. The goal is to submit a clearance application to the FDA in 2026. This could enable US commercialization of ProNephro AKI for adult use as soon as 2027.

Seeking FDA clearance for adult use is estimated to require an investment of USD 15-20 million in the period 2024-2026.

[2] Estimates based on B2N Data, BIS Data and management expectations.

Antibodies as stable source of revenue

BioPorto's revenue-generating product line also consists of a library of highly specific monoclonal antibodies for scientific, pharmaceutical, and clinical research, including specific antibodies for NGAL and other analytes in areas such as allergy and immune system disorders. BioPorto also provides in-house scaled-up production of custom antibodies in bulk volumes to meet specific customer needs, such as for diagnostic kit manufacturers.

While commercialization of the NGAL Test will be a key component for growth, BioPorto expects a stable revenue development for its antibodies business.

The product line will also, as previously, be a source for identifying expanding or new business areas, and BioPorto will have an opportunistic view on identifying new targets and paths to markets on this basis with a focus on NGAL, kidney diseases and critical care which are closely correlated with the primary focus areas of the company.

Strong revenue growth and ambition to become cash flow positive by 2026

BioPorto's key strategic focus areas through 2026 are 1) securing commercial traction in the US for clinical testing of pediatric and young adult patients using ProNephro AKI (NGAL), and 2) increasing sales of The NGAL Test for adult use in CE-marketed countries, and 3) initiating and submitting an US application to the FDA for clearance of ProNephro AKI (NGAL) for adult use.

The company expects that the US market for testing pediatric and young adult patients with the FDA-cleared ProNephro AKI (NGAL) will be the strongest contributor to growth for BioPorto through 2026. The company also believes that success in the US market will drive use of ProNephro AKI for testing pediatric, young adult and adult patients throughout the rest of the world.

As a result, BioPorto's target is to reach total revenue of USD 15-25 million by 2026. Revenue at the top of this range could enable BioPorto to become cash flow positive by 2026.

Following a potential FDA clearance of ProNephro AKI (NGAL) for adult use in the US, BioPorto's ambition would be to reach USD +100 million in revenue and be profitable by 2029.

Funding of USD 20 million to execute strategy

During this period through 2026, BioPorto plans to increase operating costs associated with sales and marketing and in particular associated with R&D with the FDA application process for ProNephro AKI for adult usage in the US.

The accumulated adjusted EBITDA loss for the period is estimated to be approximately USD 20-25 million, which BioPorto will seek to finance from existing cash and by issuing new shares of approx. USD 20 million on NASDAQ Nordics in 2024 and 2025 to enable the company to fulfill the full growth and value creation potential provided by its technology.

The board of directors is currently evaluating available strategies with the aim of initiating the first issue in Q2 2024.

Expected revenue growth of 30% in 2024

In 2024, BioPorto is targeting to achieve total revenue of DKK 40 million (USD 6 million) which would correspond to a growth rate of 30% compared to 2023. Growth will be driven by increased sales of NGAL products – primarily in the US following the FDA clearance supplemented by growth in the rest of the world. Revenue is expected to be back-end loaded, as US clinical commercialization of ProNephro AKI (NGAL) will commence in the second half of 2024.

For 2024, an adjusted EBITDA loss in the range DKK 75-90 million (USD (11) to (13) million) is expected. The higher expected loss results from higher marketing costs for ProNephro AKI (NGAL) in the US, and the cost of new clinical trials to support FDA clearance for ProNephro AKI (NGAL) in adults.

Investor meetings

Company management will host an online investor presentation on February 22, 2024, at 2:00 PM CET / 8:00 AM ET, via HC Andersen Capital. Investors interested in attending the webcast may register at https://hca.videosync.fi/2024-02-22-presentation/register.

A physical investor meeting will be held on February 22, 2024, at 3.30 PM CET at Tuborg Havnevej 15, stuen, 2900 Hellerup, Denmark. Register to attend by writing to investor@bioporto.com.

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To receive BioPorto's Company Announcements, Press Releases, Newsletters and other business relevant information, please sign up on https://bioporto.com/investor-contact/.

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About Acute Kidney Injury

Acute kidney injury is a sudden episode of kidney failure or kidney damage that happens within a few hours or a few days. AKI causes a build-up of waste products in blood and makes it difficult for kidneys to maintain the proper balance of bodily fluids. AKI can also affect other organs such as the brain, heart, and lungs and is common in patients who are in hospital intensive care units. For more information about AKI please visit: https://bioporto.com/aki/.

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.

Forward-looking Statements

This announcement contains certain forward-looking statements. Words such as "initiate", "may", "focus", "design", "guide", "plan", "estimate", "expand", "target", "potentially", "will", "should" and similar expressions identify such forward-looking statements, and such forward looking statements include statements with respect to commercialization activities in the U.S. and elsewhere, our collaboration with Roche Diagnostics GmbH (Roche), our ability to obtain regulatory approval to expand indications to analyzers other than the cobas c 501 or to other age groups and/or clinical indications, the buildout of our commercialization team and our financial guidance. Forward-looking statements involve risks, uncertainties and other factors, which may cause actual results, performance and achievements to differ materially from those contained in the forward-looking statements. These include numerous assumptions, risks and uncertainties, many of which are beyond BioPorto's control. These assumptions, risks and uncertainties are described from time to time in BioPorto's public announcements, its Interim Reports, and in its 2022 Annual Report under Risk Factors. BioPorto undertakes no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date of this presentation, except as required by applicable law.