BioPorto

On track on all parameters set out in the 2026-2028 "Forward" plan



Michael Friis
+45 20 34 94 87
michaelfriis@hcandersencapital.dk



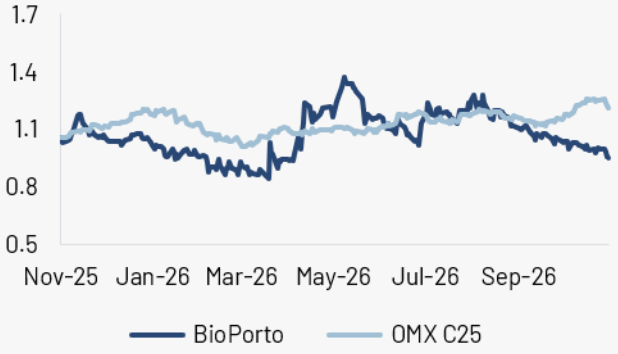
Victor Skriver
+45 22 59 27 27
victor@hcandersencapital.dk

Corporate customer
Full disclaimer on back page
23.11.2026 08:45 CET

HC ANDERSEN CAPITAL

Key Financials and Valuation

Share price



YTD:	-6.9%	1 year:	-11.2%
1 month:	-8.7%	3 year:	-59.7%

Note: Closing price from 19 November 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	53.2**
Market value	793.5	666.0	505.1	475.3

Note: *BioPorto's own 2026 guidance. NGAL revenue guidance DKK 33-42m. **Cash reflects reported Q3 2026 cash, not adjusted for debt. Lease liabilities were DKK 5.8m in Q2 2026. Source: S&P Capital IQ Pro.

Key Pipeline Overview

Indication	Clinical Study	Regulatory Status
ProNephro™ AKI (NGAL)	Completed	FDA Cleared (Dec 2023)
NGAL test (Adult)	Validation study enrolling	FDA clearance expected mid-2028
EU / ROW (IVDR)	Completed	IVDR certification date not confirmed

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, being bear, base and bull, using BioPorto's indicated market size and growth under different peak market share assumptions.

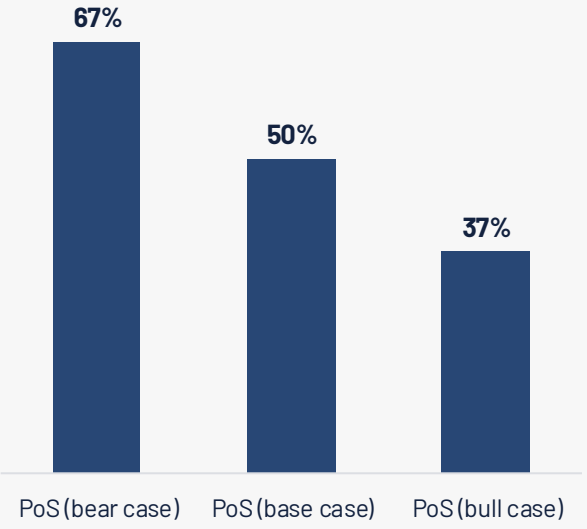
The current base-case model-implied PoS of ~50% sits below the ~59% benchmark for Phase 3 projects reaching launch, and the bull case at ~37% implies further upside if BioPorto executes against its strategic and regulatory milestones. The decline from ~60% a quarter ago reflects the lower share price, not a weaker model value.

With BioPorto still early in driving adoption and shifting treatment regimes, sizing the addressable market is inherently uncertain, which the peak share scenarios aim to bracket.

Following the sale of its AntiBody business, BioPorto expects to be funded into mid-2028 and to turn cash flow positive in H2 2028, with cash of DKK 53.2m at end-Q3. Dilution risk from further capital raises is reduced but not eliminated, given the ~DKK 20m rise in study costs.

A market re-rating of the PoS hinges on BioPorto delivering on three pillars central to its long-term sales potential. These are 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 – On track against the "Forward" plan

Key Investment Reasons

- FDA-cleared (pediatric) ProNephro AKI test: 59 US hospitals by end-Q3 2026, with US RUO sales up 73% in the quarter.
- Directly addressable ICU market $700m annual growing ~5%. Expected US adult FDA potential approval target mid-2028 could accelerate growth with expected market size 20x higher than current approved pediatric.
- KDIGO 2026 guidelines, due within months, and other indicators support early detection and could boost uptake.
- BioPorto has so far executed on the 2026 milestones of the "Forward" plan, with adoption and the adult study on track and guidance maintained.

