BioPorto

Q1 2026, advancement on the three pillars central to the long-term potential

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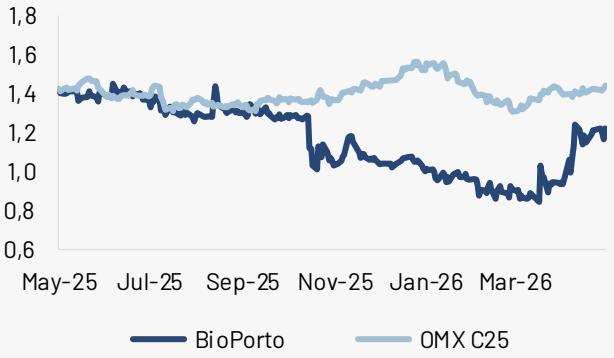
Key Financials and Valuation

Share price



YTD:	19.6%	1 year:	-14.1%
1 month:	30.3%	3 year:	-23.3%

Note: Closing price from 21 May 2026.
Source: S&P Capital IQ Pro.

Financials

DKKm	2023	2024	2025	2026E*
Revenue	31.0	36.2	40.3	38 to 48
Growth	6.9%	17.1%	11.2%	-6% to 19%
Gross Profit	20.2	24.5	30.3	N/A
Gross margin	65.2%	67.7%	75.2%	N/A
R&D costs	-25.4	-33.5	-50.5	N/A
Adj. EBITDA	-56.1	-70.6	-76.5	-58 to -68
Net income	-56.3	-68.2	-82.1	N/A
Cash flow	-55.1	-83.6	-77.1	N/A
Net cash	59.2	48.5	47.5	90.5**
Market value	793.5	666.0	505.1	604.0

Note: *BioPorto's own 2026 guidance. NGAL revenue guidance DKK 33-42m.
Source: S&P Capital IQ Pro. Net cash reflects cash minus debt minus lease liabilities. Only the cash position is updated for Q1 2026.

Key Pipeline Overview

Indication	Clinical Study	Regulatory Status
ProNephro™ AKI (NGAL)	Completed	FDA Cleared (Dec 2023)
NGAL test (Adult)	Cut-off study Completed	FDA approval target end 2027
EU / ROW (IVDR)	Completed	IVDR certification expected 2027

Note: Pipeline overview detailed on page 3, covering US pediatric, US adult, and EU/ROW.

Valuation Perspectives

We use a simplified DCF model across several scenarios. The model indicates the extent to which BioPorto's current market capitalisation reflects the implied probability of success (PoS) for final adult approval and commercialisation of the NGAL test discounted by the market. We model three scenarios — bear, base, and bull — using BioPorto's indicated market size and growth under different peak market share assumptions.

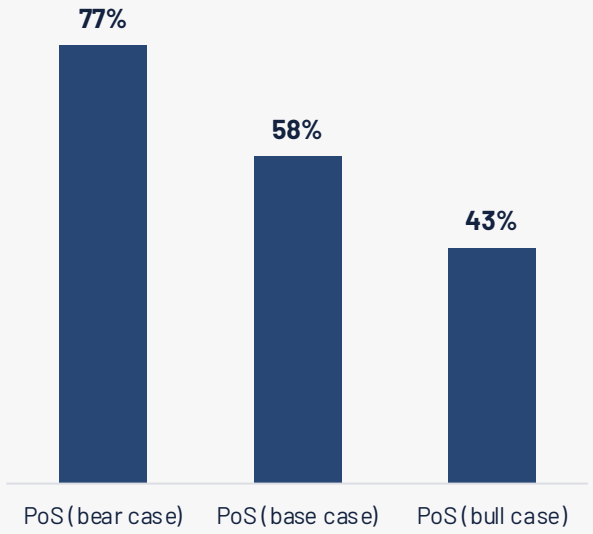
The current base-case model-implied PoS of ~58% looks low for a diagnostics company with a product already on the market and relative to typical Phase 3 approval probabilities in adults, suggesting upside if BioPorto executes against its strategic and regulatory milestones.

