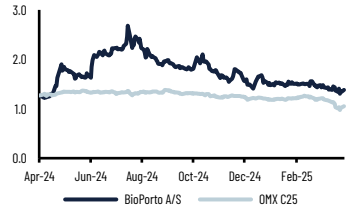
BioPorto

Market: OMXC Small Cap	Ticker: BIOPOR	Share price (DKK): 1.38	Market cap (DKK): 594m	Net cash (DKK): 82m	Enterprise value (DKK): 512m

*Includes direct issue of DKK 33.5m gross proceeds

Share information



YTD:	-10.8%	1 year:	8.0%
1 month:	-5.7%	3 years:	-2.5%

Note: *We apply the closing price from 14 April 2025
Index rebased to 15.04.2024. Source: S&P Capital IQ

Financials

(DKKm)	2023	2024	2025E
Revenue	31.0	36.2	45 - 60*
Revenue growth	*7%*	*17%*	*22% - 66%*
R&D costs	25.4	-33.5	N/A
Adj EBITDA	-56.1	-70.6	-85 to -75*
Cash flow from operations	-55.5	-83.6	N/A
Net cash	66.0	-48.5	N/A

Notes: *Company guidance for 2025E

Key pipeline assets

Indication	Partner	Market	Development
ProNephro AKI (NGAL)*	ROCHE	Pediatric US	FDA approved
NGAL test	Beckman Coulter	Pediatric & Adult EU/RoW	CE Approved
NGAL test (Adult)**	BioPorto	Adult US (available RUO)	Planned Q3'25
Antibodies	Various		Marketed

Note: *ProNephro AKI (NGAL) is the name for BioPorto's NGAL Test in the US which has been FDA approved for pediatrics. **NGAL Adults US currently commercially available for research use only (RUO)

Company description

BioPorto is a Danish in-vitro diagnostics company focused on improving patient outcomes through biomarker-based tests. BioPorto was founded in 2000, with HQ in Copenhagen, a US office in Boston, and listed on Nasdaq Copenhagen in 2004.

Its flagship product, the NGAL test, enables early detection of acute kidney injury (AKI), delivering results within 2 hours compared to the 48–72 hours required by traditional methods (serum creatine). The NGAL test is currently available for Research Use Only (RUO) in the U.S. and Canada and is commercially distributed in Europe and other global markets. In Dec 2023, BioPorto received FDA clearance for the NGAL test for pediatric use (ages 3 months–21 years) in the U.S., branded as ProNephro AKI (NGAL). BioPorto has partnered with Roche to distribute the test in the U.S. across multiple instrument platforms, while Beckman Coulter is the global distribution partner. These partnerships aim to scale adoption and expand clinical use.

The company has launched its five-year strategy plan to reach cash-flow break-even by end 2026 and achieve DKK +700 million (USD +100m) in annual revenue by 2029 (see appendix page 4).

Investments case

BioPorto is scaling the sales of its FDA-approved ProNephro AKI (NGAL) pediatric test and NGAL test for RUO, particularly in the US. The company looks to convert rising awareness to sustainable recurring revenues in the AKI diagnostic market, estimated to have a total addressable market (TAM) of USD 3.0 billion[1] and a 5% CAGR, supported by a shift in diagnostic paradigms.

In 2024, NGAL sales grew 34% y/y in the US and 24% y/y total as BioPorto progresses towards its ambitions for revenue of DKK 80-125m in 2026 (cash flow positive by end-2026) and DKK +700m (USD +100m) by 2029. Increased sales activities will be supported by existing partnerships with Roche and Beckman Coulter, two of BioPorto's five key prioritized partners, and additional partnerships. The NGAL test is FDA-approved for Roche platforms, with Beckman Coulter FDA-approval expected in 2026.

BioPorto may also benefit from inclusion in the KDIGO (Kidney Disease: Improving Global Outcomes) best-practice guidelines, which are expected to be updated in late 2025 and take effect in H1 2026. KDIGO inclusion can drive pull-through demand in the market as reimbursement decisions in developed healthcare systems often align with KDIGO recommendations. Inclusion would position the NGAL test to be the preferred diagnostic tool.

