EDISON

BioPorto Diagnostics

Clinical outlook

Multiple upcoming readouts

Healthcare equipment & services

BioPorto has started 2021 firing on all cylinders as it prepares to resubmit its application to the FDA for the paediatric NGAL Test for detecting acute kidney injury (AKI) in summer 2021. This should set it up for a clearance decision in H221, after which it plans to submit the application for the adult NGAL Test. Concurrent with this, the company is initiating clinical testing of its COVID-19 dipstick. It expects this testing to be complete in early 2021 and emergency use authorisation (EUA) to be filed thereafter. We are taking this time to provide our comprehensive clinical outlook.

Year end	Revenue (DKKm)	PBT* (DKKm)	EPS* (DKK)	DPS (DKK)	P/E (x)	Yield (%)
12/18	26.0	(42.5)	(0.24)	0.0	N/A	N/A
12/19	26.6	(71.1)	(0.39)	0.0	N/A	N/A
12/20e	23.5	(70.0)	(0.31)	0.0	N/A	N/A
12/21e	79.9	(32.0)	(0.11)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Strategy: Paediatric test clearance first

The current regulatory strategy for the company is to first seek marketing clearance for the paediatric NGAL Test via a de novo application. De novo clearance requires the product to provide evidence of safety and efficacy, but this initial clearance can pave the way for the company to submit the application for the adult test via the less rigorous conventional 510k pathway. A 510k application only requires the product to demonstrate substantial equivalence to a predicate device, and the company could use the paediatric test as the predicate device in this case. We expect this pathway to simplify the process.

COVID-19 readout expected soon

In December 2020, BioPorto announced it had completed the initial prototyping and development of its test to detect the SARS-CoV-19 virus and it would be entering the clinic immediately thereafter. Based on feedback from the FDA, BioPorto will run a clinical study at the University of California Davis with a target enrolment of 150 patients, of which 30 will need to be COIVD-19 positive. The company expects the clinical study to be complete in early 2021 and it will be able to submit it for an EUA shortly after (targeting Q221). An effective point of care antigen test has the potential of substantially simplifying the workflow for testing and expanding its capacity, although it will have to compete with other such tests already on the market.

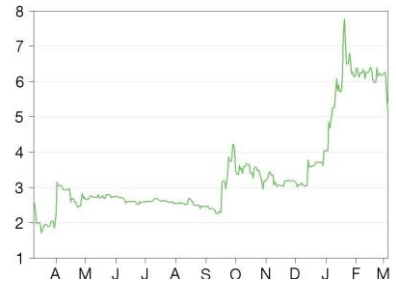
Valuation: Waiting for COVID-19 valuation

We are not valuing BioPorto's COVID-19 programme at this time due to the lack of visibility on the product's performance and the extremely competitive nature of the market it is entering. We are, however, presenting a sensitivity analysis of the programme's value. Our value for the remaining programmes is roughly flat: DKK941m or DKK3.53 per share from DKK939m or DKK3.52 per share. The only adjustments are rolling forward our NPVs, offset by exchange rate effects.

8 March 2021

Price	**DKK5.16**
Market cap	**DKK1,376m**
	DKK6.31/US$
Net cash (DKKm) at Q320 + offering	118.1
Shares in issue	266.6m
Free float	86.5%
Code	BIOPOR
Primary exchange	NASDAQ Copenhagen
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(17.3)	67.5	120.4
Rel (local)	(11.2)	67.2	87.8
52-week high/low	DKK7.78	DKK1.41	

Business description

BioPorto Diagnostics is a diagnostic company focused on the development and commercialisation of biomarker-based assays. The company's portfolio includes the NGAL Test, for prediction of acute kidney injury, and an extensive antibody library.

Next events

Paediatric NGAL Test application	Summer 2021
COVID-19 study complete	Early 2021

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Edison profile page

Investment summary

Company description: Diagnostics on the forefront of care

BioPorto is a diagnostic company focused on the development and commercialisation of biomarker-based assays. The company is revenue generating and its portfolio includes The NGAL Test, an antibody library, ELISA kits and other laboratory-use products. Its core commercial strategy is to launch the NGAL Test, a diagnostic for the rapid prediction of AKI risk, in the US. NGAL is a biomarker for AKI that increases in concentration in urine and blood plasma in a matter of hours following kidney injury, allowing for intervention before permanent damage occurs. Additionally, the company has the rights to the generic rapid assay device (gRAD), a modular lateral flow device for doing point-of-care antigen tests, which is being used to develop a COVID-19 dipstick test.

Valuation: DKK941m or DKK3.53 before COVID-19 programme

Our valuation minimally changed at this time: DKK941m or DKK3.53 per share from DKK939m or DKK3.52 per share. This change is driven by exchange rate effects and offset by rolling forward our NPV. Otherwise our assumptions remain unchanged. This valuation does not include the COVID-19 programme (despite significant price action associated with it), because the test statistics have not been released yet. However, we present an illustrative valuation analysis of the value for one year of COVID-19 test sales, parameterised by market penetration and probability of success.

Exhibit 1: COVID-19 valuation analysis

Valuation (DKKm)	Penetration				
PoS	2%	4%	6%	8%	10%
1%	7.60	15.20	22.80	30.40	38.00
5%	38.00	75.99	113.99	151.99	189.98
10%	75.99	151.99	227.98	303.97	379.96
15%	113.99	227.98	341.97	455.96	569.95
20%	151.99	303.97	455.96	607.94	759.93

Source: Edison Investment Research. Note: PoS, probability of success. $10 per test, 50% net profit margin, 3.7m tests run daily in US+UK+EU, for one year.

Financials: Financed to through near-term readouts

Our financial forecasts remain unchanged, aside from adjustments for exchange rate effects. The company raised DKK93.6m in October 2020, which should be sufficient for it to finance its clinical and regulatory programmes into 2022 (company guidance is that it is financed until Q421). If FDA hurdles are met, once the company launches the adult NGAL Test we expect it to be able to self-finance after that point.

Sensitivities: It is hard to change the standard of care

Most of the risk for BioPorto is associated with the upcoming regulatory decisions for the paediatric and adult NGAL Tests. The paediatric test is expected to be submitted for clearance in summer 2021 and the adult application will be submitted after a response for paediatric. We believe based on the available data that NGAL provides an improvement over the serum creatinine (sCr) standard of care for diagnosing AKI. The company will need to demonstrate this statistically to regulators, which can be complicated in cases where the benchmark (in this case sCr) is imperfect. Moreover, we have relatively little insight into the contents of the application package and what those statistics are. BioPorto has unsuccessfully filed for clearance with the adult test twice and with the paediatric test once. If the product gains market clearance, BioPorto will then need to change the standard of care to gain material sales, which will require significant educational outreach to physicians and may take time.

