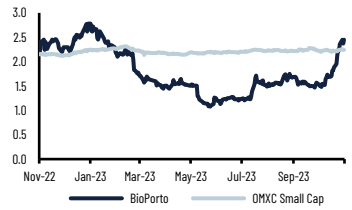
BioPorto

Market: Nasdaq Copenhagen	Ticker: BIOPOR	Share price (DKK): 2.44	Market cap (DKKm): 932	Cash position (DKKm): 69.9 (Q3 23)	Enterprise value (DKKm): 871

Share information



Ytd:	10.0%	1 year:	13.7%
1 month:	60.3%	3 year:	-17.8%

Note: We apply the closing price of 23 November 2023.

Financials

(DKKm)	2021	2022	2023E*
Revenue	24.3	29	30-33*
Revenue growth	*4.7%*	*19.3%*	*3-14%*
R&D costs	29.9	34.5	N/A
Adj EBITDA	-65.2	-78.9	-59 - -56*
Cash flow from operations	-64.6	-52.5	N/A
Cash position	45.5	81.8	N/A

*Company guidance

Key pipeline assets

Indication	Partner	Development
The Ngal Test	Pediatric US	Completed *
The Ngal Test	Pediatric EU	CE marketed and registered
The Ngal Test	Adult EU	CE marketed and registered
The Ngal Test	Adult US	
gRAD	Various	Marketed
Antibodies	Various	Marketed

* De Novo application for marketing authorization submitted to FDA

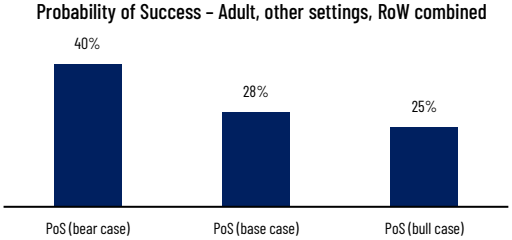
Company description

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 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 current available diagnosis in hospital and emergency room that typically take 48-72 hours. The NGAL Test is currently available in Europe, Canada, Asia, and Israel. BioPorto has received an FDA breakthrough designation for the pediatric indication and has submitted an application to the FDA in 2022 to get a marketing authorization of using the NGAL Test for pediatrics.

Investments case

The investment case is driven by the potential for the company to successfully leverage a potential approval by the FDA of the marketing authorization the NGAL Test for pediatrics, to also be approved afterward 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 is relatively small from a financial perspective, as company estimates suggests an annual addressable market of USD 25-30 million. Using a DCF-modelling approach under a set of assumptions (see pages 2 and 3), the likelihood of approval and successful launch (Probability of success, PoS) of the NGAL Test for pediatrics as implied by the stock market, can be calculated. The model suggests a likelihood of more than 100 percent, which means that the stock market has already fully discounted that BioPorto will get the marketing authorization and afterwards be successful in commercializing the NGAL Test 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 this reflects increased market confidence in BioPorto, the PoS is still only half the average historical approval rate of 55 percent 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 already a Breakthrough Status as it serves an unmet need, the NGAL Test from BioPorto is likely to receive a marketing authorization by the FDA for pediatric use in the US market based on the current use of the NGAL Test in Europe, and the medical advancement it gives to pediatric patients with the risk of AKI.

The potential grant of a marketing authorization of the NGAL Test for pediatrics will likely act as a lever to open up for adult use and other addressable markets totalling up to USD 3 billion annually growing 4 percent 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 their commercial potential as they have received a designation from the FDA for The NGAL Test and currently generates revenue.

Key investment risks

Investing in the development of drugs and life science products is generally risky and requires patience and high-risk appetite. A grant of a marketing authorization for The NGAL Test in the US is not guaranteed, even though early phases have shown significant results and BioPorto is in dialogue with the FDA to secure alignment with the FDA's request for information and data. BioPorto has previously pulled applications to the FDA regarding its NGAL Test.

There is no guarantee the launch will be commercially successful, 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 an expected launch, 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 3rd quarter report, BioPorto states that it has sufficient funding for the next 12 months, 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. When capital markets are in risk-off mode, this can be challenging in terms of timing and size of potential funding. Investors should consider that they could be required to participate in future capital raises to avoid dilution.

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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 likelihood of a grant of a marketing authorization and successful commercial launch (PoS) of the NGAL Test for different indications and settings. The DCF model considers the future potential cash flow of the company when the 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 NGAL Test is up to USD 3 billion, growing 4 percent 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 NGAL Test in relation to the different indications is estimated as follows: Paediatrics approximately USD 25-30 million, adults USD approximately 475 million, additional channels in US (emergency departments and certain outpatient settings) approximately USD 700 million, and Global launch outside US a further USD 1.8 billion.

As BioPorto will not make a full commercialization in the four different markets simultaneously, the model assumes a 1-2-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 30-50 percent 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 for simplistic reasons, the penetration curve is expected to be linear, growing 2.5-5 percentage points a year from the expected launch year.

Discount rate

The model uses a discount rate of 15 percent, 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 percent. 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 80-100m in the first years of launch into a new indication or market, but no new rights offering has been announced as BioPorto has sufficient funding for 12 months. Therefore, 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).

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Base Case Scenario

In the base case scenario, the model uses the indicated market size by BioPorto, USD 3 billion, growing 4 percent annually. The model uses industry average levels of profitability as a starting point, resulting in a EBIT margin of 50 percent from 2027 and forward. The peak market share assumption for pediatric, adults, more clinics, and RoW (Rest of the World) are 40 percent, 15 percent, 15 percent, and 10 percent, respectively. Based on these assumptions and a discount rate of 15 percent, the market currently implicitly assumes there is PoS of 100 percent for the NGAL Test for pediatrics in US, i.e it is already fully discounted.

Theoretically, the 'remaining market cap' suggest a PoS of approximately 28 percent for the launch of the 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 percent 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.

It could be argued that the market-implied likelihood for a successful launch of the NGAL Test for pediatrics should be considered lower than 100 percent – and the PoS for the adult indication etc., thus somewhat higher – but as an approval of the NGAL Test for adults etc. is conditioned on a marketing authorization for pediatrics, the adult indication has no value from a modelling perspective if the NGAL Test is not approved for pediatrics.

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 pediatric, adults, more clinics, and RoW which assumed to be 30 percent, 10 percent, 10 percent, and 5 percent, respectively. Based on this, the market currently implicitly assumes there is a 40 percent 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 assumption for pediatric, adults, more clinics, and RoW which assumed to be 50 percent, 20 percent, 20 percent, and 15 percent, respectively. Based on this, the market currently implicitly assumes there is a 25 percent probability of launch for The NGAL Test according to the model.

Conclusion

Following the recent share price increase, the three scenarios all suggest a markedly higher level of market confidence in BioPorto's ability to get the NGAL Test approved. With a PoS of approximately 30 percent, there is however still a potentially significant valuation support to the shares of BioPorto when the NGAL Test is indeed approved and commercially successfully launched. 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 The 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 NGAL Test becomes even smaller.

Importantly, a relatively 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 the company – BioPorto - will need to raise additional capital, thereby diluting the share base.

Probability of Success – Adult, other settings, RoW combined