BioPorto

Executing on the Forward strategy with adult pre-submission filed in Q1 2026

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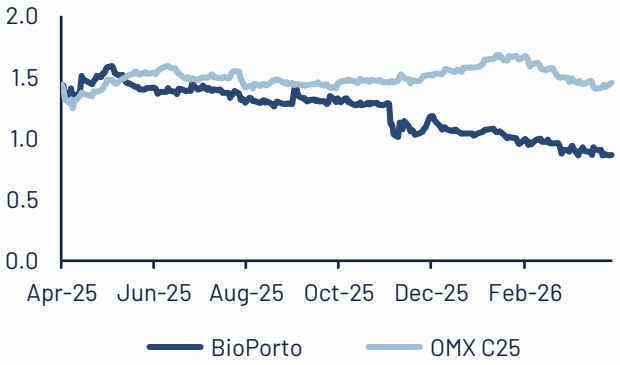
Key Financials and Valuation

Share price



YTD	-15.2%	1 year:	-37.5%
1 month:	-4.4%	3 years:	-50.9%

Note: The data are based on the closing price of the as of 31 March 2026. Source: S&P Capital IQ Pro.

Financials

DKKm	2024	2025	2026E
Revenue	36.2	40.3	48-58
Revenue growth	16.8%	11.2%	19-44%
Gross profit	24.5	30.3	
Gross margin	67.7%	75.2%	
R&D costs	-33.5	-50.5	
Adj. EBITDA	-70.6	-76.5	-60 to -50
Net income	-68.2	-82.1	
Cash flow from Operations	-83.6	-77.1	
Net cash	48.5	47.5	

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.

Key Pipeline Overview

Indication	Partner	Market	Development
ProNephro™ AKI (NGAL)*	ROCHE	Pediatric US	FDA Clearance
NGAL test	Beckman Coulter	Pediatric & Adult EU/RoW	CE Clearance
NGAL test (Adult)**	BioPorto	Adult US (available RUO)	Target end 2027
Antibodies	Various		Marketed

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

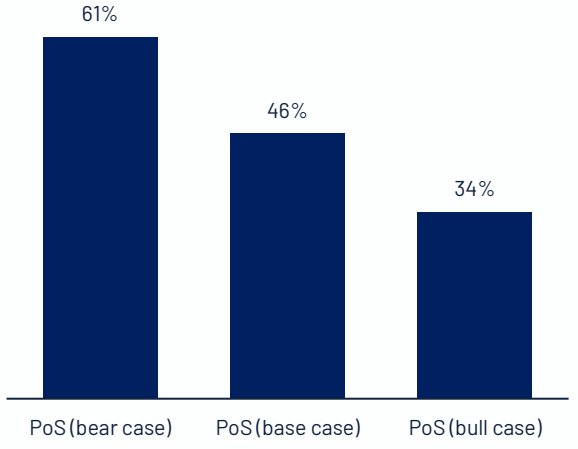
Valuation Perspectives

The "Forward" strategy to commercialize in combination with global partnerships, led by ROCHE and Beckman Coulter, supports a base case PoS of ~60%. This incorporates the likelihood of NGAL adult FDA clearance, commercial scale-up in the US and major ROW markets, via research use only acceleration and partner-led growth, and funding execution. The model includes small adjustments relating to future capital as outlined on P2.

Following the "Forward" strategy update, BioPorto's cash flow break-even has been extended by roughly one year to H2 2027. Guidance for 2026E suggests a revenue acceleration, ossibly supported by the draft KDIGO 2026 guidelines, which recommend biomarker use for AKI (pending finalisation). The mid-term revenue aspirations of DKK 150–200m by 2028 still reflect significant back-end loaded sales growth. The "Forward" strategy reset increases visibility for commercial development, while the latest capital raise in 2025 lessens financing risk and enables management to focus on execution. The longer-term commercialization journey still depends on growth with partners, but with greater emphasis on executing hospital partnerships near and medium term. Adult NGAL FDA clearance remains the key trigger in 2027. Delivery on commercial and clinical milestones are key to unlocking value in the BioPorto share.

The current model-implied PoS of ~46% remains low for a diagnostics company with a product already on the market, suggesting ongoing potential if BioPorto executes in line with the new strategy ambitions, despite some additional dilution risk as per page 6.

Model implied PoS



Investment Case – NGAL ramp up following KDIGO guidelines update

Key Investment Reasons

- BioPorto is commercializing its FDA-cleared ProNephro AKI (NGAL) test for pediatrics in the US, with the first Roche order confirmed. Partnerships with ROCHE and Beckman Coulter validate the test and support back-end loaded sales growth through 2028, with potential to secure agreements with the three remaining Big Five instrument partners.
- FDA pediatric clearance provides a foundation to access an addressable market of ~USD 700m annually at intensive care hospitals, growing at ~5%. The US adult FDA validation submission, expected H1 2027, can boost growth towards revised ambitions of DKK 150–200m by 2028.
- Draft KDIGO 2026 guidelines, published 31 March 2026, recommend biomarker use for AKI. If finalised, this can generate pull-through sales and support reimbursement eligibility.

Key Investment Risks

- Investing in life science products is inherently risky and requires patience. 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.
- Growth with partners has been slower than expected, partly due to slower approval processes, and introduces some third-party risk to the 2028 "Forward" strategy aspirations.
- BioPorto is funded through 2026 following the November 2025 private placement of DKK 43m, covering 60–70% of the capital needed to bridge the forecasted gap to break-even. Non-dilutive options such as a sale of the antibodies business are available, but some further dilution may occur to fund 2027 activities or if execution falls short.