As BioPorto is still in the early phases of driving adoption and shifting treatment regimes, there is inherent uncertainty in sizing the addressable market, which could partly explain the lower implied PoS.

Following the sale of its antibody business, BioPorto expects to be funded into mid-2028, when it also expects to turn cash flow positive. Dilution risk from further capital raises is therefore reduced and should not, in itself, justify the low PoS.

A market re-rating of the PoS hinges on BioPorto delivering on three pillars central to its long-term sales potential: i) FDA clearance and US market entry for adults, ii) strong inclusion in the KDIGO guidelines, and iii) establishing health economics for early AKI detection using NGAL.

Model implied PoS



Investment Case – Addressing large market characterized by unmet needs

Key Investment Reasons

- FDA-cleared (pediatrics) ProNephro AKI (NGAL) test targeting a market with high unmet need and strong health economics (cost savings to hospitals)
- Directly addressable ICU market $700m annual growing ~5% Expected US adult FDA potential approval target end 2027 could accelerate growth with expected market size 20x higher than current approved pediatric
- KDIGO 2026 draft guidelines recommend biomarker use for AKI and acknowledge current standard haven't delivered.
- "Forward" strategy reset improves transparency (sub-goal for investors to follow), and provides a credible path toward sustainable growth

Key Investment Risks

- FDA clearance for ProNephro AKI (NGAL) for pediatrics and partnerships with ROCHE and Beckman Coulter validate the NGAL test but do not guarantee adult clearance or broader commercial success.
- Partner rollout has been slower than expected due to approval delays, adding third-party risk to the 2028 growth targets.
- Although BioPorto, following the sale of its Antibody business, sees no funding needs until mid-2028, further dilutive capital raises can't be ruled out if expected sales under its current strategy fail to materialise.
- Generic competition to ProNephro after patent expiry in late 2028

Company description: BioPorto is a Danish in-vitro diagnostics company. Its flagship NGAL test enables early detection of acute kidney injury (AKI), delivering results within 2 hours versus the 48–72 hours required by traditional methods (serum creatinine). The test is available for Research Use Only (RUO) in the U.S. and commercially distributed in Europe and other global markets. In Dec 2023, BioPorto received FDA clearance for pediatric use (ages 3 months–21 years). Distribution partnerships with ROCHE (U.S.) and Beckman Coulter (global) aim to scale adoption and expand clinical use.

Investment case: The case rests on a clear diagnostic gap: serum creatinine can delay AKI diagnosis by 24–48 hours and may not move until ~50% of kidney function is lost, whereas NGAL detects structural injury hours earlier, enabling intervention before functional decline. The economics follow directly: AKI costs ~USD 6bn annually in the US (~GBP 1bn in the UK) and escalates at predictable clinical thresholds, exactly where earlier action interrupts the cost curve. This translates into a USD 3bn worldwide NGAL market, of which the ICU-focused USD 700m segment is the directly addressable wedge, growing ~5% annually. A US adult FDA approval, targeted for end-2027, could materially accelerate growth, with the addressable market estimated at roughly 20x the current approved pediatric segment.

KDIGO sets the global clinical standard, and US/EU reimbursement and hospital protocols are closely tethered to it. Biomarker inclusion would shift NGAL from a discretionary add-on to a compliance tool, driving pull-through demand. KDIGO inclusion, expected in the second part of 2026 is a direct prerequisite for the 2028 ambitions.

BioPorto reset its "Forward" strategy in November 2025 around measurable operational milestones: partnerships with 60+ US hospitals by end-2026, FDA submission for the adult NGAL test in H1 2027, and cash flow positive in H1 2028. The reset improves transparency and provides a credible path to sustainable growth that investors can track through the coming year.

Although pediatric FDA clearance, RUO use, and technical validations through partnerships increase the likelihood of adult approval, inherent study risk remains. Running on partner platforms makes BioPorto's scale achievable but places execution risk largely with counterparties, who control the menu and sales force, share per-test economics, and set priorities versus in-house assays. Generic competition cannot be ruled out after patent expiry, though IVD validation complexity is itself a de facto barrier, as any competitor would have to repeat the lengthy validation and approval process on each instrument platform.

