

# BioPorto Diagnostics

Continued growth in 2020 despite headwinds

Financial update

BioPorto managed to continue sales growth for its NGAL research-use only (RUO) product in 2020 despite the headwinds of COVID-19. Sales of the product increased 28% over the prior year (DKK13.4m from DKK10.5m) despite the disruption. We are encouraged to see this growth as we expect physicians with exposure to the test to become the first customers after the launch of the approved NGAL Test for clinical use.

Year end	Revenue (DKKm)	PBT* (DKKm)	EPS* (DKK)	DPS (DKK)	P/E (x)	Yield (%)
12/19	26.6	(71.1)	(0.39)	0.0	N/A	N/A
12/20	23.2	(61.5)	(0.28)	0.0	N/A	N/A
12/21e	32.2	(74.9)	(0.25)	0.0	N/A	N/A
12/22e	179.3	64.5	0.21	0.0	26.2	N/A

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

## Selling costs down in 2020 but expected to rise

The increase in NGAL sales was in spite of significant disruption to the company's ongoing efforts to promote the product. This was reflected in a reduced cost of sales (DKK20.8 from DKK39.3m), which brought down BioPorto's operating expenses as a whole (DKK76.9m from DKK91.6m). We expect this to turn around in 2021 as the company gears up for the commercial launch of the paediatric clinical NGAL Test (DKK387.9m cost of sales).

## Guidance: DKK30m sales, DKK73m EBIT loss

BioPorto provided initial guidance for 2021 of DKK30m sales and DKK73m EBIT loss, which is the same guidance it provided for 2020 initially. Based on this guidance and the company's recent clinical update, we are pushing back our timelines for the submission of the de novo application for the paediatric NGAL test to late summer 2021 (from Q221 previously). This has pushed back our forecasts for the expected clearance for the paediatric test to the end of 2021 and submission of the adult 510k application to 2022.

## COVID-19 test clinical results expected imminently

With BioPorto's earnings announcement, it reiterated the timeline for submitting an emergency use authorization (EUA) to the FDA for marketing clearance of its COVID-19 dipstick test in Q221. It additionally expects to submit a filing for CE marking in Europe at the same time. The company is continuing to collect patient samples and it is evaluating expanding to additional sites in Europe.

## Valuation: Reduced on longer timelines

We have reduced the valuation for the NGAL and research products to DKK908.5m or DKK3.41 per basic share from DKK941m or DKK3.53 per basic share. We are not valuing the company's COVID-19 test before the release of clinical data. The lower valuation is driven by the adjustment to the clinical timelines described above.

Healthcare equipment & services

22 March 2021

**Price** **DKK5.50**

**Market cap** **DKK1,466**

DKK6.31/US\$

Net cash (DKKm) at Q420 107.9

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 (8.0) 52.4 254.4

Rel (local) (6.0) 52.4 132.7

52-week high/low DKK7.78 DKK1.55

### Business description

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

### Next events

COVID-19 EUA submission Q221

Paediatric NGAL study complete Summer 2021

### Analyst

Nathaniel Calloway +1 646 653 7036

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

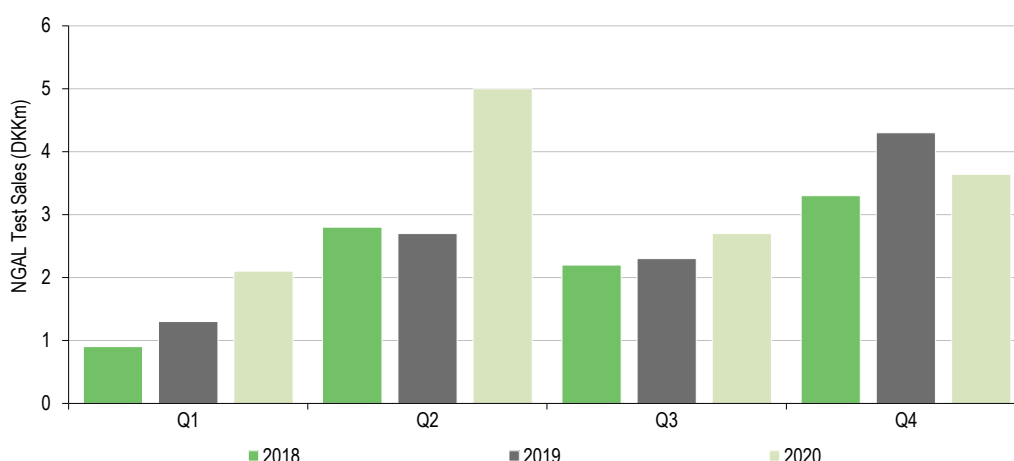
[Edison profile page](#)