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 its HQ in Copenhagen, a US office in Boston, and was 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 creatinine). The NGAL test is currently available for Research Use Only (RUO) in the U.S. 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 and Beckman Coulter as a global distribution partner. The partnerships aim to scale adoption and expand clinical use.

Investment case: BioPorto is scaling the sales of its FDA-cleared 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 within ICU (intensive care) of USD 700 million, a targeted section of the broader around USD 3.0bn total available market, according to BioPorto internal estimates.

BioPorto has reset its "Forward" strategy ambitions in November 2025, focused on measurable operational milestones. The company now targets partnerships with 60+ hospitals in US by end-2026, FDA submission for the adult NGAL test in H1 2027 (from H2 2026), and cash flow positive in H2 2027 (from end-2026). The strategic reset improves transparency and provides a credible path toward sustainable growth. The clinical timeline change relates to data collection and analysis cut-off study delays; however, the recent pre-submission March 2026 suggests the new timeline remains on track. Regulatory approval is still targeted for 2027 and can be a catalyst for growth with partners across the US as BioPorto works to become a standard of care in hospitals.

Q4 2025 growth and 2026 guidance supported continuing growth in RUO sales across the US, which may be supported by the recent update to KDIGO (Kidney Disease: Improving Global Outcomes) best-practice guidelines, which in draft form recommends using biomarkers. KDIGO inclusion can drive pull-through demand as reimbursement decisions in developed healthcare systems often align with KDIGO recommendations and could position the NGAL test to be the preferred diagnostic tool. Longer-term, partnerships with the five major instrument providers are a significant market opportunity.

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 (draft open for public comment until 27 April 2026). The next key catalyst is likely the initiation of the adult validation study following the FDA pre-submission end Q1 2026. Investor focus will center on whether BioPorto can accelerate hospital adoption toward 60+ active US sites by year-end 2026 and demonstrate that the Roche and Beckman Coulter partnerships are translating into recurring revenue.

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, 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. 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 one-pager 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.

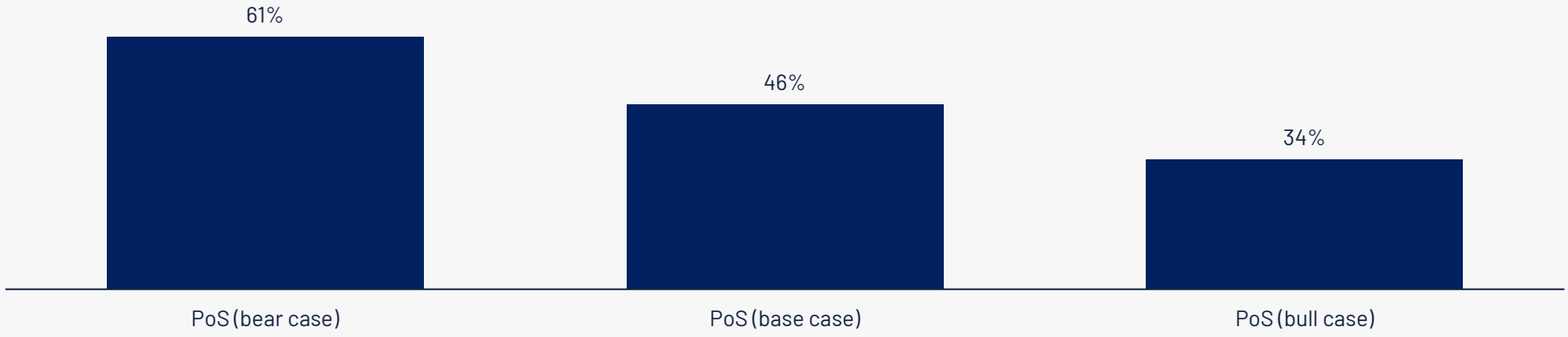
We model three scenarios: a bear- base- and bull-case scenario using the indicated level of market size and growth by BioPorto under different peak market share assumptions. For simplicity reasons, assumptions on EBIT margin, royalty rates, discount rate, launch date, and time to peak market share are 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 46% 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 61% 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 34% 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: Following the new "Forward" strategy plan (November 2025), BioPorto expects to raise an additional DKK 60-70 million to bridge the gap to cash flow positive by the end of 2027. A private placement of DKK 43 million (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, covers 60-70% of the communicated cash bridge, and funds BioPorto through 2026. The private placement was at market prices with dilution of around 8.2% for non-participating shareholders. The latest private placement de-risks the BioPorto investment case, both by extending the cash runway and by reducing future cash needs and further dilution. At current market prices, the further DKK 20-30 million to cover activities in 2027 implies further future dilution of around 4.5% - 6.8% based on outstanding shares of 495.1m. This may be higher or lower depending on future share prices. However, non-dilutive funding methods may also be used. Overall, BioPorto is well capitalized with funding to support activities through 2026.

BioPorto “Forward” strategy plan – overview

THE THREE MILESTONES OF THE "FORWARD" STRATEGY IN 2026-2028:

2026

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

2027

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

2028

Expanding **Addressable Market & Accelerate Growth**

Source: BioPorto Annual Report 2025

2026 - Building Market Adoption for BioPorto’s NGAL tests

- 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

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