Pipeline Progress and Overview

BioPorto's commercial pipeline is built around its validated biomarker NGAL for early detection of acute kidney injury (AKI). The platform is proven with the test achieving FDA clearance in the US for pediatrics (marketed as ProNephro™). Clinical and regulatory risk for subsequent indications is generally considered lower than for a first-time submission. The company's focus is on scaling US adoption via research use only (RUO) and partner sales while advancing the adult FDA pathway toward clearance in 2027.

Near-term the latest KDIGO guideline update on 31 March 2026 (first update since 2012) and inclusion of biomarker tests in the guidelines may drive pull-through demand and reimbursement eligibility, with the public comment period closed 27 April 2026 and awaiting finalisation. With the FDA pre-submission filed in March 2026, the next key catalyst is the initiation of the adult validation study following FDA feedback. Investor focus will center on whether BioPorto can accelerate hospital adoption toward 60+ active US sites by year-end 2026, currently at 48 after 4 new onboardings in Q1 2026, and demonstrate that the Roche and Beckman Coulter partnerships are translating into recurring revenue, with Q1 2026 revenue up 23% to DKK 9.4m driven by US NGAL RUO.

US Pediatric (ProNephro AKI): FDA-cleared in December 2023 for patients aged 3 months–21 years. Commercially launched on the Roche Cobas c 501 in Q3 2025, contributing DKK 4.3m in revenue in 2025, with 44 active US hospitals at year-end 2025, rising to 48 by end-Q1 2026 and targeting 60+ by end-2026.

US Adult (NGAL RUO → FDA clearance): Currently sold for research use only, contributing DKK 18.4m in 2025 (+25% YoY) and representing the core growth engine, with Q1 2026 US NGAL RUO sales continuing to drive group growth. The adult cut-off study completed patient enrolment in October 2025; a pre-submission to the FDA was submitted in March 2026, with the validation study to follow and FDA submission targeted for H1 2027, which can unlock broader market access via partners.

EU / ROW (IVDR): CE-marked under the legacy IVDD for all patient populations. IVDR certification is expected in 2027, which may unlock renewed adoption as physicians and labs have awaited stronger regulatory backing before clinical use. ROW NGAL revenue was DKK 5.5m in 2025, with growth expected to follow the US commercial playbook.

	Analytical Validation	Clinical Study	Regulatory Status	Estimated market size*
US Pediatric (ProNephro AKI)	Completed	Completed	FDA Cleared (Dec 2023)	Total addressable market based on intensive care units (ICU) around USD 700 million combined. Wider total available market up to USD 3.0 billion including wider biomarker applications Market size estimates based on management studies
US Adult (NGAL RUO → FDA)	Completed	Cut-off study complete; Validation study to follow FDA pre-submission feedback	Pre-submission submitted March 2026; FDA approval target end 2027	
EU / ROW (IVDR)	Completed	Completed	CE-marked (IVDD); IVDR certification expected 2027	

Note: Note: *The estimated market size and peak sales are based on BioPorto's Annual Report 2025.

Market implied probability of success (PoS)

The model: This investment case does not aim to determine a price target for BioPorto shares but rather provides investment perspectives using a simplified DCF model across different scenarios. The model indicates the extent to which BioPorto's current market capitalisation reflects the implied probability of success (PoS) for final adult approval and commercialization of the NGAL test implicitly discounted by the market.