Company description: Keeping kidneys safe

BioPorto was founded in 2000 in Copenhagen and publicly listed on NASDAQ Copenhagen in 2004. The company was initially founded to commercialise intellectual property licensed from the Statens Serum Institut, although it expanded its portfolio to include several important proprietary assets. The company's primary focus is on the development and commercialisation of the NGAL Test for the risk assessment of AKI, while another noteworthy asset is the gRAD, which is a generalisable point-of-care lateral flow device. Neutrophil gelatinase-associated lipocalin (NGAL) is a biomarker secreted by the kidney shortly following injury and has been studied as a potential replacement for the standard of care, sCr. The benefit of NGAL is that it has the potential to deliver a more accurate assessment in a matter of hours, enabling interventions to preserve function, whereas sCr can take over 24 hours to reach detectable levels among other limitations. The NGAL Test is commercially available in the US for research purposes and has market clearance in Europe and some Asia-Pacific countries, but the company's primary goal is market clearance in the US as a clinical diagnostic. BioPorto is completing an application for paediatric AKI, after which it plans to submit an application for the adult indication. We expect the product to initially be targeted to the intensive care unit (ICU) setting. Potential future markets include the emergency department setting and continuous monitoring of AKI patients following surgery. The product is developed for use in high throughput systems and BioPorto has already established distribution contracts with the major commercial players in this space: Roche and Siemens.

Exhibit 2: The NGAL Test launch timing

Event	Date
Application to be submitted to FDA: paediatric indication	Summer 2021
Application submission to FDA: adult indication	After response to paediatric
Launch of NGAL Test: paediatric indication (pending FDA clearance)	Late 2021

Source: BioPorto Diagnostics

AKI: Desperate need for a diagnostic

AKI is a major risk to human health and wellbeing given the range of different causative factors and the potential for it to progress to long-term renal dysfunction. It is defined as the rapid deterioration in kidney function over hours or days. However, the damage associated with the condition is frequently reversible if the injury is identified quickly and patients are treated. There is therefore significant incentive to develop diagnostics that can quickly identify AKI in at-risk individuals.

There are a wide range of causes for AKI. The single largest contributing comorbidity to these rates of AKI is sepsis, which is responsible for 26% to 50% of all cases of AKI.[1] The aetiology of sepsis-induced AKI is complex and includes both direct damage to the kidneys and a reduction in blood flow (hypoperfusion). Additionally, conditions that lead to hypoperfusion (low blood flow) can lead to AKI: as many as 30% of patients undergoing cardiac surgery have complications associated with AKI.[2] AKI is responsible for a fivefold increase in mortality associated with these procedures. Other major surgeries also carry a risk of AKI, albeit at lower rates. Other conditions that can cause a severe drop in blood pressure or fluid loss and thus hypoperfusion can cause AKI, such as bleeding, diarrhoea, overdose of NSAIDs, allergic reactions and shock associated with trauma, although this list is by no means exhaustive.

1 Alobaidi R, et al. (2015) Sepsis-Associated Acute Kidney Injury. *Semin Nephrol* 35, 2-11.

2 O'Neal JB, et al. (2016) Acute kidney injury following cardiac surgery: current understanding and future directions. *Crit Care* 20,187.

Given the range of conditions that can lead to AKI, the condition is relatively common. Based on sCr measurements (more on this test below), the rate of AKI in the US is over 0.5% per year in the general population.[3] Approximately 2% of hospital inpatients and 40% of those in intensive care have AKI.[4] It is difficult to separate the prognosis of AKI from the underlying disorders, but AKI significantly increases the risk of death in a stage specific manner: odds ratio of 2.2 for stage 1, 6.1 for stage 2 and 8.6 for stage 3.[5] Among patients with AKI severe enough to require renal replacement, mortality has been observed as high as 60%.[6] Moreover, there is increasing evidence that even after resolution of AKI, the event is correlated with increased risk of developing chronic kidney disease.[7]

Detection of AKI

AKI is classically diagnosed and staged based on the concentration of creatinine in serum and urine output. Both measurements are proxies for the glomerular filtration rate (GFR), or the rate at which the kidney can process liquid. Creatinine is the metabolic product of creatine degradation in muscle that is typically filtered from the blood by the kidney. Given that its production is relatively constant, an increase in serum levels can be indicative of renal dysfunction. The Kidney Disease International Global Organization (KDIGO) provides the criteria for staging AKI (Exhibit 3).

Exhibit 3: Staging of AKI based on KDIGO criteria

Stage	sCr	Urine output
1	1.5–1.9× baseline or ≥0.3 mg/dl above baseline	<0.5 ml/kg/hr for 6–12 hr
2	2.0–2.9× baseline	<0.5 ml/kg/hr for >12 hr
3	≥3.0× baseline, ≥4.0 mg/dl, or initiation of renal-replacement therapy	<0.3 ml/kg/hr for ≥24 hr or anuria for ≥12 hr

Source: KDIGO

Despite its widespread use, there are significant limitations in the use of sCr as a tool to diagnose AKI. The primary limitation is that changes in GFR are indicative of kidney damage, therefore some injury and loss of function has already occurred by the time a change is measurable. This is exacerbated because creatinine must build up in the serum and it can take significant time for changes in GFR to manifest as measurable changes in creatinine. The kinetics of sCr are very complex and depend on a wide range of variables (which gives more credence to it being a poor biomarker), but modelling predicts that a healthy person would need 34 hours for their sCr levels to reach steady state after losing 50% renal function, and twice as long or more for patients with prior renal impairment.[8] Renal impairment of 27% or less is undetectable even as stage 1 AKI within 48 hours in an otherwise healthy person. Because of this, sCr measurements are typically taken over several days to provide adequate time to detect changes from baseline. This substantially increases the burden on providers and increases the probability that marginal cases of AKI will go undetected under a reasonable timeframe.

Baseline rates of creatinine can differ significantly between individuals and even within the same individual due to a range of factors. Therefore, to be used as a biomarker, multiple measurements are required to establish a baseline and changes from this baseline. Patients of unknown status

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3 Hsu CY, et al. (2007) Community-based incidence of acute renal failure. *Kidney Int* 72, 208-212.

4 Bellomo R, et al. (2012) Acute kidney injury. *Lancet* 380, 756-766.

5 Thakar CD, et al. (2009) Incidence and outcomes of acute kidney injury in intensive care units: a Veterans Administration study. *Crit Care Med* 37, 2552-2558.

6 Uchino S, et al. (2005) Acute renal failure in critically ill patients: a multinational, multicenter study. *J Am Med Assoc* 294, 813-818.

7 Lakhnir S, et al. (2014) Acute kidney injury and chronic kidney disease as interconnected syndromes. *N Eng J Med* 371,58-66.

8 Waikar SS and Bonventre JV (2009) Creatinine Kinetics and the Definition of Acute Kidney Injury. *J Am Soc Nephrol* 20, 672-679.

may already have elevated creatinine when they are initially tested, confounding the detection of issues. Moreover, the clearance of other substances such as medication can significantly affect the rate of creatinine clearance.