Using a DCF model (see pages 2 and 3), we find that the market implies a Probability of Success (PoS) exceeding 100% for the pediatric ProNephro AKI (NGAL) launch, indicating full pricing of its successful commercialization in the U.S. However, when also considering NGAL for adult use, broader applications, and global markets—representing a TAM of USD 3 billion annually—the market implied base case PoS is around 43%.

Key investment reasons

BioPorto is well-positioned to achieve a successful launch of the ProNephro AKI (NGAL) test for pediatrics, with FDA clearance in the US. Partnerships with Roche and Beckman Coulter (two of BioPorto's five prioritized partners) validate the test and can support accelerated sales and adoption of the NGAL test (pediatrics and RUO adults). Partner agreements will support back-end loaded sales growth during its 2025-2026 strategy period, with aims to also secure agreements with the remaining key partners.

The grant of a marketing authorization of the ProNephro AKI (NGAL) for pediatrics can act as a foundation to access a total addressable market (TAM) estimated at USD 3.0 billion annually, with a 5% CAGR. Further FDA approval for the US adult test can boost market access.

KDIGO inclusion can trigger rapid demand growth in 2026 and beyond, as inclusion in the guidelines will generate pull-through sales and may help the NGAL test be eligible for reimbursement.

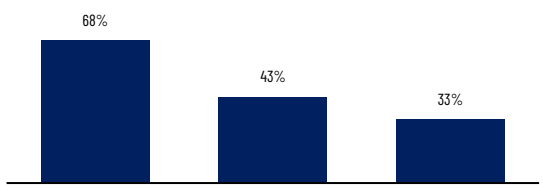
Key investment risks

Investing in the development of drugs and life science products is generally risky and requires patience and a high-risk appetite. The FDA's clearance for ProNephro AKI (NGAL) for pediatrics and partnerships with Roche and Beckman Coulter validate the NGAL test but do not guarantee clinical approval for the adult test or broader commercial success. The first patients for the first of two studies have been enrolled ahead of schedule.

BioPorto's strategy plan relies heavily on backloaded sales, which represents greater risk, particularly as partner-driven sales have been slower to materialize than initially expected (partly due to slower approval processes). Additionally, the rapid sales growth may depend on inclusion in the updated KDIGO guidelines, which reflects a significant opportunity but is not guaranteed.

Following the latest capital raise of DKK 33.5m via a private placement on 15 April 2025 (5.8% dilution), BioPorto is well capitalized. However, additional financing will likely be needed to reach its aims of being cash flow positive by end-2026. BioPorto stated that "going forward it will investigate alternative financing options to optimize shareholder value". However, further dilution is a possibility, particularly if ambitions are not achieved.

Probability of Success – Pediatrics, adult, RoW combined



Source [1]: BioPorto annual report 2024 investor presentation.
Note: Probability of success (PoS) model based on company guided market assumptions and HC Andersen Capital assumptions.

Note: Probability of success (PoS) model based on company communicated assumptions, market assumptions and HC Andersen Capital assumptions. Graph is illustrative.

Appendix – Discussion of assumptions in DCF model

The model
This one-pager does not aim to determine a price target for BioPorto shares but rather provides investment perspectives using a simplified discounted cash flow (DCF) model across different scenarios. The model uses scenarios to indicate the extent to which BioPorto's current market capitalization reflects the implied probability of success (PoS) for its ProNephro AKI (NGAL) adult test (US) to attain FDA clearance and successful commercialization for all indications across its markets, based on the model assumptions described below.

Market size and market growth
According to BioPorto, the total available market (TAM) for its ProNephro AKI (NGAL) test is around USD 3.0 billion, growing at a 5% CAGR over the next 5-6 years across its global markets. BioPorto estimates the TAM for the US at USD 1.2 billion (pediatric and adult), Europe USD 1.0 billion, and the rest of the world USD 800 million.

As BioPorto currently has full FDA marketing authority for its US ProNephro AKI (NGAL) test for pediatrics and CE mark for pediatric and adults in RoW, the growth curve continues in these markets. Sales of the adult test in the US are also forecast to grow slowly under research use only (RUO) until full ProNephro AKI (NGAL) adult FDA approval is received - FDA submission expected in late 2026 with expected launch in 2028. We model that the market will grow annually at the company-guided 5% level until 2030 and then slow to 3% until the terminal period.