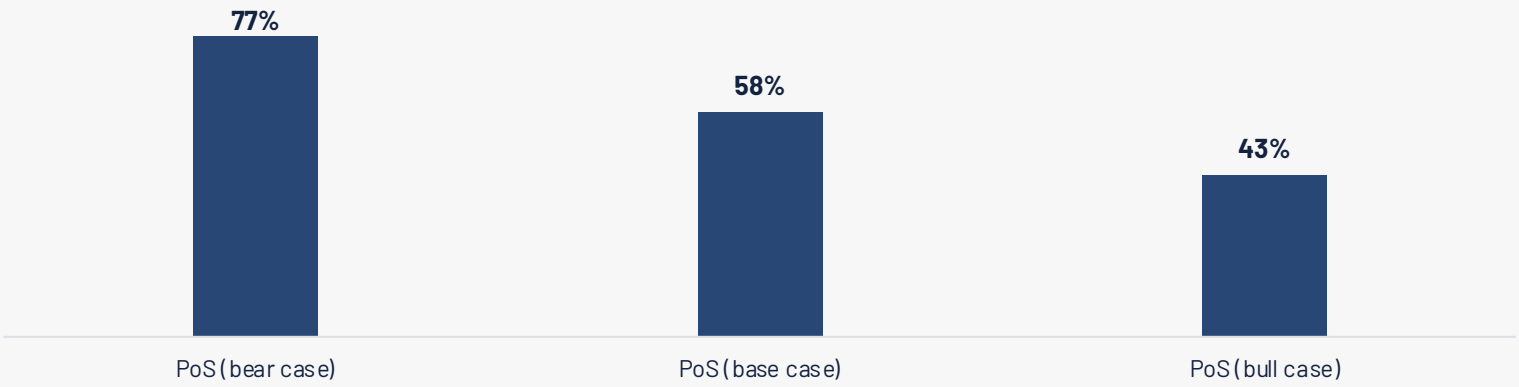
We model three scenarios: a bear- base- and bull-case scenario using the indicated level of market size and growth by BioPorto under different peak market share assumptions. For simplicity reasons, assumptions on EBIT margin, royalty rates, discount rate, launch date, and time to peak market share are held constant across all scenarios.

Base Case Scenario: In the base case scenario, the model uses the indicated addressable market size by BioPorto, USD 700 million, 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 35%, 25%, and 20%, respectively. Based on these assumptions and a discount rate of 15%, the market currently implicitly assumes there is a PoS of around 58% for BioPorto to commercialize in line with its revised communicated ambitions across global markets, both with research use only and partner sales, and predominantly partner sales after FDA NGAL Adult approval end-2027.

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 25%, 15%, and 15%, respectively. Based on these assumptions and a discount rate of 15%, the market currently implicitly assumes there is PoS of around 77% for BioPorto to commercialize in line with the bear case assumptions outlined in the model, adjusted to reflect the new "Forward" strategy.

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%, 35%, and 25%, respectively. For the bull case, the penetration curve is also accelerated. Based on these assumptions and a discount rate of 15%, the market currently implicitly assumes there is PoS of around 43% for BioPorto to commercialize across markets and indications, in line with the bull case assumptions outlined in the model, adjusted to reflect the new "Forward" strategy.

Model-implied Probability of Success (PoS) – Pediatrics, adult, RoW combined



Note: Graph is illustrative.

Discussion of assumptions in DCF model

Market size and market growth: According to BioPorto, the total available market for its ProNephro™ AKI (NGAL) test is around USD 3.0 billion, while the directly addressable market, focused on hospitals with intensive care units, is around USD 700m annually across the US and EMEA. The market is assumed to grow at around a 5% CAGR across its global markets as the use of biomarkers broadens.

BioPorto has FDA clearance for its US ProNephro™ AKI (NGAL) test for pediatrics (Dec 2023) and CE mark for pediatric and adult in Europe, and has the potential to grow with partners to capture significant market share. BioPorto is commercializing the NGAL test under the research use only RUO label, focused on hospitals with intensive care units, while it awaits FDA clearance in the US, targeted for 2027.

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: While BioPorto will have the benefit of being the first to launch an NGAL Test, the model assumes a gradual growth to peak market shares of 20-35% of the directly addressable market 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 clearance. In line with company guidance, we have a back-end loaded penetration curve across indications as BioPorto, ramp-up with existing partners, attain FDA approval for the NGAL adult, KDIGO guidelines inclusion, and additional partner onboarding. An accelerating penetration curve also reflects the gradual shifts in practitioner behavior, with the growth curve adjusted to reflect individual indication and market dynamics.