A problem in evaluating the utility of sCr as a diagnostic tool is that historically AKI has been defined in terms of sCr and little corroborative evidence has been available. One study, however, used biopsy data from deceased kidney donors to retrospectively evaluate the performance of sCr as a diagnostic.[9] Biopsies from these patients were examined for evidence of acute tubular injury (ATI) and compared to sCr measurements. It should be noted that ATI is a subtype of AKI and is the leading cause of AKI in a hospital setting (approximately 50%).[10] The results from this study suggest sCr is a very poor indicator of ATI (Exhibit 4). The area under the curve (AUC) for sCr to identify any grade of ATI was 0.52. This value increased marginally to 0.58 when the test was evaluated for the detection of severe ATI. AUC is a measure of the strength of a diagnostic irrespective of the particular cut-off value used for diagnosis, where 1.00 is a perfect test and 0.50 indicates no diagnostic value. So, in this case, sCr performed poorly; in fact we are unaware of any other diagnostic tool in routine use that shows such a low AUC.

Exhibit 4: Performance of sCr versus histology of ATI

	Severe ATI versus no ATI		Any ATI versus no ATI	
Sample size	483		581	
AUC	0.58		0.52	
sCr criteria	**Sensitivity**	**Specificity**	**Sensitivity**	**Specificity**
Stage I AKI or higher	51%	61%	42%	61%
Stage II AKI or higher	26%	84%	20%	84%

Source: Moledina et al.

As an alternative to sCr, urine output can be used. However, monitoring of urine is unwieldy in clinical practice and is generally limited to patients with a catheter. Moreover, this measurement is rendered ineffective when patients are taking diuretic medications. There are not as much clinical data to support urine output, because retrospective data are generally unavailable and clinical studies have had mixed results.[11]

NGAL: A better alternative

Due to the limitations of sCr, there has been an effort by scientists to identify other biomarkers with improved performance. The most concerted effort has been focused on the investigation of NGAL. It was first identified as a marker for AKI by researchers in 2003 and has subsequently been the subject of multiple studies. Perhaps the clearest benefit of NGAL over sCr is evident in the time course of its elevation following kidney injury (Exhibit 5). NGAL is elevated within hours of the damage that results in AKI, as opposed to sCr, which requires a prolonged period of impaired GFR. Patients undergoing cardiopulmonary bypass (a procedure known to induce AKI in some cases) had NGAL peak two hours after surgery, whereas diagnosis with sCr took 2-3 days.[12] Moreover, there is increasing evidence that patients that are identified by NGAL carry an increased risk for adverse events such as need for replacement therapy and death, even when they are sCr

[9] Moledina DG, et al. (2017) Performance of serum creatinine and kidney injury biomarkers for diagnosing histologic acute tubular injury. *Am J Kidney Dis* 70, 807-816.

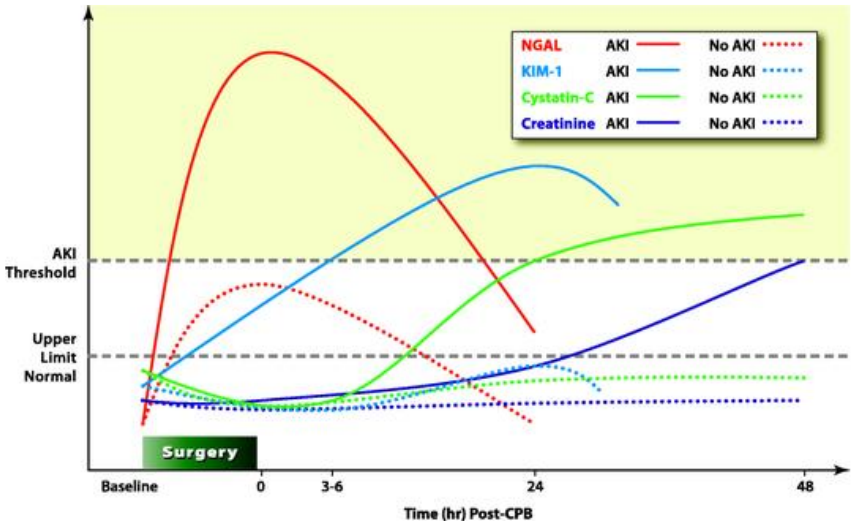
[10] Perazella MA, et al. (2010) Urine Microscopy Is Associated with Severity and Worsening of Acute Kidney Injury in Hospitalized Patients. *Clin J Am Soc Nephrol* 5, 402-408.

[11] Cruz DN, et al. (2009) Clinical review: RIFLE and AKIN – time for reappraisal. *Crit Care* 13, 211.

[12] Devarajan P (2008) Emerging urinary biomarkers in the diagnosis of acute kidney. *Exp Op Med Diag* 2, 387-398.

negative.[13] NGAL is elevated before major loss of function, which should enable earlier intervention to halt progressive deterioration.

Exhibit 5: Time course of biomarker elevation in AKI



Source: BioPorto Diagnostics

NGAL is a member of the lipocalin family, a class of proteins that bind hydrophobic molecules. It binds specifically to siderophores, proteins that bind to iron and aid in its metabolism. A range of different tissues, including but not limited to the kidney, secrete NGAL in response to cellular damage. Due to this, an increase in serum concentrations of the protein is associated with a range of indications including infection, inflammatory disorders, cancer and obesity. NGAL can be isolated from either the urine or plasma, with differing results. Urine NGAL provides a more direct readout of protein released in the kidney, but is affected by urine production and complicated by common conditions such as urinary tract infection. Plasma NGAL provides a less variable baseline but can be complicated by injury or inflammation in other tissues. Whether urine or plasma NGAL is a better indicator is an unsettled question, although BioPorto is advancing a plasma-based test, initially citing better reproducibility.

Two products have previously been developed for use as a NGAL diagnostic test in the clinical setting, although neither was cleared in the US for diagnosis of AKI. Abbott developed a urine NGAL-based test for use with its Architect clinical chemistry platform. It was submitted to the FDA in 2010 but did not receive clearance. Alere also developed a point-of-care plasma NGAL based test for use with its Triage MeterPro platform. However, it was not submitted for FDA clearance. Alere was subsequently purchased by Abbott in 2017 and as the Triage NGAL diagnostic test was one of its many products, it was likely not a motivating factor. BioPorto launched its first NGAL-based bioassay in 2006. This was the first commercially available NGAL ELISA kit available worldwide, although limited to research purposes. In 2010 the company subsequently launched a new version of the assay prepared for use in a high-throughput clinical chemistry analyser, branded the NGAL Test.

