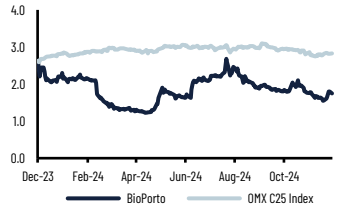
BioPorto

Market: OMXC Small Cap	Ticker: BIOPOR	Share price (DKK): 1.75	Market cap (DKK): 751.9m	Net cash (DKK): 71.7m	Enterprise value (DKK): 680.2m

Share information



YTD	-16.3%	1 year:	-41.0%
1 month:	-0.9%	3 years:	-36.8%

Note: *We apply the closing price from 09 December 2024
Index rebased to 10.12.2023. Source: S&P Capital IQ

Financials

(DKKm)	2022	2023	2024E
Revenue	29.0	31.0	40.0*
Revenue growth	*19.3%*	*7%*	*around 30%*
R&D costs	34.5	N/A	N/A
Adj EBITDA	-78.9	-56.0	-75 to -90*
Cash flow from operations	-52.5	N/A	N/A
Cash position	81.8	66.0	N/A

Notes: *Company guidance for 2024E

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	BioPorto	Adult US (RUO)	Initiated
gRAD	Various		Marketed
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. Adults US RUO stands for research use only

Company description

BioPorto is a Danish life-science diagnostics company with a US office in Boston. BioPorto was founded in 2000 and listed on Nasdaq Copenhagen in 2004. The company's primary product is the NGAL Test, designed for early detection of acute kidney injury (AKI) risk. Unlike current hospital and emergency room diagnostics, which typically take 48–72 hours, the NGAL Test provides results within 2 hours. The NGAL Test is currently available for Research Use Only (RUO) in the US and Canada for Adults and is commercially distributed in Europe and Rest of World (RoW). In December 2023, the test received FDA marketing authorization for pediatric use (up to 21 years old) in the US under the brand name ProNephro AKI (NGAL). Roche is partnering with BioPorto to distribute the ProNephro AKI (NGAL) test across multiple instruments in the US. Following the authorization BioPorto has announced a five-year strategy plan to reach USD 100 million in annual revenue and be profitable by 2029 (see appendix page 4)

Investments case

The investment case for BioPorto focuses on leveraging the FDA marketing authorization of ProNephro AKI (NGAL) for pediatric use as a foundation for future approvals for adult use and broader applications. In February 2024, the company announced a five-year strategy (2024–2029) targeting USD 100 million in annual revenue and profitability by 2029 (see Appendix, page 4).

Phase 1 of BioPorto's strategy (2024-25) focuses on advancing its ProNephro AKI (NGAL) pipeline and partnerships, with FY2024 guidance for revenue of USD 6m and negative cash flow reaffirmed after Q3 2024. Sales are driven by RUO, in the US, Canada, and RoW, with revenue from its Roche partnership expected from early 2025. Key developments include expanding ProNephro AKI (NGAL) testing instruments with Roche, securing a global partnership with Beckman Coulter (Europe-focused), and holding CE approval for pediatric and adult NGAL use in Europe.

From a funding perspective, BioPorto raised USD 12m of the outlined USD 20m for its Phase 1 strategy, to finance new FDA trials for adult ProNephro AKI approval, the first of which began ahead of schedule, and expanded sales and marketing activities. BioPorto looks to accelerate sales in 2025, supported by its partnerships with Roche and Beckman Coulter, as it seeks to gain market share via its tests' unmet medical need, in its total addressable market estimated at USD 3.0bn, growing 5% annually, driven by a shift in diagnostic paradigms.

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, including adult use, broader applications, and global markets—representing a TAM of USD 3 billion annually—the base case PoS is just 54%.

Note: Probability of success (PoS) model based on company guided market assumptions and HC Andersen Capital assumptions.

Key investment reasons

BioPorto is well-positioned to achieve a successful launch of the ProNephro AKI (NGAL) Test for pediatrics globally, with recent FDA approval and marketing authorization for ProNephro AKI (NGAL) for pediatric use in the U.S., an expanded collaboration with leading diagnostic provider Roche. In addition, the ongoing use of the NGAL Test in Europe and recent partnership with Beckman Coulter accelerate commercialization of its adult test.