We assume large partners, including ROCHE and Beckman Coulter, will support the market share gains, with BioPorto receiving royalty revenues of 25% from partner sales. 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, and some delays have been experienced; however, the partners' greater size, financial resources, and existing ecosystem of machines to run the test enable a greater peak market share. BioPorto will also maintain a significant share of own sales. 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): For BioPorto, the probability of success (PoS) should be viewed as the probability of successful commercialization in line with the company's ambitions, since the NGAL test is already available on the market. Successful commercialization for BioPorto and meeting the revised "Forward" strategy outlook includes achieving FDA clearance for the Adult NGAL test, securing broad licensing and distribution across major instrument partners, and attain a significant market share in the AKI diagnostics market and become a standard of care. Market implied PoS also reflects funding risk, despite being adjusted for mid-point announced financing, at market prices. From a clinical perspective, biostatistics data across 5,764 pipeline projects in pharmaceutical and biotech companies suggest a clinical probability of success of a Phase III pipeline project passing through to commercial launch of around 59%. BioPorto's diagnostic NGAL test undergoes a different clinical pathway as a 510(k) Class II diagnostic product. With the cut-off study complete and the validation study submission targeted for H1 2027, it provides a rough clinical benchmark. Generally, diagnostic products have a higher chance of clinical success, which may also be boosted given the NGAL pediatrics FDA clearance and ROCHE and Beckman Coulter partnership validations.

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: A private placement of DKK 43 million end last year (13/11/2025), which was fully subscribed, supported by both existing and new institutional and private investors, as well as BioPorto's Board and management, covered 60-70% of the communicated cash bridge needed for delivering on its new strategy targets. The sale of the Antibody business closed that gap. Overall, BioPorto is well capitalized with funding to support activities through mid-2028, where it expect to be cash flow positive. We therefore use the current share count of 495.1m. In our PoS model.

BioPorto "Forward" strategy plan + financial target (overview)

The three milstones of the "Forward" strategy in 2026-2028

2026

Building **Market Adoption** for BioPorto's NGAL test

- Increase market adoption in the US
- Reach +60 active hospitals in the US
- Initiate the clinical validation study for adults

2027

Capturing **High Growth** within the Addressable Market of USD 700m

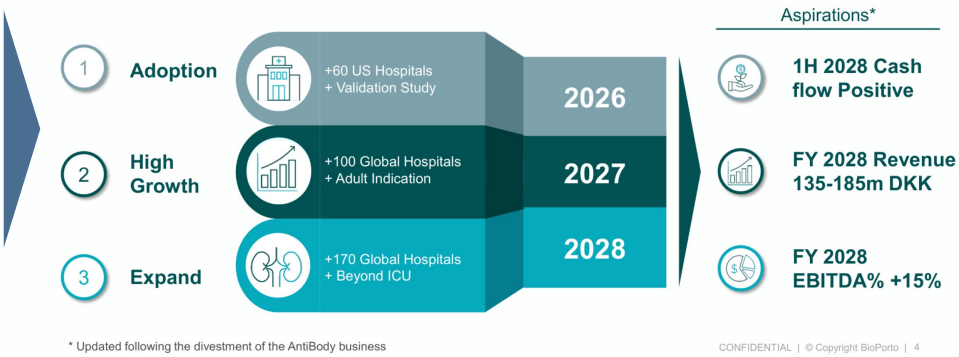
- Increase market adoption in the EU
- Reach +100 active hospitals globally
- FDA submission for adults by first half of 2027 & EU IVDR in 2027

2028

Expanding **Addressable Market & Accelerate Growth**

- Expand market adoption in the EU
- Reach +170 active hospitals globally
- Unlock broader market potential by targeting new segments

Source: BioPorto Annual Report 2025



Source: BioPorto Q1 presentation 2026.

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