Previous noteworthy NGAL studies

The NGAL biomarker has been investigated in a large number of clinical studies, in urine and in plasma and by BioPorto and others, and significant variability between results has been observed. A recent meta-analysis was performed that examined the capacity of biomarkers to predict the

[13] Haase M, et al (2011) The outcome of neutrophil gelatinase-associated lipocalin-positive subclinical acute kidney injury: a multicenter pooled analysis of prospective studies. *J Am Coll Cardiol* 57, 1752–1761.

initiation of renal replacement therapy, an intervention to limit the damage from AKI.[14] Urine NGAL biomarker was evaluated in 12 studies and showed a pooled AUC of 0.720 and plasma NGAL was evaluated in 16 studies with a pooled AUC of 0.787. AUCs in the meta-analysis for NGAL ranged from 0.260 to 0.884. A consistent factor that has been cited as a source of this variability has been the differing response of patients with sepsis. As mentioned above, sepsis is the most common cause of AKI in intensive care patients, but the systemic inflammation associated with the condition results in the release of NGAL from neutrophils. Although the biomarker retains utility in sepsis patients, the AUC for predicting renal replacement therapy can drop significantly, to 0.700 in one targeted study.[15] NGAL may be a better biomarker in patient populations outside the ICU , where there are lower rates of confounding factors such as sepsis. For instance, one study using BioPorto's NGAL antibodies (although not performed by the company) that examined 635 patients presenting in an emergency department (instead of an ICU) showed dramatically better statistics: 90.0% sensitivity, 99.5% specificity and an AUC of 0.948.[16]

Another issue that has limited the interpretation of NGAL studies is that frequently the readout used to evaluate the test is the presence of AKI, as evaluated under the standard diagnostic criteria, namely, sCr. This is a problem intrinsic to this field, and has been highlighted in research.[17] Even a perfect test (100% sensitivity and specificity) will have substantially lower apparent statistics when measured against an imperfect gold standard. The fact that NGAL can identify patients at increased risk of major intervention or death that are sCr negative is also supportive of this fact.[11]

A significant factor that can be difficult to capture in these statistical studies is the improvement in care NGAL can provide. In particular, the ability to identify patients sooner and before significant loss of function can translate into improved outcomes and the associated reduction in costs. One study modelled these factors and estimated costs savings in the range of $408–522 per patient admitted to an emergency department.[18] The models in the study were using real world outcomes data from two emergency departments in New York tested for urine NGAL and sCr.

Earlier BioPorto clinical data

BioPorto has released relatively little data detailing the performance of the NGAL Test from its earlier clinical studies. The most information is from the company's first US registrational study, which was performed in 2014 and 2015 across four clinical centres. The purpose of the trial was to identify the correct parameters, such as NGAL thresholds for the clinical identification of AKI using both plasma and urine. The study compared blood preserved with two anticoagulants (EDTA and heparin) so see if that had an impact as well. It enrolled 245 patients from ICUs and AKI was determined using the KDIGO guidelines by a panel of physician adjudicators. The data reported by the investigators segregated the patients into two populations: those with stage 2 or 3 AKI, and those with stage 1 AKI or no AKI. Samples were taken from the patients daily.

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[14] Klein SJ, et al. (2018) Biomarkers for prediction of renal replacement therapy in acute kidney injury: a systematic review and meta-analysis. *Int Care Med* 44, 323-336.

[15] Hjortrup PB, et al. (2015) Predictive value of NGAL for use of renal replacement therapy in patients with severe sepsis. *Acta Anaesthesiol Scand* 59, 25–34.

[16] Nikolas TL, et al. (2008) Sensitivity and Specificity of a Single Emergency Department Measurement of Urinary Neutrophil Gelatinase–Associated Lipocalin for Diagnosing Acute Kidney Injury. *Ann Int Med* 148, 810-819.

[17] Waikar SS, et al. (2012) Imperfect Gold Standards for Kidney Injury Biomarker Evaluation. *J Am Soc Nephrol* 23, 12-21.

[18] Parikh A, et al. (2017) Does NGAL reduce costs? A cost analysis of urine NGAL (uNGAL) & serum creatinine (sCr) for acute kidney injury (AKI) diagnosis. *PLOS One* 12, e0178091.

Exhibit 6: The NGAL Test statistics for stage 2/3 AKI

Fluid	Sensitivity	Specificity	AUC
EDTA plasma	78.8%	73.0%	0.76
Heparin plasma	72.7%	73.8%	0.77
Urine	69.7%	76.8%	0.79

Source: Tecson et al. 2017

The statistics from the study were positive. AUC measurements were 0.76 and above, and sensitivity and specificity measurements were approximately 70% or higher. These results are largely in line or better than those previously presented in the literature on NGAL, although it should be noted they represent the identification of just stages 2 and 3 of AKI. When the investigators then focused on patients with persistent (two days or more) stage 2/3 AKI, the results were further improved to a maximum AUC of 0.85 with the use of EDTA plasma.

The FDA rejected the company's application package including these data. There are limited details on the reason behind the FDA's decision, although BioPorto has stated the rejection was 'primarily because the dataset for mild cases of AKI did not support approval'. When explaining the decision to exclude patients with stage 1 AKI from the primary end point, the investigators cited the observation from prior studies that many patients classified in this category are subject to transient sCr elevations without AKI associated with tissue damage. In other words, the stated reason for this exclusion was aforementioned variability in the sCr gold standard.

Registrational pathway

BioPorto currently has two development programmes for the NGAL Test: adult AKI using blood NGAL and paediatric AKI using urine NGAL. The product for adults represents the biggest market opportunity for the product, but BioPorto believes the paediatric programme may be easier from a regulatory perspective and provide insight for the adult application process.

The company has had additional clinical and regulatory setbacks on its pathway towards clearance of the NGAL Test. After the initial rejection by the FDA above, in 2018 BioPorto conducted an additional study and submitted a second 510(k) application to the FDA for clearance of the NGAL Test in adults based on this data from over 500 ICU patients across 17 clinical sites in the US where it only enrolled hypotensive patients within the first 24 hours of their admission to the ICU. Four blood samples were collected from each patient and AKI was subsequently graded based on KDIGO guidelines by an independent adjudication panel. In October 2018, the FDA requested additional information to continue the application process citing further data was needed to support the claim that the test could rule-out AKI. The company initially estimated it can complete the dataset with an additional 150–200 patients.

Concurrent with this, however, the company's application for the paediatric NGAL Test was rejected in late 2019. The data in the paediatric 510(k) application were based on samples collected in a third-party study of AKI in children (the AWARE study) and tested urine samples for NGAL retrospective to the study. The AWARE dataset had 4653 paediatric patients, of which 1261 had AKI (543 severe AKI). A subset of these patients were tested, finding a sensitivity of 65.0% and a specificity of 81.8%. We believe these performance metrics are sufficient to support market authorisation. However, the FDA was concerned that the enrolment criteria for the AWARE study may have introduced a bias in the data, as only patients expected to be in the ICU for 48 hours or more were tested, which was evaluated by just the general impression of the investigators. The company determined it would need to collect new data to support an application given the FDA feedback. Based on our communication with the company, management believes that 300 paediatric ICU patients should suffice.

