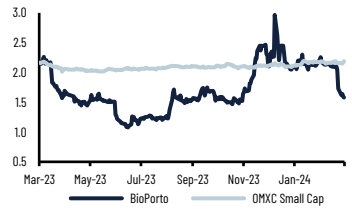
BioPorto

Market: Nasdaq Copenhagen	Ticker: BIOPOR	Share price (DKK): 1.58	Market cap (DKK): 605m	Cash position (DKK): 66m	Enterprise value (DKKm): 547m

Share information



Ytd:	-29.0%	1 year:	-27.1%
1 month:	-27.2%	3 year:	-73.4%

Note: We apply the closing price of 29 February 2023

Financials

(DKKm)	2022	2023	2024E
Revenue	29.0	31.0	40.0*
Revenue growth	*19.3%*	*7%*	*c. 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: 2023 results are preliminary from BioPorto's press release on 22.02.2024. *Company guidance for 2024E

Key pipeline assets

Indication	Partner	Development
ProNephro AKI*	Pediatric US	FDA approved
NGAL Test	Pediatric EU/RoW	CE approved
NGAL Test	Adult EU/RoW	CE approved
NGAL Test	Adult US	Initiated
gRAD	Various	Marketed
Antibodies	Various	Marketed

Note: *ProNephro AKI (NGAL) is the name for BioPorto's NGAL Test in the US. The product ProNephro AKI and NGAL Test are, therefore, the same.

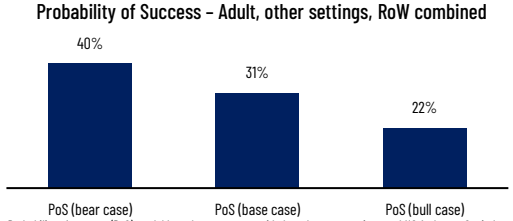
Company description

BioPorto is a Danish life-science diagnostics company with headquarters in Copenhagen and an office in Boston. BioPorto was founded in 2000 and listed on Nasdaq Copenhagen in 2004. BioPorto's primary product is the NGAL Test, called ProNephro AKI in US, which is a test that can make an early assessment in 2 hours of the risk of acute kidney injury (AKI) in patients, which compares to currently available diagnosis in hospital and emergency room that typically take 48-72 hours. The NGAL Test is currently available in Europe, Canada, and RoW, while the ProNephro AKI test has received marketing authorization by FDA in December 2023 for pediatric use (ages 3 months through 21 years). BioPorto has just 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 is driven by the potential for BioPorto to successfully leverage the marketing authorization (FDA approval) for ProNephro AKI for pediatrics, to also be approved for adult use, as well as, for use in other settings and in other geographical areas (Rest of World). Although important as a validation of the NGAL Test, the market for pediatric use in US is relatively small from a financial perspective, as company estimates suggests an annual addressable market of USD 150-200 million. Using a DCF-modelling approach under a set of assumptions (see pages 2 and 3), the likelihood of a successful launch (Probability of success, PoS) of the ProNephro AKI for pediatrics as implied by the stock market, can be calculated. The model suggests a likelihood of more than 100%, which means that the stock market has already fully discounted that BioPorto will be successful in commercializing the ProNephro AKI for pediatrics in the US. However, for the more important and valuable indications for adults, in other settings and RoW with an addressable market totalling up to approximately USD 3 billion annually, the market implicitly assesses there is a PoS of approximately 30% in the base case scenario. Although BioPorto has been granted a marketing authorization for the ProNephro AKI, the PoS (for adult use) is still only just above half the average historical sector approval rate of 55% for product candidates in Phase 3, according to Biostatistics.

Probability of Success – Adult, other settings, RoW combined



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

Key investment reasons

Having recently received a marketing authorization (FDA approval) of the ProNephro AKI for pediatric use in the US, and announced a collaboration with leading test analyzer provider Roche, as well as, the current ongoing use of the NGAL Test in Europe, BioPorto has the potential to successfully launch ProNephro AKI/NGAL Test for pediatrics globally.

The grant of a marketing authorization of the ProNephro AKI for pediatrics can act as a lever to open up for adult use and other addressable markets totalling up to USD 3 billion annually, growing 4% as the use of the NGAL Test could be broadened to other settings and geographical areas than hospitals in US.

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 high-risk appetite. The grant of a marketing authorization for ProNephro AKI for pediatrics in US does not guarantee commercial success, particularly considering the special sales, reimbursement, and payer structure of the US market for life science product.

Also, the level of revenue In Europe, where the NGAL Test has been available for sale, has not been high. BioPorto plans to build its own US sales organization for the upcoming launch of ProNephro AKI, as well as partnership and distribution channels. Although this is a sign of high conviction, there are risks associated with carrying out the commercialization process by BioPorto itself.