**BioPorto Diagnostics is a research client of Edison Investment Research Limited**

## NGAL continues upward trajectory

BioPorto reported revenue of DKK23.2m in 2020, of which DKK13.4m was from sales of the NGAL RUO product, growth of 28% over the prior year (DKK10.5m, or 15% y-o-y growth if DKK1.2m of additional non-product sales-related NGAL revenue in 2019 is included). This is in spite of the obvious headwinds associated with COVID-19. On a quarterly basis, NGAL revenue for Q420 was down slightly over the previous year (DKK3.6m versus DKK4.3m), although we attribute this mostly to lumpiness in the sales pattern (Exhibit 1). We are encouraged to see the continued growth in NGAL sales, because we believe it is indicative of future interest in the clinical use of NGAL test products. As a whole, total revenue for 2020 was down compared to 2019 (DKK26.6m), due to the company's strategic decision to focus its sales efforts on NGAL. This being said, Q420 sales of the company's non-NGAL products were the strongest they have been in a year and a half (DKK3.9m).

**Exhibit 1: NGAL RUO sales**



Source: BioPorto reports

Operating expenses were down significantly in 2020 (DKK76.9m from DKK91.6m in 2019), primarily due to a reduction in sales expenses (DKK20.8 from DKK39.3m). We expect these sales expenses to increase significantly in 2021 (DKK38.7m) and 2022 (DKK51.7m) as BioPorto gears up for the launch of the paediatric and adult NGAL products.

BioPorto ended the year with DKK107.9m in cash, after its Q420 rights offering of DKK93.6m. We believe this should be sufficient to finance the company until after the approval of the NGAL test for both paediatric and adult indications, at which point we expect BioPorto to achieve profitability.

## Company guidance and timelines

BioPorto provided financial guidance for 2021, with expectations of DKK30m in revenue and DKK73m in EBIT losses. The majority of these sales are attributed to sales of the company's existing products, with a small contribution due to sales for the paediatric NGAL test at the end of the year (although the company did not give any details). Based on this guidance and the recent pipeline [update](#) from the company, we are revising our expectation for the timing of the approval of the paediatric and adult NGAL tests. The company is continuing to experience delays in recruitment due to COVID-19 for its study of critically ill (hospitalized) paediatric patients, although significant efforts have been made to mitigate this. Eight sites are enrolling patients in the US and it is evaluating potential sites in Europe. We have pushed the expected regulatory submission of the paediatric test into late summer 2021, with a clearance decision at the very end of the year. The

current plan is to submit a 510k application for the adult test, using the paediatric test as the predicate device, but we no longer expect this to occur in 2021 based on the above guidance. Based on these combined delays, we have reduced our expected 2021 revenue estimates to DKK32.2m from DKK79.9m.

## Valuation

We are continuing our policy of valuing BioPorto's NGAL and research products separately from its COVID-19 test programmes. We are withholding the valuations for all COVID-19-based diagnostic products before clinical data are available. We have reduced the valuation for the NGAL and research products to DKK908.5m or DKK3.41 per basic share from DKK941m or DKK3.53 per basic share. This reduction is driven by the above adjustment to the timeline for the launch of the paediatric and adult NGAL tests. Additionally, we have adjusted for lower cash at the end of Q420 (DKK107.9 from our previous pro forma estimates of DKK118.1m). Additionally, our valuation is moved slightly lower due to adjustments in the run rates for the research products. Otherwise, our models are unchanged.

### Exhibit 2: Valuation of BioPorto

Program	Market	Probability of success	Peak revenue (\$m)	Valuation (DKKm)
The NGAL Test	ICU	50%	176.6	594.2
	ED	30%	167.1	299.7
	Post-surgery	30%	54.1	85.6
	Research	100%	3.8	6.3
	Paediatrics	50%	15.4	14.8
Other products	Research	100%	1.5	2.5
Unallocated costs				-202.7
Total				800.6
Net cash and equivalents (Q420) (DKKm)				107.9
Total firm value (DKKm)				908.5
Total shares (m)				266.6
Value per share (DKK)				3.41
Dilutive warrants (m)				4.6
Total diluted shares				271.1
Value per diluted share (DKK)				3.40

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

In lieu of a valuation for the company's COVID-19 gRAD test programme, we are presenting a contingency analysis, which remains unchanged from our previous report. 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). BioPorto has guided to completion of clinical testing in Q221, at which time we expect to present a formal valuation based on the results of the study.