The rejections of the company's marketing applications have caused unfortunate delays, but do not lessen our opinion of the ultimate approvability of the product because the FDA decisions to date

have mostly centred on the statistical strength of the application package as opposed to providing doubt on the test's utility. For this the upcoming submission for the paediatric NGAL Test, BioPorto is planning on preparing a De Novo application (as opposed to 510(k)), which has more stringent safety and efficacy guidelines, but we expect the completion of the clinical studies to answer any questions of safety or efficacy. BioPorto is in the final stages of gathering the clinical data and the current timeline for submission of the application is in Q121. A response from the agency is expected after the 150 day statutory review period.

The plan is for BioPorto to seek clearance for the test initially with the paediatric NGAL Test and to subsequently follow this with an application for the adult test. This will allow the company to tailor the application based on the feedback provided by the FDA during the paediatric review process. Additionally, BioPorto will be able to use the paediatric test as the predicate device for the 510(k) application. In Europe the product has received a CE mark, making it commercially available, but adoption in that region is largely limited to research use as in the US currently. Adoption of diagnostics in Europe is driven more by guidelines and other decisions by organising bodies than simply marketing approval. More widespread adoption and more routine diagnostic use will require the company to publish the upcoming results from its registrational studies.

Sales, licensing and intellectual property

The NGAL Test is already commercially available for research purposes and sales were DKK11.6m in 2019 and DKK9.8m for the first nine months of 2020, an improvement of 58% over the same period in 2019. BioPorto has global distribution agreements with Roche and Siemens, as well as a small direct sales channel that provides the test. We expect these distributors to be the primary sales channels following FDA market clearance, although we expect BioPorto to hire a small sales team dedicated to the promotion of the NGAL Test. The primary commercial hurdle will be altering the longstanding clinical practice on the use of sCr for AKI, which will take physician outreach and education, which we expect the internal sales team to perform. Other aspects of the launch should be smooth considering the product seamlessly integrates into the existing workflow and is billable under existing DRG codes.

BioPorto entered into an arrangement with Abbott in 2014 to cross license their respective intellectual property after Abbott's NGAL diagnostic test was rejected. BioPorto has also in-licensed additional patents from Columbia University regarding the NGAL technology. The company's proprietary and in-licensed patent families cover a range of aspects of the NGAL technology and its applications including the use of urine and plasma, the use of serial sampling and the diagnostic threshold, among others. BioPorto's NGAL Test is not without some degree of intellectual property risk: patents begin to expire in 2025, although we expect the portfolio as it stands to provide a decent commercial runway to approximately 2028. To our knowledge, there are no other NGAL-based tests under active development as a commercial use AKI diagnostic.

Other testing methodologies

In addition to NGAL, a number of other biomarkers have been investigated as alternatives to sCr (Exhibit 7). The most prominent research (other than into NGAL) has been into kidney injury molecule 1 (KIM-1) and IL-18. KIM-1 is a protein that is upregulated in the kidney following reperfusion injury in renal tubules and is a direct measure of injury (although not exclusively kidney injury). IL-18 in contrast is a proinflammatory cytokine secreted by macrophages that are released in response to various inflammatory conditions, including AKI. The performance of these biomarkers has generally underperformed NGAL in the clinic (AUC of 0.68 and 0.63 respectively compared to 0.74 for NGAL in one study).[19] However, the performance of these markers tends to

[19] Hall IE, et al. (2011) Risk of poor outcomes with novel and traditional biomarkers at clinical AKI diagnosis. *Clin J Am Soc Nephrol* 6, 2740-2749.

improve with more severe AKI and one study demonstrated superior results for the use in combination: AUC of 0.93 for KIM-1 + IL-18 compared to 0.89 for NGAL + sCr for the ability to predict stage 3 AKI or death.[20]

Exhibit 7: Selection of alternative AKI biomarkers

Marker	Name	Notes
NGAL	Neutrophil gelatinase-associated lipocalin	Component of the innate immune system, secreted by neutrophils and the kidney and other tissues following injury.
L-FABP	Liver-type fatty acid-binding protein	Long chain fatty acid transporter, elevated in response to tissue damage of multiple types.
IL-18	Interleukin 18	Proinflammatory cytokine produce from macrophages, associated with ischemic injury.
KIM-1	Kidney injury molecule 1	Protein specific to the kidney, upregulated following ischemia.
Cys C	Cystatin C	Protease inhibitor, ubiquitously expressed, clearance rate associated with GFR like sCr.
TIMP-2 + IGFBP-7	NephroCheck	Only branded proprietary AKI test available for the identification if imminent stage 2/3 AKI.

Source: Various

The only commercially available alternative to sCr is NephroCheck, 510(k) cleared and marketed by Astute Medical. Astute Medical was a private healthcare company that was acquired by BioMérieux in April 2018 for approximately $90m. NephroCheck and associated systems are its sole products, but there is limited visibility on sales.

The test combines readouts of two biomarkers, TIMP-2 and IGFBP-7, in the company's proprietary linear flow devices to be used in a dedicated testing platform (the Astute140 device). These proteins were discovered in a longitudinal study of 300 biomarkers in 2013 and thus have a shorter history of study compared to other biomarkers.[21] The test is intended for use in patients following major cardiac or pulmonary events for AKI monitoring. NephroCheck was evaluated in two clinical studies. The first clinical study enrolled 408 patients and found a sensitivity of 90–93% and a specificity of 45–49% (with values varying based on the laboratory used). However, in the second clinical study of 126 patients, sensitivity dropped significantly to 76% with a specificity of 51%. This implies a negative predictive value of only 88% in the second study, meaning 12% of patients that were ruled as AKI free in the study really had kidney injury. However, despite these limitations, given the low bar set by sCr the test has been shown to improve outcomes following cardiac surgery,[22, 23] and the test (or more accurately TIMP-2 and IGFBP-7 testing) was recently included in the consensus guidelines from the Enhanced Recovery after Surgery (ERAS) Cardiac Surgery group presented to the American Association for Thoracic Surgery (moderate level of recommendation).

The gRAD

Aside from BioPorto's biologic products, it has developed a generalisable lateral flow device called the gRAD (Exhibit 8). The device consists of a paper test strip similar to that used for at-home diagnostics such as urine glucose strips, ovulation tests, etc. However, unlike these products, the

[20] Arthur JM, et al. (2014) Evaluation of 32 urine biomarkers to predict the progression of acute kidney injury after cardiac surgery. *Kidney Int* 85, 431-438.

[21] Kashani K, et al. (2013) Discovery and validation of cell cycle arrest biomarkers in human acute kidney injury. *Crit Care* 17, R25.