Key Investment Risks

- Pediatric clearance validates NGAL but does not guarantee adult clearance, which rests on a study still enrolling.
- Running on partner platforms places execution risk with counterparties who control the menu, the sales force and the priority against in-house assays.
- Any deviation from the "Forward" plan or the timeline could mean further dilutive capital raises before break-even in H2 2028.
- IVDR certification has no confirmed date against a statutory end-2028 deadline, with EU and ROW sales resting on a legacy IVDD mark.

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 to 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 to 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 to 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 mid-2028, 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 and EU reimbursement and hospital protocols are closely tethered to it. The 2026 draft guidelines recommend biomarker use in AKI and acknowledge that the current standard has not delivered. Inclusion would shift NGAL from a discretionary add-on to a compliance tool, driving pull-through demand. Finalisation is expected within the coming months and is a direct prerequisite for the 2028 ambitions. WHO and US health authorities also raised the profile of kidney disease during 2026.

BioPorto reset its "Forward" strategy in November 2025 around measurable milestones, with FDA submission pushed out by a year in June 2026 to H1 2028 and cash flow positive moved to H2 2028. Execution has been consistent. The validation study began enrolling in Q3, the hospital base reached 59 against the 60+ targeted for year-end, guidance was maintained, and cash stood at DKK 53.2m.

The hospital count is the most informative leading indicator in the case. The installed base is what Roche and Beckman Coulter scale against once the adult indication is cleared, and it reads through with a lag, visible in the 12-month rolling US NGAL RUO figure of DKK 26.3m.

Although pediatric FDA clearance, RUO use, and technical validations through partnerships increase the likelihood of adult approval, inherent study risk remains. Generic competition cannot be ruled out after patent expiry in late 2028, 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 mid-2028.

Near-term, the KDIGO guideline update of 31 March 2026, the first since 2012, and the inclusion of biomarker tests may drive pull-through demand and reimbursement eligibility. The public comment period closed on 27 April 2026 and the company expects finalisation within the coming months. With the adult validation study now enrolling across 12 US sites, inclusion in the final KDIGO guidelines is the next key catalyst. BioPorto had 59 active US hospitals at the end of Q3 2026 after five additions in the quarter, leaving the 60+ year-end target within reach, and investor focus shifts to whether the Roche and Beckman Coulter partnerships convert into recurring revenue. Revenue excluding the divested AntiBody business rose 11% to DKK 22.7m in 9M 2026, or 24% to DKK 25.5m excluding the voluntary recall, driven by US NGAL RUO.

US Pediatric (ProNephro AKI): FDA-cleared in December 2023 for patients aged 3 months to 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 59 by the end of Q3 2026 and targeting 60 or more by year-end.

US Adult (NGAL RUO to FDA clearance): Currently sold for research use only, contributing DKK 18.4m in 2025, up 25% year on year, and representing the core growth engine. US NGAL RUO sales rose 73% in Q3 2026, taking the 12-month rolling figure to DKK 26.3m at a constant USD/DKK of 6.5 as reported by the company, up 63% year on year. The adult cut-off study completed patient enrolment in October 2025 and a pre-submission was filed in March 2026. The validation study was initiated in August 2026 and began enrolling in Q3 across 12 US sites, targeting approximately 900 patients and at least 75 confirmed AKI cases for the analysis, with FDA submission targeted for H1 2028 and clearance expected mid-2028.

EU / ROW (IVDR): CE-marked under the legacy IVDD for all patient populations. IVDR certification has no confirmed date, with a statutory deadline at end-2028, and in our view partner-driven scaling in ROW is unlikely to begin before certification is in place. Certification 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 enrolling (12 US sites, ~900 patients)	Pre-submission submitted March 2026, FDA clearance expected mid-2028	
EU / ROW (IVDR)	Completed	Completed	CE-marked (IVDD); IVDR certification date not confirmed	

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.