The grant of a marketing authorization of the ProNephro AKI (NGAL) for pediatrics can act as a lever to open for adult use and other addressable markets totalling up to USD 3 billion annually, growing 5% as the use of the NGAL Test could be broadened to other settings and indications.

At the moment, there are no competing NGAL tests commercially available in the US, and BioPorto has already de-risked its commercial potential as they currently generate revenue.

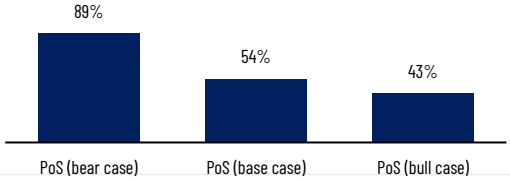
Key investment risks

Investing in the development of drugs and life science products is generally risky and requires patience and a high-risk appetite. The FDA's marketing authorization for ProNephro AKI (NGAL) for pediatrics in the US does not guarantee commercial success, particularly considering the special sales, reimbursement, and payer structure of the US life science product market. Additionally, approval of the ProNephro AKI (NGAL) for Adults is not guaranteed and represents some clinical risk, however, the first patients for the first of two studies have been enrolled ahead of schedule.

BioPorto has entered a partnership with Roche for ProNephro AKI (NGAL), US pediatrics, and Beckman Coulter for the CE marked NGAL Test, pediatric and adult in Europe. Although this is a sign of high conviction, there are third-party risks associated with the partners' execution and speed of the commercialization process.

BioPorto reported a cash position of DKK 76 million, after raising USD 11.7m via an oversubscribed direct share issue at market price. This was the first part of its strategy to raise USD 20m for Phase 1 of its strategy, running 2024-2025. BioPorto has ambitions to be cash flow positive in 2026, and therefore is still reliant on access to capital markets, despite some de-risking as sales grow. Investors should consider that they could be required to participate in future capital raises to avoid dilution.

Probability of Success – Pediatrics, adult, RoW combined



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 pipeline products to achieve marketing authority for the ProNephro AKI (NGAL) adult test (US) and successful commercialization across its markets, based on the model assumptions described below.

Market size and market growth

According to BioPorto, the total addressable market (TAM) for its ProNephro AKI (NGAL) Test is around USD 3 billion, growing 5% annually when combining indications and geographical markets. The latest company-guided annual TAM for the individual market segments are as follows: US pediatrics: USD 60-80 million, US Adult: USD 1.1 billion, rest of the world pediatrics (ROW) USD 90-120 million, ROW Adults: USD 1.7 billion.

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 begins in these markets from 2024 onwards. Whereas the ProNephro AKI (NGAL) US adult test is undergoing clinical trial (submission to FDA expected late 2026) with an expected launch in 2028. We model that the market will grow annually at the company-guided 5% level until 2030 then slowing to 3% until the terminal period.

Longer term, BioPorto will most likely face competition, so BioPorto will likely see its sales growth slow or even drop at some point. 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 does not assume that BioPorto will immediately obtain a high market share. Instead, the model uses a peak market share of 10-40% after 6-8 years, in the base case, depending on the different indications and markets, with pediatrics US assumed to attain the highest market share.

Generally, 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. The likely penetration curve can take different paths, but we model a ramping up in growth rate towards peak market share with varying penetration rates for the different indications.

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 marketing authorization 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, enables a greater peak market share.

We also model a small value based on BioPorto's other products (ELISA Kits, gRAD platform, and 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 containing 5,764 pipeline projects in pharmaceutical and biotech companies, the average historical likelihood of a Phase 3 pipeline project passing through to launch is approximately 59%. This is calculated across all medical indications, including those areas that are typically perceived as being very difficult to pass. BioPorto is within diagnostic where it is generally considered easier to get approval of new products, while approval of the ProNephro AKI (NGAL) Test for pediatric use, successful CE mark, and partnerships with Roche and Beckman Coulter validate the test. BioPorto expects to submit Adult trial submission in late 2026 with approval estimated to take 12-18 months after submission. BioPorto expects that the US Adult market will be the most significant of all markets at peak level. A low PoS indicates, that the market currently implies a low possibility of success for the company to attain approval of its US Adult test and successful commercialization in line with the DCF assumptions.