[22] Göcze I, et al. (2017) Biomarker-guided intervention to prevent acute kidney injury after major surgery: the prospective randomized BigpAK Study. *Ann Surg* 267, 1013-1020.

[23] Meersch M, et al. (2017) Prevention of cardiac surgery-associated AKI by implementing the KDIGO guidelines in high risk patients identified by biomarkers: the PrevAKI randomized controlled trial. *Intensive Care Med* 43, 1551-1561.

gRAD does not come preloaded with detection antibodies. Instead, it can be arbitrarily used in any detection system consisting of a biotinylated antibody and a gold conjugated antibody. The strip contains a biotin binding region (presumably with some type of avidin, a protein that binds biotin tightly and used extensively in this context) that captures the biotinylated antibody and immobilises the analyte, which is subsequently detected by the gold conjugated antibody. The product can therefore be used to assay biomarkers that otherwise lack a point-of-care test, without the need for high-cost capital equipment such as clinical chemistry instruments. The product has potential in segments of healthcare where capital equipment is unavailable, such as in field work, at the bedside and in the office of general practitioners. The gRAD was launched in 2015, but only constitutes a small portion of the company's revenues to date.

gRAD development programmes: From COVID-19 to snake bites

BioPorto has several early-stage programmes using the gRAD as a platform with its proprietary antibodies. The first and most obvious programme is to use this platform with the company's NGAL antibodies to provide a dipstick for assessment of NGAL. In December 2020, the company received a CE mark for the so-called NGALds (ds for dipstick). This product could provide a rapid assessment of kidney health, for instance in the triage environment, where no such testing capacity exists. Other potential uses include monitoring post-surgery, allowing a patient to leave the hospital and test for kidney issues over the following days at home.

Another programme in development intending to use the gRAD as a platform is BioPorto's COVID-19 programme. The company partnered with the University of Southern Denmark to develop antibodies to be used on the platform to detect the SARS-CoV-2 virus. In December 2020, BioPorto announced it had completed development and was ready to start testing patients. The FDA previously guided the company that it could move forward with the test with 150 patient samples, of which at least 30 would need to be positive. The company noted that non-invasive samples will be taken, presumably nasal swabs. Patients are being enrolled at the University of California Davis. BioPorto believes it can complete this study in early 2021 and it expects to file a EUA and CE mark application shortly thereafter if the results are positive. This product would fill a niche in the COVID-19 testing landscape. Tremendous improvements have been made in the throughput of COVID-19 testing, but the majority of testing in the US remains nucleotide based (eg, PCR). This still requires significant infrastructure and resources to perform. A dipstick-based antigen test, like the one in development at BioPorto, could be used to prescreen patients and provide an immediate feedback on COVID-19 status to be followed up with more robust nucleotide based testing (if positive), which would dramatically improve resource utilisation for COVID-19 testing. Moreover, there are many circumstances in which individuals undergo routine screening, such as healthcare workers, and a robust antigen test could improve screening capacity in these circumstances by providing immediate results without the need for infrastructure. That said, the utility of the test in any circumstance will be entirely dependent on its performance (eg sensitivity and specificity) and will be demonstrated in the clinical study. There are already a number of antigen-based tests that have EUAs and are commercially available, many with sensitivities over 95% and specificities at 100%. Therefore, we believe the bar is high for the performance of the BioPorto test.

Finally, BioPorto has two other announced development programmes using the gRAD, about which we know relatively little. First, the company has announced it is developing a gRAD assay for sepsis, using thrombomodulin as the biomarker. Thrombomodulin is a protein that is released as a result of damage to the lining of blood vessels, which is common with sepsis. Finally, BioPorto has partnered with VenomAid Diagnostics to develop a series of test to quickly identify the venom from snake bites for immediate treatment. A dipstick test is attractive in this case because snakebites are a more prevalent problem in regions that are underserved by medical care. Relatively few details has been released about either the sepsis programme or the snake bite programme.

Research products

BioPorto has historically sold a wide range of antibodies and related products for research purposes, which generates recuring revenue. Its portfolio of products is extensive (Exhibit 8) and includes antibodies, ELISA kits associated with these antibodies and a small number of proteins (predominantly NGAL standards) and sera for research use. However, despite the extensive catalogue, NGAL-related products are the biggest fraction of sales. This includes the research use only (RUO) version of the turbidometric NGAL Test currently seeking clearance in the US, as well as NGAL ELISA tests for humans and animals. The company had sales of DKK26.6m in 2019, of which DKK11.6m was derived from sales of the NGAL Test. BioPorto has been deprioritising its other products in favour of NGAL to focus its resources and promote the adoption of NGAL as a standard for AKI testing. In 2019 it announced it would reduce its commercial offering to focus exclusively on products owned by BioPorto. The company's customers for the portfolio span the healthcare space and include almost every large pharma company, such as Pfizer, Eli Lilly, Merck, GSK, etc. Additionally, it counts large academic institutions and research institutes as clients, such as the Karolinska Institutet and the La Jolla Institute.

Exhibit 8: Classes of antibodies provided by BioPorto

Category	Examples	Notes
Animal NGAL Tests	Mouse, rat, dog, pig, monkey	For use in drug development to assess renal toxicity
Allergy	Human IgE	Only commercially available human monoclonal IgE
Appetite hormones	GLP-1, Peptide YY	Useful for diabetes and obesity research
Complement system	C1s, C9	Used for study of infectious disease and immunodeficiency
Coagulation	Factor XII, antithrombin, D dimer	Study of common and rare clotting disorders

Source: BioPorto

Sensitivities

The greatest risks faced by BioPorto are associated with the clearance of the company's NGAL Test by regulatory authorities in the US. The utility of NGAL for detecting AKI has been studied for decades and we believe it provides a clear benefit over the sCr standard of care. However, this benefit will need to be demonstrated to regulators with concrete data, which has been difficult for the company thus far. The company has applied for regulatory clearance for the NGAL multiple times so far without receiving clearance. One of the factors complicating the evaluation of the NGAL Test is that the condition it is designed to detect, AKI, is defined in terms of the imperfect sCr gold standard. This makes it difficult to demonstrate superiority statistically. The current strategy for the company is to seek clearance initially for the paediatric indication and then follow this submission with an application for the adult product. This may simplify the regulatory pathway because the paediatric test can be used as a predicate device for the adult test, reducing the burden of demonstrating efficacy for the product. These products have the benefit of having speedy clinical evaluation times given that they can be administered in the ICU, but with the limitation that patients in the ICU have a high degree of variability, again complicating the analysis of the clinical data.

If it receives market clearance, the NGAL Test will also face commercial risks. The standard of care will need to be changed to market the product optimally, which will require extensive educational outreach to physicians. We believe that the groundwork is already laid for this given the history of research into NGAL, and the traction it already has when sold as a RUO product. The primary sales channel for the product will be through BioPorto's existing distributer relationships, which we assume will be supported by a small internal sales force. Because of this arrangement, in many ways the company will be dependent on its distributors and it cannot be guaranteed they will make decisions in the best interests of BioPorto.

