

# BioPorto Diagnostics

Focused on the upcoming paediatric AKI results

Earnings update

BioPorto has reported its results for Q121, which included DKK5.6m in sales from all its research use only products. This is up from Q120 (DKK4.2m) but comparable to Q119 (DKK5.5m). The biggest near-term driver for the company's revenue will be the pending results of its pivotal paediatric acute kidney injury (AKI) clinical study, which is slated to complete in summer 2021, and the subsequent regulatory submission to the FDA for De Novo 510(k) clearance.

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	(74.5)	(0.25)	0.0	N/A	N/A
12/22e	179.3	65.2	0.21	0.0	19	N/A

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

## Research use only NGAL sales flat

Sales of the research use only (RUO) NGAL test were flat from Q120 at DKK2.1m. Historically Q1 sales have been lower than other quarters. Although these sales are small on an absolute basis, we use the RUO NGAL test sales to gauge the eventual interest in the clinical tests in the future. The trajectory for RUO sales have generally been positive: ~24% CAGR since 2018, and we hope that the product will remain on this trajectory in future periods.

## Big turning points coming

BioPorto is facing a major turning point as it continues the enrolment of its pivotal study of paediatric AKI. The study is using NGAL measured in urine to gauge the risk of AKI in paediatric patients, and the company recently guided towards the study being completed in summer 2021. BioPorto expects to file an application for De Novo 510(k) clearance shortly thereafter. Moreover, this study and the results of the application will inform how the company will pursue clearance for the adult NGAL Test, which is expected to progress after the FDA response.

## Shakeup in upper management

The company announced two departures from its C-suite in Q221: both the company's CEO and CFO will be moving on from the company. The tenure of CFO Ole Larsen will end in May 2021, whereas the CEO Peter Mørch Eriksen will remain with BioPorto until early 2022 and remain CEO until a successor is found.

## Valuation: DKK916m or DKK3.42 per share

Our valuation is up slightly: DKK916m from DKK909m previously, and DKK3.42/share from DKK3.41/share. This does not include the contribution from the COVID-19 program, as in previous reports. Our valuations increased from rolling forward our NPVs, but this was offset by lower net cash (DKK91.1m pro forma following recent warrant exercises from DKK108m at the end of Q420).

Healthcare equipment & services

13 May 2021

**Price** **DKK3.97**

**Market cap** **DKK1,062**

DKK6.31/US\$

Net cash (DKKm) at March 2021 adjusted for capital increase 91.1

Shares in issue 267.8m

Free float 86%

Code BIOPOR

Primary exchange Nasdaq Copenhagen

Secondary exchange N/A

### Share price performance



% 1m 3m 12m

Abs (26.2) (36.7) 72.9

Rel (local) (28.1) (38.2) 32.1

52-week high/low DKK7.78 DKK1.90

### 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

Paediatric AKI study complete Summer 2021

COVID-19 gRAD results Q221

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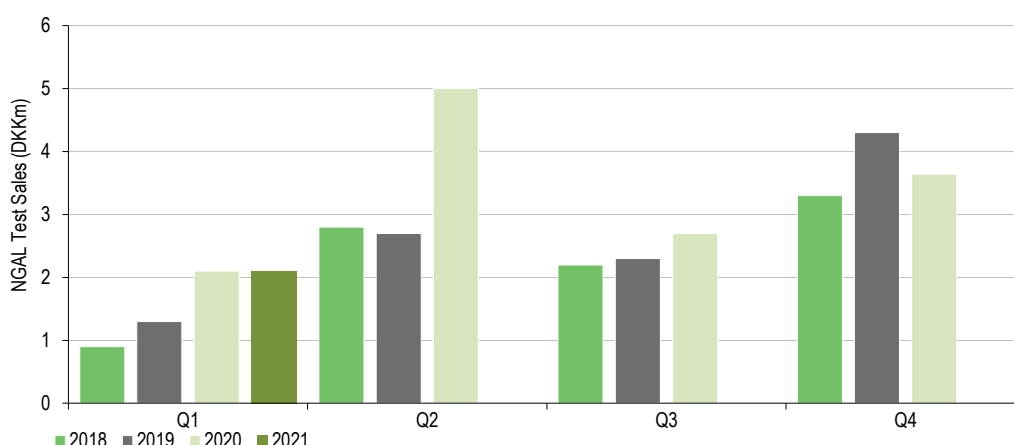
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## Commercial and financial update

BioPorto continues to market its suite of RUO products, and it reported sales of DKK5.6m for Q121. This is up from DKK4.2m in Q120 (33%), but that prior quarter had uncommonly low sales, and current sales are more in line with Q119 (DKK5.5m). The increase in revenue in Q121 was driven by sales of antibodies (DKK2.9m compared to DKK1.7m for Q120). Sales of RUO NGAL tests were flat from Q120 at DKK2.1m (Exhibit 1). Sales of NGAL tests have always been seasonally low in Q1, but the year-on-year trends have generally been positive (a 24% CAGR using an exponential regression). We view the growing adoption of NGAL for research as an indicator for the future commercial interest in the test assuming it becomes approved for the detection of AKI. If growth in the product sales remains flat, that may indicate that the product has fully penetrated the RUO market, but it is too early to draw conclusions on that score. Moreover, the biggest determinants of future sales will likely be the results from the ongoing paediatric AKI study and the subsequent regulatory clearance decisions.