Longer term, BioPorto will most likely face competition, particularly as patents expire. The expiry dates for some of BioPorto's patents are only a few years out, but the management is confident that BioPorto can effectively defend its position for a longer period than the expiry dates suggest, as any new competitor needs to go through the same investigational and development process as BioPorto's NGAL test has been through. The model assumes effective competitive protection until 2036, followed by a terminal growth rate of -25%.

Market share and revenue
Although BioPorto will have the first-mover benefit of potentially being the first to launch an NGAL Test, the model assumes a gradual growth to peak market shares of 10-40% over 6-8 years in the base case, depending on indication and market. Our penetration curve reflects the time to onboard and scale with its priority partners and ramp-up sales of the ProNephro AKI (NGAL) adult test post-FDA approval. Pediatrics US is assumed to attain the highest market share across our scenarios. Additionally, a high market share is difficult to obtain immediately after a product launch due to established workflow processes, which sometimes limits the adoption of new products. Accelerating the behavior shift can be supported by inclusion in the KDIGO guidelines. The penetration curve can take different paths, but we model an accelerating penetration rate towards peak market share with varying penetration rates for indications and markets.

We also assume large partners, including ROCHE and Beckman Coulter, will drive the market share gains, with BioPorto receiving royalty revenues of 25%. The high royalty rate reflects the fact that the ProNephro AKI (NGAL) test has achieved FDA clearance in the US pediatrics sector and the CE mark in ROW markets. The tests are also compatible with existing machinery. The use of a partner strategy introduces some third-party risk regarding the speed of market penetration, however, the partners' greater size, financial resources, and existing ecosystem of machines to run the test enable a greater peak market share. We also model a small value for BioPorto's antibodies based on the company-guided assumption of stable revenues moving forward.

Discount rate
The model uses a discount rate of 15%, reflecting the generally high level of investment risk and uncertainty typically associated with forecasting future cash flows from biotech companies. As BioPorto is active within the space of diagnostic products, which is generally perceived as being less risky, it can be argued that a lower discount rate is appropriate, but the model uses the widely accepted 15% within the industry.

Probability of successful launch (PoS)
Based on historical data from Biostatistics research covering 5,764 pipeline projects in pharmaceutical and biotech companies, the average historical probability of success (PoS) of a Phase 3 pipeline project passing through to launch is approximately 59%, calculated across all indications. Studies suggest that the PoS for medical devices is typically above this level, including within the 510(k) Class II category, which is the pathway for BioPorto's diagnostics NGAL test. However, we maintain the lower benchmark of around 60% to remain conservative. The FDA approval of the ProNephro AKI (NGAL) test for pediatric use, successful CE mark, and partnerships with Roche and Beckman Coulter validate the test and may suggest a higher than benchmark probability of success for BioPorto to receive FDA clearance.

BioPorto expects to submit its adult trial submission in late 2026, with approval estimated to take 12-18 months after submission. A low PoS suggests that the market currently implies a low probability for the company to attain regulatory approval US Adult test and successful commercialization in line with the DCF assumptions. However, a low market implied PoS may also indicate additional needs for capital and dilution risk.

EBIT – margin
According to the S&P Capital IQ Financial System, five-year average EBIT margins within major pharmaceutical, life science, and biotech companies are approximately 30%. Looking at biotech companies specifically, the five-year average is approximately 50%, reflecting a generally more focused business model and higher economies of scale. Lower R&D costs, an effective distribution model, and the current level of gross margin for the NGAL test, when sold for research use only, suggest that BioPorto will ultimately be able to obtain a similarly high EBIT margin.

Capital increase and share count
BioPorto announced in its strategy plan that it plans to raise a total of USD 20 million during 2024/25, to support development towards its aims for cash-break-even by the end of 2026, if the top-end of guidance is met. In June 2024, the company raised USD 11.7 million in an oversubscribed direct share issue at market prices. On 14 April 2025, BioPorto announced a further private placement, raising gross proceeds of DKK 33.5 million (around USD 5.1m) via 25 million new shares (5.8% dilution).

Following the issue, BioPorto has 454.7 million total shares outstanding and a cash position of around DKK 82.0 million. (FY 2024 cash and equivalents + gross proceeds). Given the midpoint, 2025 guidance suggests a negative Adj. EBITDA of DKK 80 million, BioPorto is sufficiently capitalized until around the end of 2025. Therefore, some additional financing, either via debt or equity, will likely be necessary to reach the cash flow break-even ambition at end-2026.