Finally, BioPorto faces a series of risks as a pre-profit company. It is generating revenue, but it does not cover its operational expenses. We do not expect BioPorto to need additional capital before profitability, but this may change if there are any delays to the development or regulatory clearance of the NGAL Test beyond our anticipated timelines.

Valuation

Our valuation has minimally changed at this time: DKK941m or DKK3.53 per share from DKK939m or DKK3.52 per share. We have rolled forward our NPVs, but this was almost exactly offset by exchange rate effects (based on trailing six-month exchange rates US$:DKK6.31 from 6.63). Our fundamental assumptions remain unchanged. Our valuation is based on a risk-adjusted NPV analysis. We have modelled four target markets for the NGAL Test:

- ICU patients: this market is supported by the ongoing adult AKI programme, which is estimated as 4.6 million people in the US per year.[24] All of these patients of unknown AKI status are a potential market. We model four tests per patient in this setting as we expect continued evaluation for development of AKI. We model a peak penetration of 30%.
- Emergency department patients: we believe BioPorto will need to perform an additional clinical study (modelled for 2021) to support clearance in 2022 for this indication. As a potential market, we model the population of patients that would normally receive creatinine testing (approximately 7%) of the 140 million annual emergency department admissions in the US.[25] We estimate one test per patient and 30% peak penetration.
- Monitoring following cardiothoracic surgery: an additional study is needed and projected to occur in 2021 to support clearance in 2022. This population has been heavily studied in the literature and has a clear medical need, so we estimate 50% peak penetration with an average of four tests per patient. We project a higher penetration here than for other indications as NGAL has been more widely studied in this context and there are fewer complicating conditions (such as sepsis).
- An estimated 530,000 cardiothoracic surgeries were performed in 2010 in the US and this is estimated to increase to 850,000 by 2035.[26]
- Paediatric ICU patients: the subject of the upcoming FDA submission, an estimated 240,000 paediatric ICU admissions in the US per year.[27] Our other assumptions are similar to the adult ICU market: 30% peak penetration and four tests on average per patient.

We model each indication for the US and Europe. Our valuations are based on a $20 list price per assay for the NGAL Test. This corresponds to approximately $2,000 for a 100-assay kit, which is in line with current RUO pricing, although we forecast a modest 2% increase in price per year. We model the price to distributors at approximately 50% the list price ($10 per assay). Our valuation for the pre-commercial indications is based on a risk-adjusted NPV model at a 12.5% discount rate (our standard for pre-commercial products). We model the company's research products (including the NGAL Test for the research market) using a DCF model at a 10% discount rate (our standard for commercial products) and a -5% terminal growth rate.

[24] Healthcare Cost and Utilization Project.

[25] National Hospital Ambulatory Medical Care Survey, CDC.

[26] American Associated for Thoracic Surgery.

[27] Folafoluwa O, et al. (2005) A National Survey of Pediatric Critical Care Resources in the United States. *Pediatrics* 115, e382.

Exhibit 9: Valuation of BioPorto

Programme	Market	Prob. of success	Peak revenue ($m)	Valuation (DKKm)
The NGAL Test	ICU	50%	176.6	609.8
	ED	30%	167.1	299.7
	Post-surgery	30%	54.1	85.6
	Research	100%	4.3	11.5
	Paediatrics	50%	15.4	15.0
Other products	Research	100%	1.3	3.4
Unallocated costs				(202.7)
Total				822.4
Net cash and equivalents (Q320 + offering) (DKKm)				118.1
Total firm value (DKKm)				940.5
Total shares (m)				266.6
Value per share (DKK)				3.53
Dilutive warrants (m)				8.4
Total diluted shares (m)				275.0
Value per diluted share (DKK)				3.52

Source: BioPorto reports, Edison Investment Research. Note: ED, emergency department.

We do not include the gRAD or any of the associated programmes such as the COVID-19 test or the NGALds in our valuation, but we may do so at a later point if the products show promise clinically or commercially. The NGALds was recently CE marked, which makes it commercially available in Europe, but we want to see some traction before including it in our valuation.

The COVID-19 test recently advanced to the clinic, with results expected in Q221. This product could be on the market quickly if it receives an EUA. There are a very large number of other tests that are available with EUA including antigen tests (such as BioPorto's dipstick), including many that are high sensitivity and specificity. For illustrative purposes, however, we have presented a contingency analysis based on the probability of success and market penetration (Exhibit 10. This analysis assumes commercialisation in the US, UK and EU, and assumes testing rates will remain relatively similar to current values throughout 2020 (roughly 3.7m tests a day). We acknowledge, however, that these rates vary significantly based on infection rates and by region. We are only modelling revenue for one year post launch as we expect declining testing needs after the launch of the COVID-19 vaccines in 2020. We assume a $10 price per test and a 50% margin to the company.

Exhibit 10: COVID-19 valuation analysis

Valuation (DKKm)	Penetration				
PoS	**2%**	**4%**	**6%**	**8%**	**10%**
1%	7.60	15.20	22.80	30.40	38.00
5%	38.00	75.99	113.99	151.99	189.98
10%	75.99	151.99	227.98	303.97	379.96
15%	113.99	227.98	341.97	455.96	569.95
20%	151.99	303.97	455.96	607.94	759.93

Source: Edison Investment Research. Note: PoS, probability of success. $10 per test, 50% net profit margin, 3.7m tests a day in US+UK+EU, for one year.

Financials

We are not updating our financial forecasts, aside for updating the exchange rate (prior forecasts shown here). We believe the company's DKK93.6m offering completed in October 2020 should be sufficient to finance the company through 2021 and into 2022 (company guidance is that it is financed until Q421). We are forecasting a marketing application for the adult NGAL in H221, but we may further adjust this depending on the timing of any of the intervening events.