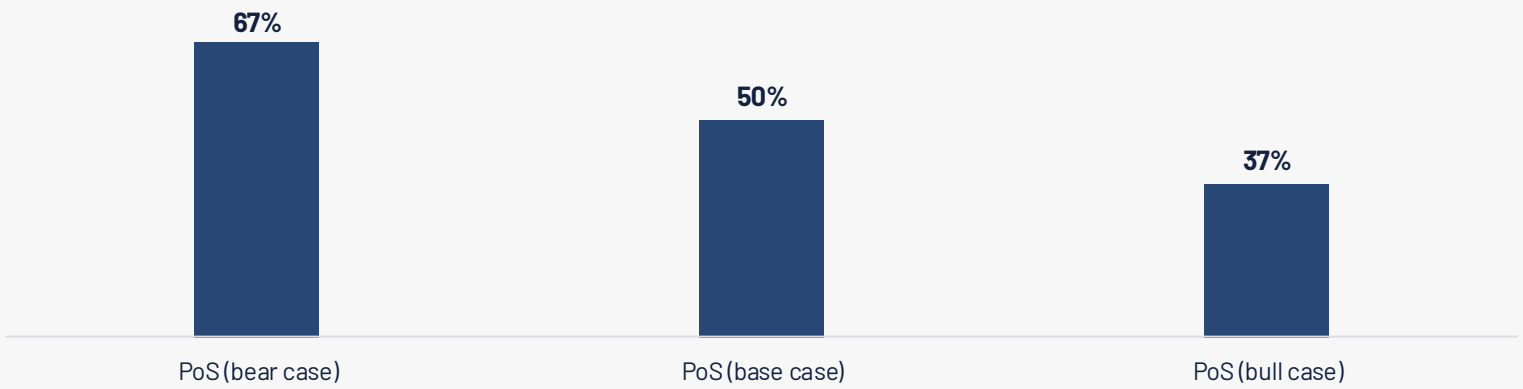
We model three scenarios, a bear- base- and bull-case scenario using the indicated level of market size and growth by BioPorto under different peak market share assumptions. For simplicity reasons, assumptions on EBIT margin, royalty rates, discount rate, and launch date are held constant across all scenarios. PoS is measured at DKK 0.98, against DKK 1.16 a quarter ago, and the lower implied PoS reflects the share price rather than a weaker model value.

Base Case Scenario: In the base case scenario, the model builds the addressable market to USD 770 million across its three segments, 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 50% for BioPorto to commercialize in line with its communicated ambitions across global markets, both with research use only and partner sales, and predominantly partner sales after FDA NGAL Adult clearance mid-2028.

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 and penetration rate assumptions for US Pediatric, US Adults, and RoW, where peak shares are 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 67% for BioPorto to commercialize in line with the bear case assumptions outlined in the model, adjusted to reflect the "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 37% for BioPorto to commercialize across markets and indications, in line with the bull case assumptions outlined in the model, adjusted to reflect the "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. The model translates these markets at USD/DKK 6.79, against 6.45 in the previous vintage, which lifts the addressable market measured in DKK by around 5% and raises modelled revenue accordingly.

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, expected mid-2028.

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. Patent expiry falls close to the expected US adult market entry, but management is confident that BioPorto can defend its position for longer 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%. We regard 2036 as the single most aggressive assumption in the model and test shorter protection periods as a sensitivity rather than in the scenario set.

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 each addressable segment over 6-8 years in the base case, depending on indication and market. Our penetration curve reflects the time to onboard and scale with priority partners and to ramp up sales of the adult test post-FDA clearance, modelled from 2028. Because clearance is guided for mid-2028, the model now assumes half a year of adult partner sales in the launch year, against a full year previously. In line with company guidance, we have a back-end loaded penetration curve across indications as BioPorto ramps up with existing partners, attains FDA clearance for the NGAL adult test, achieves KDIGO guideline inclusion, and onboards additional partners.

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, and that the tests run on existing instrument platforms. The partner strategy places execution risk with counterparties, and delays have been experienced in the past, but the partners' size, financial resources and installed base enable a greater peak market share. For ROW, the model now assumes that partner-driven sales begin in 2028 rather than 2027. BioPorto sells today under the legacy IVDD CE mark, and we take the view that partners will scale only on the back of IVDR certification, which has not been given a confirmed date in the 2026 reporting. The statutory backstop for the relevant class is end-2028. Following the AntiBody divestment, we model non-NGAL revenue at a stable DKK 6m annually, consistent with the 9M 2026 run rate, against DKK 12m previously.

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 operates within diagnostics, which is generally perceived as less risky, a lower discount rate could be argued, but the model uses the widely accepted 15% within the industry. We have deliberately left the rate unchanged in this update so that the movement in implied PoS is attributable to share price, currency and net cash rather than to a change in our own discounting.

Probability of successful launch (PoS): For BioPorto, the probability of success 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 and meeting the "Forward" strategy outlook includes achieving FDA clearance for the adult NGAL test, securing broad licensing and distribution across major instrument partners, attaining a significant market share in AKI diagnostics, and becoming a standard of care. Market implied PoS also reflects funding risk, despite being adjusted for the DKK 20m capital requirement, at market prices. PoS is measured at DKK 0.98, against DKK 1.16 a quarter ago.