In its annual report for 2023, BioPorto states it has a cash position of DKK 66 million, but BioPorto still has a high dependence on the ability to secure ongoing funding of the company, either through capital raises in the market or by issuing warrants and options to internal management and employees. To finance its new strategic five-year plan, BioPorto will raise USD 20 million between Q2 2024 and H1 2025, but when capital markets are in risk-off mode, this can be challenging in terms of timing and size of the required funding. Investors should consider that they could be required to participate in future capital raises to avoid dilution.

Appendix – Discussion of assumptions in DCF model

The model

The objective of this investment case is not to calculate a price target for BioPorto shares. Instead, the investment case uses a simplified DCF (Discounted Cash Flow) model to give investment perspectives based on different scenarios. In particular, the model can use simulations to give an indication as to how much the current market cap of BioPorto is implicitly discounting, in terms of the likelihood of a successful commercial launch (PoS) of the ProNephro AKI/NGAL Test, for different indications and settings. The DCF model considers the future potential cash flow of the company when the ProNephro AKI/NGAL Test is launched. To do this, the inputs in the DCF model are based on several assumptions, which will be discussed below.

Market Size and Market Growth

According to BioPorto, the addressable market for the ProNephro AKI/NGAL Test is up to USD 3 billion, growing 4% annually when combining the different indications and geographical markets. Based on the available information and assessment in the prospectus published by BioPorto, the individual annually addressable market size for the ProNephro AKI/NGAL Test in relation to the different indications is estimated as follows: Pediatrics approximately USD 150-200 million, adults US approximately USD 1.1 billion, and adults RoW USD 1.7 billion.

As BioPorto will not make a full commercialization in the four different markets simultaneously, the model assumes a 2-3-year timespan when BioPorto moves from the first pedriatic indication to the other indications. Longer term, BioPorto will most likely face competition, so BioPorto will likely see its sales growth slow or even drop at some point. The patent expiry dates for BioPorto's different patents is only a few years out for some of its patents, but the management is confident that BioPorto will be able to effectively defend its position for a longer period than the expiry dates suggests, as any new competitor needs to go through the same investigational and development process as BioPorto has been with the NGAL Test. In the model, an effective 'competitive protection' period of 10 years has been used.

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 8-10 years, depending on the different indications and markets. Generally, a high market share is often difficult to obtain immediately after product launch due to established workflow processes which sometimes limits 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.

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 from Phase 2 is approximately 55%. 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 to be easier to get approval of new products. A low PoS indicates, that the market currently implies a low possibility of success for the company and its given product candidates.

EBIT – Margin

According to Refinitiv 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 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

The model typically uses a yearly cash burn of DKK 70-80 million in the first years of launch into a new indication or market, and since no details of the upcoming capital raise in Q2 2024 have been announced, the model uses the current company share count of 379.7 million.

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 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).

Appendix – Results and conclusion

Base Case Scenario

In the base case scenario, the model uses the indicated market size by BioPorto, USD 3 billion, growing 4% annually. The model uses industry average levels of profitability as a starting point, resulting in a EBIT margin of 50% from 2027 and forward. The peak market share assumption for pediatric, adults, and RoW (Rest of the World) are 40%, 15%, 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 for pediatrics in US, i.e it is already fully discounted.

Theoretically, the 'remaining market cap' suggests a PoS of approximately 30% for the launch of the ProNephro AKI/NGAL Test to adults and further indications and settings according to the model. This compares to a historical average level of success of approximately 55% for pipeline projects across all indications, and likely even higher likelihood for companies developing diagnostic-type products, similar to those currently in development at BioPorto.

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 pediatrics, adults, and RoW, which is assumed to be 30%, 10%, and 5%, respectively, and a slight fall in the penetration curve. Based on this, the market currently implicitly assumes there is approximately a 40% probability of successful launch for The NGAL Test 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%, 20%, and 15%, respectively. For the bull case the penetration curve is also accelerated. Based on this, the market currently implicitly assumes there is approximately 20% probability of launch for The NGAL Test according to the model.

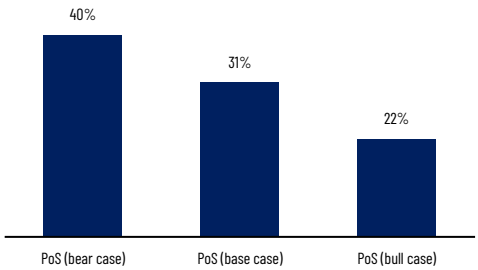
Conclusion

Following the recent share price decrease, the three scenarios all suggest a lower level of market confidence in BioPorto's ability to successfully launch the ProNephro AKI/NGAL Test and use this as a lever to get the ProNephro AKI approved for adult use and successfully launched. With a PoS of approximately 30%, 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 in other settings etc. Comparing the scenarios, the market implicitly assess that there is the highest likelihood for the bear-case scenario to unfold.

The model only includes potential cash flows from ProNephro AKI/NGAL Test, thereby implicitly assuming the market paying no value to the other potential future cash flows from other products. If a value is paid to the other BioPorto products (ELISA Kits, gRAD platform, and antibodies), the implicit market confidence for the ProNephro AKI/The NGAL Test becomes even smaller.