Appendix – Results and conclusion

Scenarios

Based on the previously mentioned assumptions regarding market size and growth, level of profitability, market share, and discount rate, different scenarios can be simulated to assess the probability of a successful launch and commercialization of the NGAL test implicitly discounted by the market. As illustrated, the model has simulated the implicit likelihood in 3 scenarios: a bear-, base- and bull-case scenario using the indicated level of market size and growth by BioPorto under different peak market share assumptions. For simplicity reasons, the remaining criteria discussed are assumed to be the same in all scenarios (using industry average levels).

Base Case Scenario

In the base case scenario, the model uses the indicated market size by BioPorto, USD 3 billion, growing 5% annually towards 2030. The model uses industry average levels of profitability as a starting point, resulting in an EBIT margin of 50% from 2030 forward. The peak market share assumptions for US Pediatric, US Adults, and RoW (Rest of the World) are 40%, 25%, and 10%, respectively. Based on these assumptions and a discount rate of 15%, the market currently implicitly assumes there is PoS of 100% for the ProNephro AKI (NGAL) for pediatrics in US, i.e, the market also attributes weight to the commercialization of NGAL in RoW, and for the adult test in the US.

When also considering the commercial potential of other markets (RoW) and indications (Adult), the implied probability of successful commercialization of the ProNephro AKI (NGAL) across all markets is around 43%, according to the model. This compares to a historical average PoS of approximately 59% for Phase III pipeline projects across all indications.

Bear Case Scenario

In the bear case scenario, the model uses the same assumptions as in the base case except for the peak market share assumption for US Pediatric, US Adults, and RoW, which are assumed to be 30%, 10%, and 7.5%, respectively. Based on this, the market currently implicitly assumes there is around a 68% probability of a successful launch for the ProNephro AKI (NGAL) test for adults and successful commercialization according to the bear case assumptions.

Bull Case Scenario

In the bull-case scenario, the model uses the same assumptions as in the base case except for the peak market share and penetration rate assumptions for pediatric, adults, and RoW, which are assumed to be 50%, 30%, and 15%, respectively. For the bull case, the penetration curve is also accelerated. Based on this, the market currently implicitly assumes there is approximately a 33% probability of launch for the ProNephro AKI (NGAL) test for adults and successful commercialization according to the bull case assumptions.

Conclusion

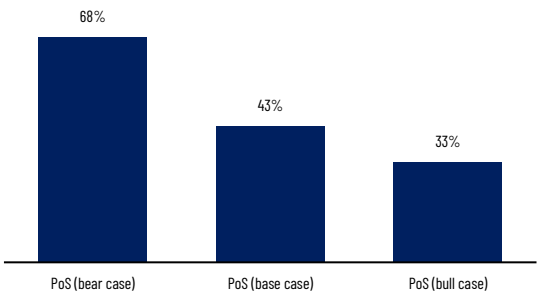
The strategy to commercialize via partners, initially with Roche driving the ProNephro AKI (NGAL) test for pediatrics in the US, and Beckman Coulter in Europe, RoW and the US, returns a probability of successful for the US ProNephro AKI (NGAL) adult test's approval, and global commercialization of around 43%, based on our base case model and current market prices. Given that BioPorto has attained FDA clearance for its ProNephro AKI (NGAL) test for pediatrics, validation via two commercial partner agreements, and limited additional financing requirements (as per 2026 ambitions) it could be argued BioPorto's PoS for FDA clearance of its ProNephro AKI (NGAL) test, adults (US) is fairly high.

Greater risk may exist in the commercialization of the NGAL tests across indications and markets as BioPorto has downwardly adjusted its 2026 targets in connection with its FY2024 results to USD 12-18m from USD 15-25m previously. Despite maintaining the 2029 ambitions, the increased emphasis on backloaded sales has greater forecasting uncertainty and may be difficult to attain without excellent execution.

However, if the ProNephro AKI (NGAL) test is successfully cleared for all indications and commercially launched across global markets in line with company-led model assumptions, the market implicitly assesses that there is potential for valuation improvement towards a higher benchmark PoS.