Exhibit 11: Financial summary

DKK'000s	2018	2019	2020e	2021e	2022e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT					
Revenue	26,016	26,622	23,477	79,890	181,221
Cost of Sales	(8,181)	(9,293)	(10,195)	(13,680)	(23,887)
Gross Profit	17,835	17,329	13,282	66,210	157,335
Sales	(20,935)	(39,268)	(25,447)	(42,190)	(52,453)
R&D	(18,676)	(24,556)	(33,821)	(34,171)	(15,089)
Administrative	(20,005)	(27,804)	(26,437)	(26,701)	(26,701)
EBITDA	(42,103)	(68,333)	(63,508)	(30,840)	69,104
Operating Profit (before amort. and except.)	(42,646)	(71,190)	(68,088)	(32,517)	67,427
Amortisation of acquired intangibles	0	0	0	0	0
Exceptionals	0	0	0	0	0
Share-based payments	865	(3,109)	(4,335)	(4,335)	(4,335)
Reported operating profit	(41,781)	(74,299)	(72,423)	(36,852)	63,092
Net Interest	164	52	(1,925)	508	356
Joint ventures & associates (post tax)	0	0	0	0	0
Exceptionals	0	0	0	0	0
Profit Before Tax (norm)	(42,482)	(71,138)	(70,013)	(32,009)	67,783
Profit Before Tax (reported)	(41,617)	(74,247)	(74,348)	(36,344)	63,448
Reported tax	3,569	4,605	4,611	2,254	(3,935)
Profit After Tax (norm)	(38,124)	(66,726)	(65,671)	(30,024)	63,579
Profit After Tax (reported)	(38,048)	(69,642)	(69,737)	(34,090)	59,512
Minority interests	0	0	0	0	0
Discontinued operations	0	0	0	0	0
Net income (normalised)	(38,124)	(66,726)	(65,671)	(30,024)	63,579
Net income (reported)	(38,048)	(69,642)	(69,737)	(34,090)	59,512
Average Number of Shares Outstanding (m)	157	170	210	277	291
EPS - normalised (DKK)	(0.24)	(0.39)	(0.31)	(0.11)	0.22
EPS - diluted normalised (DKK)	(0.24)	(0.39)	(0.31)	(0.11)	0.22
EPS - basic reported (DKK)	(0.24)	(0.41)	(0.33)	(0.12)	0.20
Dividend (DKK)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Fixed Assets	3,563	8,218	14,985	14,353	13,722
Intangible Assets	1,374	4,799	11,995	11,363	10,732
Tangible Assets	1,437	1,710	1,302	1,302	1,302
Investments & other	752	1,709	1,688	1,688	1,688
Current Assets	62,638	34,464	115,289	92,883	157,476
Stocks	3,631	4,155	3,352	4,497	7,853
Debtors	8,036	5,695	2,894	9,849	22,342
Cash & cash equivalents	46,709	18,122	101,665	71,159	119,903
Other	4,262	6,492	7,377	7,377	7,377
Current Liabilities	(9,217)	(14,858)	(28,991)	(35,709)	(35,823)
Creditors	(4,451)	(3,237)	(2,383)	(9,101)	(9,215)
Tax and social security	(141)	(2,306)	(3,348)	(3,348)	(3,348)
Short term borrowings	0	0	0	0	0
Other	(4,625)	(9,315)	(23,260)	(23,260)	(23,260)
Long Term Liabilities	(787)	(2,502)	(10,275)	(10,275)	(10,275)
Long term borrowings	0	0	0	0	0
Other long term liabilities	(787)	(2,502)	(10,275)	(10,275)	(10,275)
Net Assets	56,197	25,322	91,007	61,252	125,100
Minority interests	0	0	0	0	0
Shareholders' equity	56,197	25,322	91,007	61,252	125,100
CASH FLOW					
Op Cash Flow before WC and tax	(42,103)	(68,333)	(63,508)	(30,840)	69,104
Working capital	(631)	4,453	15,793	(1,383)	(15,735)
Exceptional & other	(74)	159	113	508	356
Tax	4,799	3,557	5,224	2,254	(3,935)
Net operating cash flow	(38,009)	(60,164)	(42,379)	(29,460)	49,790
Capex	(1,483)	(1,106)	(1,071)	(1,046)	(1,046)
Acquisitions/disposals	0	0	0	0	0
Net interest	0	0	0	0	0
Equity financing	39,319	35,983	129,894	0	0
Dividends	0	0	0	0	0
Other	(198)	(3,332)	(2,861)	0	0
Net Cash Flow	(371)	(28,619)	83,583	(30,506)	48,744
Opening net debt/(cash)	(47,080)	(46,709)	(18,122)	(101,665)	(71,159)
FX	0	0	0	0	0
Other non-cash movements	0	32	(40)	0	0
Closing net debt/(cash)	(46,709)	(18,122)	(101,665)	(71,159)	(119,903)

Source: BioPorto reports, Edison Investment Research

Contact details	Revenue by geography
Tuborg Havnevej 15, st. 2900 Hellerup Denmark +45 45 29 00 00 www.bioporto.com	N/A

Management team

CEO: Peter Mørch Eriksen	COO: Jan Kuhlmann Andersen
Peter Mørch Eriksen was appointed CEO of BioPorto in July 2013. He has more than 15 years of experience within medtech/life science in Denmark and abroad. Before joining BioPorto, Peter was CEO of Sense and before this, he held positions as vice president of Medtronic in both the US and Denmark. In addition to being CEO of BioPorto, he chairs the board of MTIC, is a board member at Nervex, member of Lund University Advisory Board, and director of PMEconsult ApS.	Jan Kuhlmann Andersen was appointed COO of BioPorto in August 2016. He is an experienced executive having worked with sales within the life sciences area, mostly in US-owned companies such as FMC, Cambrex, Fisher Scientific and Thermo Fisher Scientific since 1995. From 2007 and until joining BioPorto, Jan was vice president, sales and marketing, in the animal health and nutrition division of Chr. Hansen.
CFO: Ole Larsen	**Chairman: Thomas Magnussen**
Ole Larsen was appointed CFO of BioPorto in June 2018. He most recently came from Bavarian Nordic, a NASDAQ-listed Danish biotechnology company focused on cancer immunotherapies and vaccines for infectious diseases. From 2008, Ole Larsen served as executive vice president and CFO and was responsible for finance, IR and IT. Before this, Ole Larsen held CFO positions at two of the largest Danish and Nordic media groups, Nordisk Film and Berlingske Tidende.	Thomas Magnussen is chairman and co-founder and partner in QuantumWise and Zylinc, respectively, as well as an entrepreneur in the high-tech space, engaging in start-up companies with global business scope. He has experience in commercialisation strategies and from industries including nanotechnology, ICT and medtech.
CMO: Christopher Bird	**President, BioPorto Diagnostics: Amy Winslow**
Christopher Bird was appointed CMO of BioPorto in August 2019. He has a robust scientific background and a track record of delivering strong results in business development, finance, sales and marketing. He most recently served as head of North American medical and scientific affairs at Roche Diagnostics Corp, where he had responsibility for strategy and execution of all clinical education, study management and field support during his 10-year tenure.	Amy Winslow was appointed president of BioPorto Diagnostics in April 2019. She is an experienced diagnostics executive, who most recently served as president and CEO of Magellan Diagnostics, a Boston-based point-of-care diagnostics company. While at Magellan, she led the company's restructuring for growth, increased profitability, built a dedicated commercial team and ultimately ran a successful sale of the company to Meridian Bioscience. Prior to Magellan, among other roles, Amy served as VP of marketing for Athena Diagnostics, a neurodiagnostic specialty laboratory testing business that was later acquired by Quest Diagnostics and as marketing manager at Genzyme Transgenics.

Principal shareholders	(%)
Ejendomsselskabet Jano	+10%
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