

BioPorto Diagnostics

Headed in the right direction

Earnings update

BioPorto Diagnostics reported sales of DKK26.6m for 2019, driven in the largest part by sales of The NGAL test for research purposes (DKK11.6m). The company reported 9% growth in NGAL Test sales year-on-year for the US (DKK4.9m) and 9% growth as a whole, representing increasing interest in the technology. The company remains on track to submit a De Novo 510(k) application for the paediatric NGAL Test in mid-2020.

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	35.5	(63.3)	(0.33)	0.0	N/A	N/A
12/21e	135.2	17.2	0.09	0.0	N/A	N/A

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

Total sales roughly flat year-on-year

Despite a 9% increase in sales of The NGAL Test, total sales for the year were roughly flat compared to 2018 (DKK26.0m). One factor contributing to this is that in Q4 a collaboration with a supplier of antibodies ended, which tempered sales in that segment (DKK0.9m compared to DKK1.4m for Q319). BioPorto will be focusing on internally sourced antibodies and expects lower sales in this segment for 2020.

On track for new paediatric NGAL submission

The company is currently collecting additional data for its application package for the paediatric NGAL test, and has guided toward submission of the application in Q220. Also based on feedback from experts, the company believes that it is likely that the correct regulatory pathway for the product is a De Novo 510(k). Standard 510(k) applications require a predicate device, whereas the De Novo application is for products that lack such a predicate. De Novo devices have the burden of demonstrating safety and efficacy in lieu of demonstrating substantial equivalence to another device. The company has scheduled discussions with the agency on the correct pathway forward in Q120. The submission of the paediatric application is expected in Q220, and the company is guiding towards submission of the adult application sometime in 2020.

Valuation: Slightly lower to DKK932m or DKK5.33/share

We have lowered our valuation slightly to DKK932m or DKK5.33 per share, from DKK942m or DKK5.39 per share. We have delayed our initial revenue expectations for the adult NGAL test and lowered our expectations for the research products.

Healthcare equipment & services

13 March 2020

Price **DKK1.97**

Market cap **DKK345m**

DKK6.63/US\$

Net cash (DKKm) at 31 December 2019 18.1

Shares in issue 174.9m

Free float 79%

Code BIOPOR

Primary exchange NASDAQ Copenhagen

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (33.4) (30.7) (50.8)

Rel (local) (14.4) (19.3) (48.7)

52-week high/low DKK4.05 DKK1.97

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 submission Q220

Adult NGAL submission 2020

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BioPorto Diagnostics is a research client of Edison Investment Research Limited

Financial update: Guidance to DKK73m EBIT loss

The company guided to DKK30m in sales for 2020 and an EBIT loss of DKK73m. The revenue guidance is based on an increase in NGAL revenues, offset by declines in sales of antibodies and ELISA kits due to BioPorto's narrower focus on its own antibody library. Importantly the firm's guidance does not factor in any sales for a FDA-cleared NGAL Test, whereas we would expect a small but significant revenue if the test is cleared in 2020 as distributors order their initial stock. We currently forecast sales of DKK35.5m for 2020 including this revenue and an EBIT loss of DKK66.5m.

The company also guided towards its intent to complete studies for the adult NGAL study and submit an application to the FDA in 2020. To align with company guidance, we have delayed some R&D expenditure to 2021. The delayed R&D is associated with the continuation of the clinical development of the adult NGAL test we expect to occur after the initial approval. Given the uncertainty regarding the timing of the program we have delayed initial costs associated with the label expansion. We now expect an R&D spend for 2020 of DKK27.9m (from DKK47.5m previously). We have also delayed the initial ramp for the adult NGAL test, which has had a negative impact on our valuation for the product (see below). This has contributed to our lower 2020 revenue expectation from DKK42.1m previously.

Concurrent with the release of the earnings report, the company initiated a rights offering of up to 24,992,054 new shares at a subscription price of DKK2.20 (gross proceeds of DKK55m). We previously forecasted the company needing approximately this much cash (DKK50m in previous models) to reach profitability, but have slightly increased this to the same value (but modelled as illustrative debt at this time) as the potential gross proceeds from the rights offering because it aligns with current costs. BioPorto has received binding commitments for subscription of more than 37% of the rights issue.

Valuation

We have lowered our valuation slightly to DKK932m or DKK5.33 per basic share, from DKK942m or DKK5.39 per basic share, previously. This is primarily due to a lower valuation for the adult NGAL test for the ICU market (DKK663.9m from DKK691.5m previously) due the delay in initial revenue described above, and lower net cash (DKK18.1m from DKK34.1 at Q319). Our valuation for research products is also lower (DKK7.7m from DKK13.7m previously) due to low growth in this segment and the loss of the antibody supply contract.