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 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. In June 2024, the company raised USD 11.7 million in a direct share issue. Following Q3 2024 BioPorto had a cash position of DKK 76.3 (USD 11.5 million). The midpoint 2024 guidance shows operating and R&D costs of DKK 122.5m, with an Adj. EBITDA of DKK -75 to -90 million.

The company is therefore well capitalized going into 2025, with an additional capital raise expected to meet the 2024/25 target of USD 20m. BioPorto's strategy plan aims for the company to achieve break even in 2026 if revenue lands at the top end of its revenue target of USD 15-25m. Following the private placement in June 2024, leading to the issuance of 50,000,000 new shares, yielding gross proceeds of DKK 81.4m, BioPorto's total shares outstanding are 429,670,461.

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 and 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 it is already fully discounted.

However, 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 55%, according to the model. This compares to a historical average PoS of approximately 59% for Phase III pipeline projects across all indications. However, given BioPorto's approval within pediatrics and existing revenue, and commercial partners, the PoS for ProNephro AKI (NGAL) for adults, is likely higher than the benchmark.

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, are assumed to be 30%, 10%, and 7.5%, respectively. Based on this, the market currently implicitly assumes there is approximately a 90% probability of a successful launch for The ProNephro AKI (NGAL) Test for adults and successful commercialization according to the model.

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 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 45% probability of launch for The ProNephro AKI (NGAL) Test for adults and successful commercialization according to the model.

Conclusion

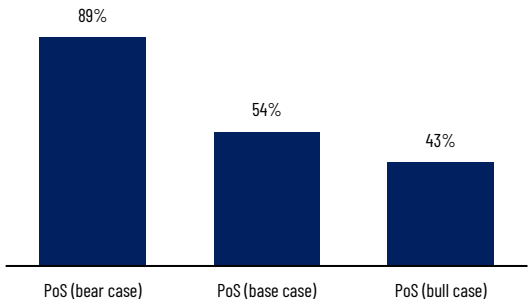
The strategy to commercialize via partners with Roche driving the ProNephro AKI (NGAL) Test for pediatrics in the US, and Beckman Coulter driving sales for pediatrics and adult tests in Europe returns a probability of successful approval of the US ProNephro AKI (NGAL) Adult Test, and global commercialization of around 55%, based on our base case model.

A general benchmark of historic PoS for pharmaceutical and biotech companies with a pipeline candidate in Phase III passing through to marketing authorization based on historical data across all indications is around 59% based on biostatistics. However, given that BioPorto has attained FDA approval for its ProNephro AKI (NGAL) Test for pediatrics, has validation via two commercial partner agreements, and limited additional financing requirements, ahead of ambitions for break-even cash flow in 2026, it can be argued that BioPorto's PoS should be higher than the historical benchmark, also when considering the general greater ease of approval within diagnostics products.

With a PoS of around 55%, there is potentially significant valuation support to the shares of BioPorto if the ProNephro AKI (NGAL) Test is commercially successfully launched for adult use and commercialized across global markets. Comparing the scenarios, the market implicitly assesses that there is the highest likelihood for the bear-case scenario to unfold.