A low PoS is not uncommon for life science companies still in their developing phase and can also reflect that the market assesses there is a high likelihood that BioPorto will need to raise additional capital. Following the latest capital raise of DKK 33.5 million via a private placement on 15.04.2025, BioPorto is well capitalized, but additional debt/equity financing will likely be required to meet the 2026 cash-flow ambitions. However, additional capital needs are low compared to earlier-stage biotech companies. With the latest capital raise finalized, positive developments relating to the ongoing commercialization of the NGAL test and clinical progress in the NGAL adult test may be triggers to valuation improvement.

Probability of Success – Pediatrics, adult, RoW combined



Note: Probability of success (PoS) model based on company communicated assumptions, market assumptions and HC Andersen Capital assumptions. Graph is illustrative.

Appendix – BioPorto strategy plan materials

BioPorto strategy plan - overview

Targets for 2025-2026

Building commercial platform:

- Accomplish commercial launch of NGAL test in the US and drive usage pediatrics/young adults (US)
- Consolidate Adult usage in ROW
- Expand the number of FDA cleared instruments with existing partners
- Engaging in more strategic partnerships with the remaining three of the "Big 5" clinical chemistry instrument vendors

Initiation of NGAL for adult use in US

- Enrolment of the first patient in the AKI (NGAL) validation study in Q3 2025
- FDA submission of ProNephro AKI (NGAL) for adults, end 2026

Other

- Financing targeting USD 8.3 million in H1 2025 to meet target of USD 20m
- Submission for the new EU regulation on in vitro medical devices (IVDR) by end 2026

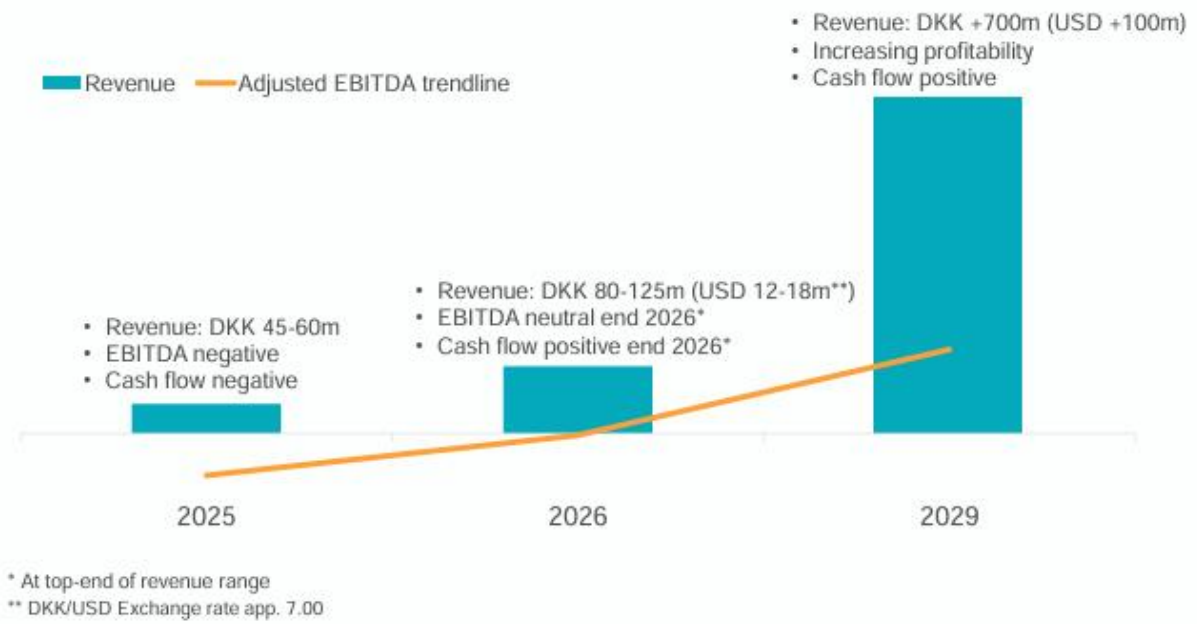
Targets for 2027-2029

Key objectives :

- Commercialization of ProNephro AKI (NGAL) for Adult use in US
- Strengthen Adult usage in ROW
- NGAL Label expansion (FDA / IVDR) to increase the serviceable market

Source: BioPorto FY 2024 Investor Presentation

BioPorto strategy plan - path to profitability



Source: BioPorto FY 2024 Investor Presentation