Exhibit 1: Valuation of BioPorto

Program	Market	Probability of success	Peak revenue (\$m)	Valuation (DKKm)
The NGAL Test	ICU	50%	184.6	663.9
	ED	30%	172.9	324.1
	Post-surgery	30%	55.4	97.8
	Research	100%	2.6	4.2
	Paediatrics	100%	16.8	16.4
Other products	Research	100%	2.1	3.5
Unallocated costs				(196.0)
Total				913.9
Net cash and equivalents (YE19) (DKKm)				18.1
Total firm value (DKKm)				932.0
Total shares (m)				174.9
Value per share (DKK)				5.33
Dilutive warrants (m)				16.5
Total diluted shares (m)				191.5
Value per diluted share (DKK)				5.19

Source: BioPorto Diagnostics reports, Edison Investment Research

Exhibit 2: Financial summary

	DKK000s	2018	2019	2020e	2021e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT					
Revenue		26,016	26,622	35,518	135,181
Cost of Sales		(8,181)	(9,293)	(9,805)	(18,093)
Gross Profit		17,835	17,329	25,713	117,088
Sales		(20,935)	(39,268)	(41,601)	(48,603)
R&D		(18,676)	(24,556)	(27,941)	(31,597)
Administrative		(20,005)	(27,804)	(22,676)	(22,902)
EBITDA		(42,103)	(68,333)	(63,161)	17,329
Operating Profit (before amort. and except.)		(42,646)	(71,190)	(63,396)	17,094
Amortisation of acquired intangibles		0	0	0	0
Exceptionals		0	0	0	0
Share-based payments		865	(3,109)	(3,109)	(3,109)
Reported operating profit		(41,781)	(74,299)	(66,505)	13,985
Net Interest		164	52	91	86
Joint ventures & associates (post tax)		0	0	0	0
Exceptionals		0	0	0	0
Profit Before Tax (norm)		(42,482)	(71,138)	(63,306)	17,180
Profit Before Tax (reported)		(41,617)	(74,247)	(66,415)	14,071
Reported tax		3,569	4,605	4,119	(873)
Profit After Tax (norm)		(38,124)	(66,726)	(59,379)	16,115
Profit After Tax (reported)		(38,048)	(69,642)	(62,295)	13,199
Minority interests		0	0	0	0
Discontinued operations		0	0	0	0
Net income (normalised)		(38,124)	(66,726)	(59,379)	16,115
Net income (reported)		(38,048)	(69,642)	(62,295)	13,199
Average Number of Shares Outstanding (m)		157	170	179	188
EPS - normalised (DKK)		(0.24)	(0.39)	(0.33)	0.09
EPS - diluted normalised (DKK)		(0.24)	(0.39)	(0.33)	0.09
EPS - basic reported (DKK)		(0.24)	(0.41)	(0.35)	0.07
Dividend (DKK)		0.00	0.00	0.00	0.00
Revenue growth (%)		3.4	2.3	0.0	0.0
Gross Margin (%)		68.6	65.1	72.4	86.6
EBITDA Margin (%)		-161.8	-256.7	-177.8	12.8
Normalised Operating Margin		-163.9	-267.4	-178.5	12.6
BALANCE SHEET					
Fixed Assets		3,563	8,218	7,983	7,748
Intangible Assets		1,374	4,799	4,799	4,799
Tangible Assets		1,437	1,710	1,475	1,240
Investments & other		752	1,709	1,709	1,709
Current Assets		62,638	34,464	35,656	54,150
Stocks		3,631	4,155	3,224	5,948
Debtors		8,036	5,695	8,758	33,332
Cash & cash equivalents		46,709	18,122	17,183	8,378
Other		4,262	6,492	6,492	6,492
Current Liabilities		(9,217)	(14,858)	(75,002)	(76,953)
Creditors		(4,451)	(3,237)	(8,381)	(10,332)
Tax and social security		(141)	(2,306)	(2,306)	(2,306)
Short term borrowings		0	0	(55,000)	(55,000)
Other		(4,625)	(9,315)	(9,315)	(9,315)
Long Term Liabilities		(787)	(2,502)	(2,502)	(2,502)
Long term borrowings		0	0	0	0
Other long term liabilities		(787)	(2,502)	(2,502)	(2,502)
Net Assets		56,197	25,322	(33,865)	(17,557)
Minority interests		0	0	0	0
Shareholders' equity		56,197	25,322	(33,865)	(17,557)
CASH FLOW					
Op Cash Flow before WC and tax		(42,103)	(68,333)	(63,161)	17,329
Working capital		(631)	4,453	3,013	(25,348)
Exceptional & other		(74)	159	91	86
Tax		4,799	3,557	4,119	(873)
Net operating cash flow		(38,009)	(60,164)	(55,939)	(8,805)
Capex		(1,483)	(1,106)	0	0
Acquisitions/disposals		0	0	0	0
Net interest		0	0	0	0
Equity financing		39,319	35,983	0	0
Dividends		0	0	0	0
Other		(198)	(3,332)	0	0
Net Cash Flow		(371)	(28,619)	(55,939)	(8,805)
Opening net debt/(cash)		(47,080)	(46,709)	(18,122)	37,817
FX		0	0	0	0
Other non-cash movements		0	32	0	0
Closing net debt/(cash)		(46,709)	(18,122)	37,817	46,622

Source: BioPorto Diagnostics reports, Edison Investment Research

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