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. The adult validation study was initiated in August 2026 and enrolled its first patients in Q3 2026, running across 12 US sites with a target of approximately 900 patients and at least 75 confirmed AKI cases for the analysis, with submission targeted for H1 2028. This provides a rough clinical benchmark. Diagnostic products generally have a higher chance of clinical success, which may be further supported by the pediatric FDA clearance and partnership validations already achieved.

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 more focused business model and higher economies of scale. Lower R&D costs, an effective distribution model, and the current 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 in November 2025, fully subscribed and supported by existing and new institutional and private investors as well as BioPorto's Board and management, covered 60-70% of the communicated cash bridge needed to deliver on the new strategy targets. The sale of the AntiBody business closed that gap, leaving funding into mid-2028, while the enlarged adult study added some DKK 20m of costs and moved break-even to H2 2028. At 30 September 2026, cash stood at DKK 53.2m, against DKK 75.6m at 30 June 2026, implying a cash outflow of DKK 22.4m in the quarter. The buffer behind the mid-2028 funding horizon has therefore narrowed over the year, and further dilutive capital raises cannot be ruled out. We continue to model a DKK 20m capital requirement on the current share count of 495.1m.

BioPorto "Forward" strategy plan and progress towards FDA adult clearance

Status against the "Forward" plan and the path to adult clearance

2026, Adoption: Both 2026 milestones are on track. BioPorto had 59 active US hospitals at the end of Q3 2026 after five additions in the quarter, against a year-end target of 60 or more, and the adult validation study was initiated in August 2026 and began enrolling patients in Q3. Management framed 2026 as the year of building market adoption, and the operational evidence supports that.

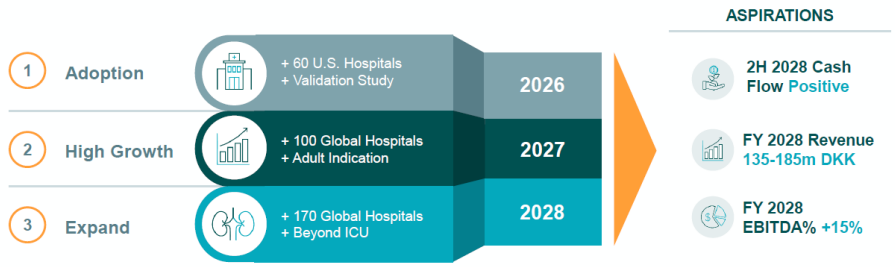
2027, High Growth: The ambition is 100 active hospitals globally and progress on the adult indication. Two dates from the 2025 Annual Report have since moved. FDA submission for the adult test was pushed from H1 2027 to H1 2028 in June 2026 when the validation study was enlarged, and clearance is now guided for mid-2028. IVDR certification for the EU was indicated for 2027 in the Annual Report but has not been given a confirmed date in any 2026 reporting, and our model assumes partner-driven ROW sales from 2028.

2028, Expand: The plan targets 170 active hospitals globally and an expansion beyond the ICU, underpinned by the financial aspirations of FY 2028 revenue of DKK 135-185m, an EBITDA margin above 15%, and cash flow positive in H2 2028, moved from H1 2028 in June 2026. Delivery rests on adult clearance arriving on time, since the adult indication is what unlocks the step change in addressable volume.

The three dimensions of market access: BioPorto frames the USD 700m ICU opportunity as the product of indication, market and instrument platform. Today the test is cleared for pediatric ICU AKI risk stratification, commercially focused on North America, and runs on the Roche Cobas c 501. Each dimension is a separate lever, and the adult indication is the largest of the three.

The "Forward" Strategic Plan

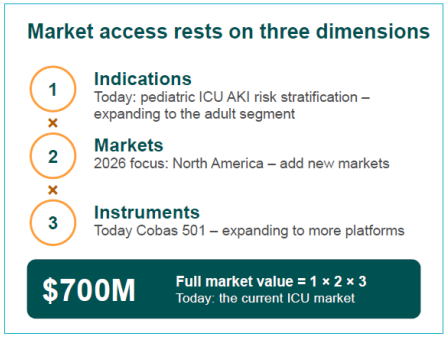
*Focus on execution of **Market Access** & **Commercialization** to transform kidney care*