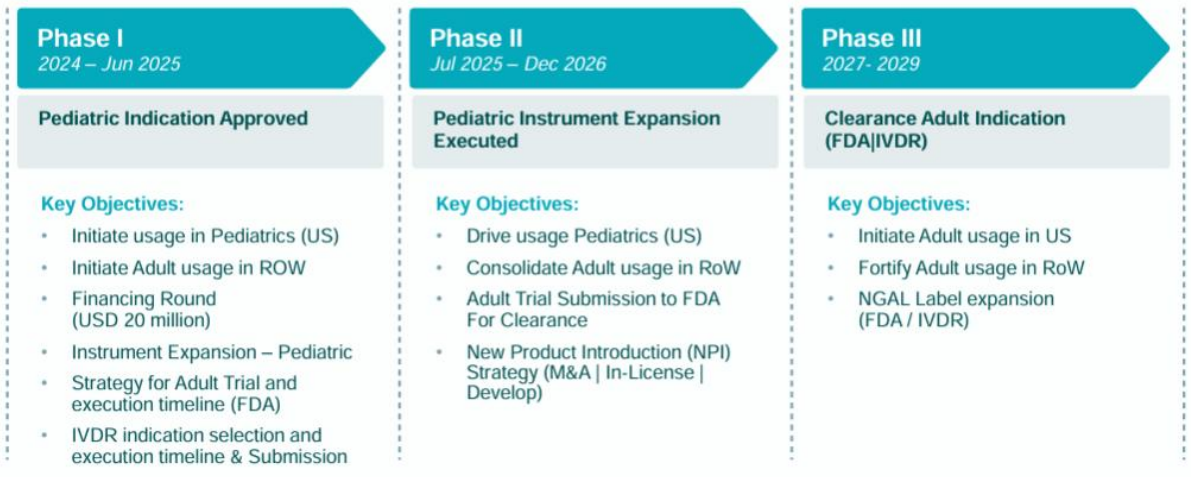
A low PoS is not uncommon for life science companies still in their developing phase and can also reflect that the market assesses there is a high likelihood that BioPorto will need to raise additional capital. However, as BioPorto has raised USD 11.7m of its planned USD 20m for 2024-2025, with ambitions for break even cash flow by 2026, we deem future capital raise requirements and, in turn, existing shareholder dilution to be more limited than is often seen within biotech companies. But shareholders should expect some further dilution as outlined in BioPorto's strategy plan.

Probability of Success – Pediatrics, adult, RoW combined



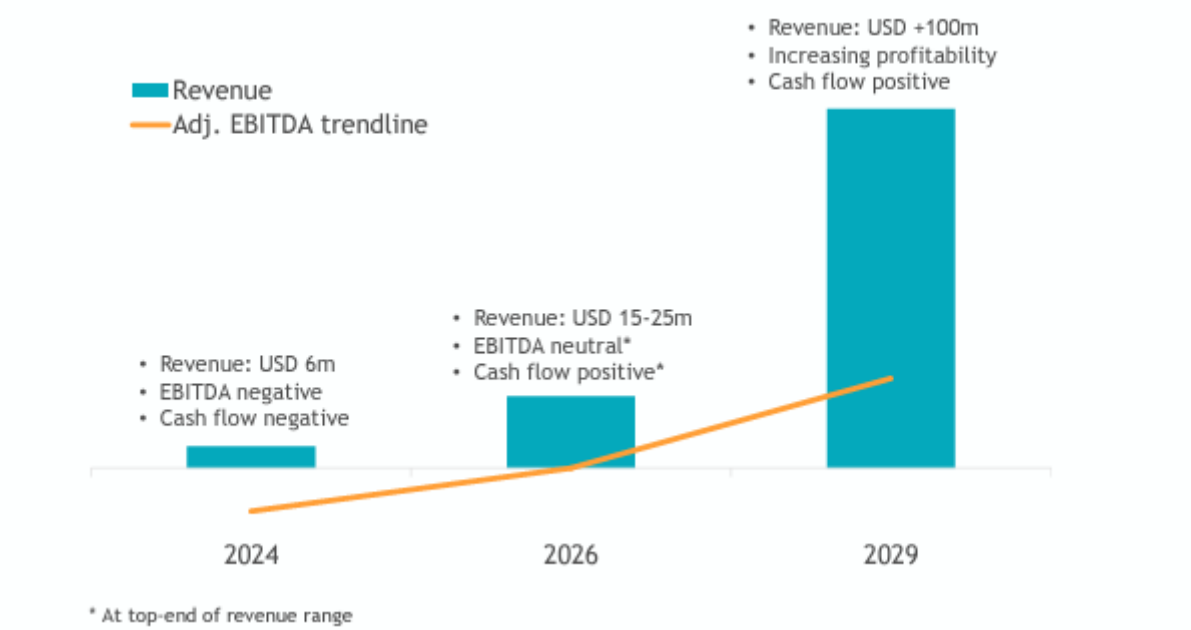
Appendix – BioPorto strategy plan materials

BioPorto strategy plan - overview



Source: BioPorto Q3 2024 Investor Presentation

BioPorto strategy plan - path to profitability



Source: BioPorto Q3 2024 Investor Presentation