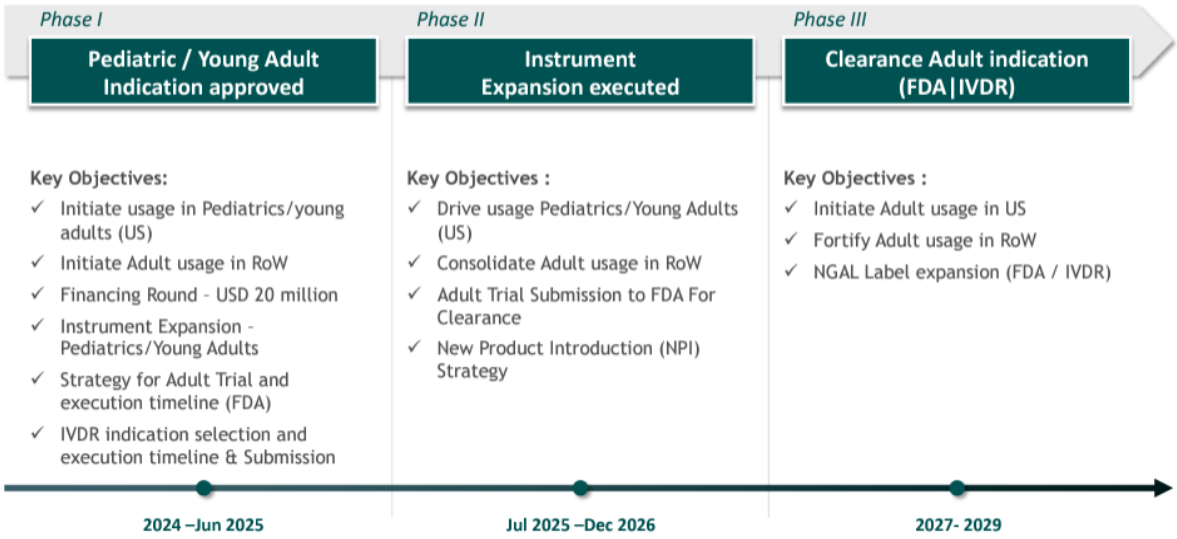
A low PoS is not uncommon for life science companies still in their developing phase and can also reflect that the market assesses there is a high likelihood that BioPorto will need to raise additional capital as it is the case with the expected USD 20 million raise, thereby diluting the share base.

Probability of Success – Pediatrics, adult, RoW combined



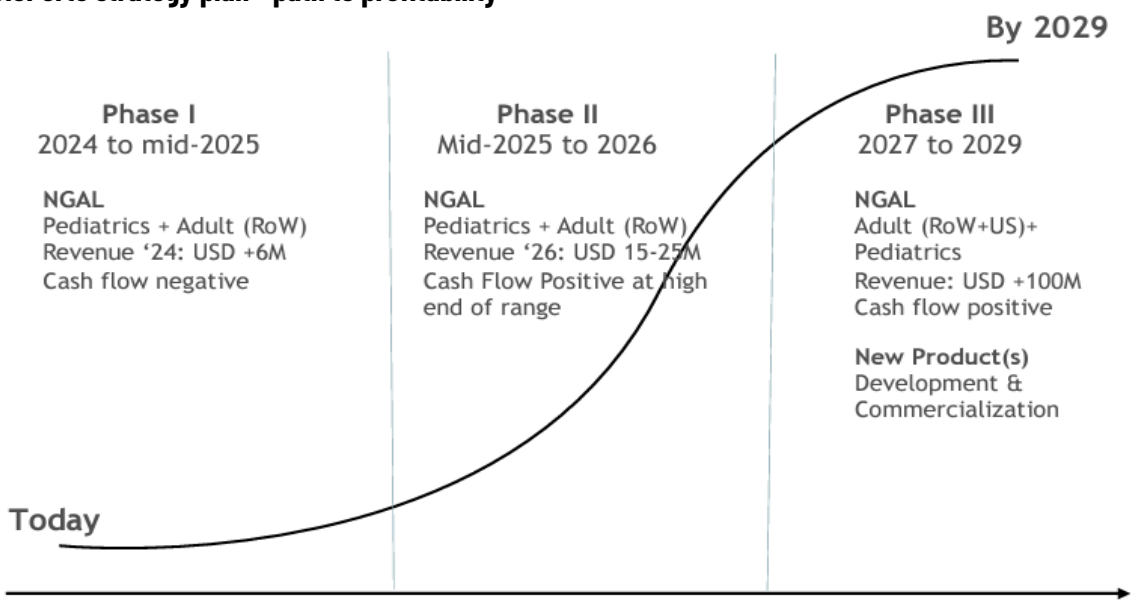
Appendix – BioPorto strategy plan materials

BioPorto strategy plan - overview



Source: BioPorto Investor Presentation, 22.02.2024

BioPorto strategy plan - path to profitability



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