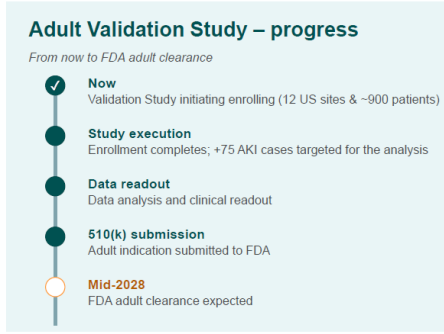


Source: BioPorto Q3 2026 Investor Presentation, 19 November 2026

Adult Validation Study; Market Access

Progressing as planned; and focuses on the $700M market at ICU





Source: BioPorto Q3 2026 Investor Presentation, 19 November 2026

HC Andersen Capital

HC Andersen Capital digitalizes and democratizes the relationship between investors and listed companies.

Through digital investor events, commissioned research, advisory services, and related IR services, we engage investors with information and access to the companies' management. We want equal access to information for all investors, private as well as institutional.

We believe that all information should be equally accessible for all investors, and that improving the symmetry of information between companies and all investors strengthens company-investor relationships and trust in the financial markets.

Our team of analysts has many years of experience in the financial markets, previously with leading Nordic institutions.

HC Andersen Capital is based in Copenhagen, Denmark, and operates in the Nordics. HC Andersen Capital works closely in partnership with the leading Finnish-based equity research company, Inderes Oyj.

HC Andersen Capital

Bredgade 23B 2. sal
1260 København K, Denmark
CVR: 41474793

All research available at **inderes.dk**

Equity research team



Michael Friis
Head of Equities



Rasmus Køjborg
Head of Research



Victor Skriver
Equity Analyst Assistant



Jacob Frehr
Equity Analyst Assistant



William Jørck
Equity Analyst Assistant



Nikolaj Pedersen
Equity Analyst Assistant

Disclaimer

This research report (the "Investment Case") has been commissioned and paid for by the company that is the subject of this report. HC Andersen Capital has received payment from the covered company for the preparation and distribution of this Investment Case.

The information presented in HC Andersen Capital reports is obtained from several different public sources that HC Andersen Capital considers to be reliable. HC Andersen Capital aims to use reliable and comprehensive information, but HC Andersen Capital does not guarantee the accuracy of the presented information. Any opinions, estimates and forecasts represent the views of the authors. HC Andersen Capital is not responsible for the content or accuracy of the presented information. HC Andersen Capital and its employees are also not responsible for the financial outcomes of investment decisions made based on the reports or any direct or indirect damage caused by the use of the information. The information used in producing the reports may change quickly. HC Andersen Capital makes no commitment to announcing any potential changes to the presented information and opinions.

The reports produced by HC Andersen Capital are intended for informational use only. The reports should not be construed as offers or advice to buy, sell or subscribe investment products. This report does not contain and should not be interpreted as containing: (i) price targets or fair value estimates for the company's securities; (ii) buy, sell, hold, accumulate, reduce or any equivalent investment recommendations; or (iii) personalised investment advice. Customers should also understand that past performance is not a guarantee of future results. When making investment decisions, customers must base their decisions on their own research and their estimates of the factors that influence the value of the investment and take into account their objectives and financial position and use advisors as necessary. Customers are responsible for their investment decisions and their financial outcomes.

Reports produced by HC Andersen Capital may not be edited, copied or made available to others in their entirety, or in part, without HC Andersen Capital's written consent. No part of this report, or the report as a whole, shall be transferred or shared in any form to the United States, Canada or Japan or the citizens of the aforementioned countries. The legislation of other countries may also lay down restrictions pertaining to the distribution of the information contained in this report. Any individuals who may be subject to such restrictions must take said restrictions into account.

The analysts who produce HC Andersen Capital's research cannot have shareholdings in the companies they cover. The remuneration of the analysts who produce the analysis is not directly or indirectly linked to the content, conclusions, or any views expressed in the reports.

HC Andersen Capital or its partners whose customer relationships may have a financial impact on HC Andersen Capital may, in their business operations, seek assignments with various issuers with respect to services provided by HC Andersen Capital or its partners. Thus, HC Andersen Capital may be in a direct or indirect contractual relationship with an issuer that is the subject of research activities. HC Andersen Capital and its partners may provide different services to issuers.

More information about research disclaimers can be found at inderes.dk/research-disclaimer.

This research is produced and distributed in accordance with the EU Market Abuse Regulation (MAR) (Regulation EU 596/2014) and Commission Delegated Regulation (EU) 2016/958. HC Andersen Capital ApS is based in Denmark.


Connecting investors
and listed companies.
HC ANDERSEN
CAPITAL