### Exhibit 3: 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.

**Exhibit 4: Financial summary**

	DKK000s	2019	2020	2021e	2022e
Year-end 31 December		IFRS	IFRS	IFRS	IFRS
<b>INCOME STATEMENT</b>					
Revenue		26,622	23,204	32,232	179,324
Cost of Sales		(9,293)	(9,865)	(13,169)	(26,468)
Gross Profit		17,329	13,339	19,063	152,855
Sales		(39,268)	(20,786)	(38,924)	(52,087)
R&D		(24,556)	(28,125)	(34,171)	(15,089)
Administrative		(27,804)	(28,018)	(26,701)	(26,701)
EBITDA		(68,333)	(54,280)	(71,423)	68,289
Operating Profit (before amort. and except.)		(71,190)	(58,274)	(75,417)	64,295
Amortisation of acquired intangibles		0	0	0	0
Exceptionals		0	0	0	0
Share-based payments		(3,109)	(5,316)	(5,316)	(5,316)
Reported operating profit		(74,299)	(63,590)	(80,733)	58,979
Net Interest		52	(3,244)	540	232
Joint ventures & associates (post tax)		0	0	0	0
Exceptionals		0	0	0	0
Profit Before Tax (norm)		(71,138)	(61,518)	(74,877)	64,526
Profit Before Tax (reported)		(74,247)	(66,834)	(80,193)	59,210
Reported tax		4,605	5,272	4,974	(3,672)
Profit After Tax (norm)		(66,726)	(57,702)	(70,233)	60,524
Profit After Tax (reported)		(69,642)	(61,562)	(75,219)	55,538
Minority interests		0	0	0	0
Discontinued operations		0	0	0	0
Net income (normalised)		(66,726)	(57,702)	(70,233)	60,524
Net income (reported)		(69,642)	(61,562)	(75,219)	55,538
Average Number of Shares Outstanding (m)		170	205	277	291
EPS - normalised (DKK)		(0.39)	(0.28)	(0.25)	0.21
EPS - diluted normalised (DKK)		(0.39)	(0.28)	(0.25)	0.21
EPS - basic reported (DKK)		(0.41)	(0.30)	(0.27)	0.19
Dividend (DKK)		0.00	0.00	0.00	0.00
<b>BALANCE SHEET</b>					
Fixed Assets		8,218	15,506	12,827	10,148
Intangible Assets		4,799	11,412	11,412	11,412
Tangible Assets		1,710	2,448	(231)	(2,910)
Investments & other		1,709	1,645	1,645	1,645
Current Assets		34,464	124,780	61,439	125,579
Stocks		4,155	3,165	4,329	8,702
Debtors		5,695	6,886	3,974	22,108
Cash & cash equivalents		18,122	107,943	46,350	87,982
Other		6,492	6,786	6,786	6,786
Current Liabilities		(14,858)	(30,930)	(34,814)	(35,420)
Creditors		(3,237)	(4,636)	(8,520)	(9,126)
Tax and social security		(2,306)	(2,828)	(2,828)	(2,828)
Short term borrowings		0	0	0	0
Other		(9,315)	(23,466)	(23,466)	(23,466)
Long Term Liabilities		(2,502)	(8,444)	(8,444)	(8,444)
Long term borrowings		0	0	0	0
Other long term liabilities		(2,502)	(8,444)	(8,444)	(8,444)
Net Assets		25,322	100,912	31,008	91,862
Minority interests		0	0	0	0
Shareholders' equity		25,322	100,912	31,008	91,862
<b>CASH FLOW</b>					
Op Cash Flow before WC and tax		(68,333)	(54,280)	(71,423)	68,289
Working capital		4,453	15,593	5,631	(21,901)
Exceptional & other		159	(1,672)	540	232
Tax		3,557	4,743	4,974	(3,672)
Net operating cash flow		(60,164)	(35,616)	(60,278)	42,948
Capex		(1,106)	(1,499)	(1,315)	(1,315)
Acquisitions/disposals		0	0	0	0
Net interest		0	0	0	0
Equity financing		35,983	130,064	0	0
Dividends		0	0	0	0
Other		(3,332)	(3,051)	0	0
Net Cash Flow		(28,619)	89,898	(61,593)	41,633
Opening net debt/(cash)		(46,709)	(18,122)	(107,943)	(46,350)
FX		32	(77)	0	0
Other non-cash movements		0	0	0	0
Closing net debt/(cash)		(18,122)	(107,943)	(46,350)	(87,982)

Source: BioPorto reports, Edison Investment Research

---

## General disclaimer and copyright

This report has been commissioned by BioPorto Diagnostics and prepared and issued by Edison, in consideration of a fee payable by BioPorto Diagnostics. Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

**Accuracy of content:** All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

**Exclusion of Liability:** To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out of or in connection with the access to, use of or reliance on any information contained on this note.

**No personalised advice:** The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

**Investment in securities mentioned:** Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright: Copyright 2021 Edison Investment Research Limited (Edison).

---

## Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

---

## New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

---

## United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

---

## United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960  
Schumannstrasse 34b  
60325 Frankfurt  
Germany

London +44 (0)20 3077 5700  
280 High Holborn  
London, WC1V 7EE  
United Kingdom

New York +1 646 653 7026  
1185 Avenue of the Americas  
3rd Floor, New York, NY 10036  
United States of America

Sydney +61 (0)2 8249 8342  
Level 4, Office 1205  
95 Pitt Street, Sydney  
NSW 2000, Australia