**Exhibit 1: RUO NGAL sales**



Source: BioPorto reports

BioPorto's results for the quarter were generally consistent with our estimates. The loss for the quarter was DKK15.3m. We now forecast the company will report a loss of DKK74.9m for 2021, which remains largely unchanged from our previous estimate (DKK75.2m). This assumes that BioPorto will be undergoing launch activities for the NGAL test following a positive clearance decision from the FDA. If the company does not receive positive results from the ongoing paediatric study or is not cleared by the FDA, we would expect losses more similar to 2020 (DKK61.6m as reported). The company also maintained its 2021 guidance of DKK30m in revenue and an EBIT loss of DKK73m.

BioPorto ended March 2021 with DKK86.7m in cash, which we expect will be sufficient to complete the paediatric study and submit the NGAL Test to the FDA. We currently forecast the company reaching profitability in 2022 if the NGAL test is approved in the US, but BioPorto may need to seek additional financing if this application is rejected.

## Management departures

BioPorto announced recently in Q221 that both the CFO Ole Larsen and CEO Peter Mørch Eriksen would be leaving the company. Mr Larsen [announced](#) in April 2021 that he would be leaving for

other opportunities and would stay with the company through the current Q121 report. Mr Eriksen followed this with an [announcement](#) in May 2021 that he would be resigning as CEO, but would be staying on with the company during the search for a replacement and will remain CEO until a replacement is found. He stated that as the company approaches the commercial launch of the NGAL test that it would be seeking out a successor to guide the company through this launch.

The optimistic view of these departures is that the company is shifting its operational focus to the potential commercial sales of the NGAL test once approved for clinical use (from the current focus on development) in the near future and that these departures are reflective of that. However, it is hard to ignore that these departures are coming very shortly before the ultimate culmination of the company's hard work over the preceding years: the readout from the paediatric clinical trial and the subsequent De Novo submission. The company expects to complete the pivotal clinical study in the summer of 2021. The company also has an additional near-term clinical readout from the testing of its gRAD platform for the detection of COVID-19, which is expected in Q221.

## Valuation

Our valuation is up slightly: DKK916m from DKK909 previously, and up on a per share basis to DKK3.42 from DKK3.41, previously. Our valuations increased from rolling forward our net present valuations (NPVs), but this was offset by lower net cash (DKK91.1m pro forma following DKK4.4m in warrant exercises after Q121, from DKK108m at the end of Q420). This does not include any value associated with the COVID-19 testing program. We as a policy are not valuing COVID-19 programs before the announcement of clinical data. Please see our previous [report](#) for an illustrative analysis of this asset.

Share counts increased slightly from employee warrant exercises (268m from 267m). Otherwise our valuation assumptions remain unchanged. We expect to update our valuation following the announcement of results from the paediatric clinical study and following its clearance decision.

### Exhibit 2: Valuation of BioPorto

Program	Market	Probability of success	Peak revenue (\$m)	Valuation (DKKm)
The NGAL Test	ICU	50%	176.6	612.0
	ED	30%	167.1	308.7
	Post-surgery	30%	54.1	88.2
	Research	100%	3.8	6.5
	Paediatrics	50%	15.4	15.2
Other products	Research	100%	1.5	2.6
Unallocated costs				(208.7)
Total				824.4
Net cash and equivalents (pro forma Q121 + warrant exercises) (DKKm)				91.1
Total firm value (DKKm)				915.6
Total shares (m)				267.8
Value per share (DKK)				3.42
Dilutive warrants (m)				4.6
Total diluted shares (m)				272.3
Value per diluted share (DKK)				3.41

Source: BioPorto reports, Edison Investment Research

**Exhibit 3: 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)	890	890
Joint ventures & associates (post tax)		0	0	0	0
Exceptionals		0	0	0	0
Profit Before Tax (norm)		(71,138)	(61,518)	(74,527)	65,185
Profit Before Tax (reported)		(74,247)	(66,834)	(79,843)	59,869
Reported tax		4,605	5,272	4,952	(3,713)
Profit After Tax (norm)		(66,726)	(57,702)	(69,905)	61,142
Profit After Tax (reported)		(69,642)	(61,562)	(74,891)	56,155
Minority interests		0	0	0	0
Discontinued operations		0	0	0	0
Net income (normalised)		(66,726)	(57,702)	(69,905)	61,142
Net income (reported)		(69,642)	(61,562)	(74,891)	56,155
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	66,168	130,925
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	51,078	93,328
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	35,737	97,208
Minority interests		0	0	0	0
Shareholders' equity		25,322	100,912	35,737	97,208
<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)	890	890
Tax		3,557	4,743	4,952	(3,713)
Net operating cash flow		(60,164)	(35,616)	(59,950)	43,565
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	4,400	0
Dividends		0	0	0	0
Other		(3,332)	(3,051)	0	0
Net Cash Flow		(28,619)	89,898	(56,865)	42,250
Opening net debt/(cash)		(46,709)	(18,122)	(107,943)	(51,078)
FX		32	(77)	0	0
Other non-cash movements		0	0	0	0
Closing net debt/(cash)		(18,122)	(107,943)	(51,078)	(93,328)

Source: BioPorto reports, Edison Investment Research

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