Healthcare

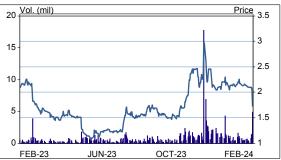
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BioPorto A/S (BIOPOR.CO) Rating: Buy

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2023 Preliminary Results Reported; Reiterate Buy

Stock Data			02/22/2024					
Price			DKK1.73					
Exchange		CSE						
Price Target			DKK5.00					
52-Week High			DKK3.85					
52-Week Low			DKK1.07					
Enterprise Valu	ıe (M)		DKK591					
Market Cap (M)		DKK657					
Shares Outstar	nding (M)		379.7					
3 Month Avg V		1,575,466						
Short Interest (M)		NA					
Balance Shee	t Metrics							
Cash (M)			DKK66.0					
Total Debt (M)			DKK0.0					
Total Cash/Sha		DKK0.17						
Book Value/Sh		DKK0.29						
EPS (DKK) Dile								
Full Year - Dec	2022A	2023E	2024E					
1Q	(0.06)	(0.05)A	, ,					
2Q	(0.05)	(0.06)A	,					
3Q	(0.05)	(0.03)A	, ,					
4Q	(0.07)	(0.03)	(0.02)					
FY (DICK	(0.24)	(0.16)	(0.10)					
Revenue (DKK Full Year - Dec) 2022A	2023E	2024E					
1Q	6.5	8.0A	8.2					
1Q 2Q	6.5 8.5	7.7A	o.∠ 8.4					
3Q	5.3	7.7A 8.6A	10.3					
3Q 4Q	5.5 8.7	6.7	13.3					
l FY	29.0	31.1	40.0					
Vol. (mil)		U 11	Price o s					



Revenue grew 7% in 2023; NGAL test for pediatric use cleared by the FDA. Yesterday, BioPorto announced its preliminary financial results for full-year 2023. Total revenue was DKK31M (USD 4.5M). representing 7% YoY growth. Adjusted EBITDA was DKK(56M). At the end of December 2023, the company had DKK66M (USD 9.8M) in cash. Importantly, the company received FDA 510(k) clearance for its NGAL test in December 2023, which would be marketed as ProNephro AKI (NGAL). ProNephro AKI (NGAL) is the first acute kidney injury (AKI) biomarker test cleared for pediatric use (aged 3 months through 21 years) in the U.S. It is designed to identify patients at risk of developing or having persistent, moderate-to-severe AKI within 48-72 hours in the intensive care unit (ICU) setting. The current standard of care, serum creatinine, is a muscle by-product and rises slowly in AKI. In comparison, NGAL is a direct real-time marker of kidney cell damage (NGAL rises within hours of kidney injury), which could detect AKI days earlier than serum creatinine and enable prompt intervention. Management expects to achieve total revenue of DKK40M in 2024, representing a growth rate of 30% and primarily driven by U.S. commercialization of ProNephro AKI (NGAL). We reiterate our Buy rating and DKK5 PT.

U.S. commercialization expected to commence in 2H24. The 510(k) clearance for ProNephro AKI (NGAL) is on the Roche cobas c 501 analyzer. BioPorto expects the U.S. sales through its distribution agreement with Roche Diagnostics (RHHBY; not rated) to begin in 2H24. ProNephro AKI (NGAL) would be added to Roche's portfolio of approved assays before commercialization. The primary target accounts include nephrologists, cardiologists, intensivists and laboratory directors at large pediatric hospitals and centers. The company plans to boost awareness of the test via KOLs and has initiated a dialogue with KDIGO to pursue the inclusion of ProNephro AKI (NGAL) into KDIGO's highly important guidelines for AKI. The company also plans to secure expansion of the instruments FDA cleared for ProNephro AKI (NGAL) use in order to enable more laboratories to implement the test. While the U.S. sales focus is driving the use of ProNephro AKI (NGAL) for testing pediatric and young adult patients at risk of AKI, use of the test in CE-market countries outside the U.S. is currently focused on adult patients and would be expanded to cover pediatric and young adult testing market as well.

Potential expansion into U.S. adult testing market. BioPorto has initiated activities to seek FDA clearance for use of the test with adult patients. The company is currently designing clinical trials for this purpose with a goal to submit a clearance application to the FDA in 2026. The estimated cost for seeking FDA clearance for adult use is USD 15-20M during the period 2024-2026. The company plans to issue new shares of USD 20M on NASDAQ Nordics in 2024 and 2025, with the first issue in 2Q24. Management aims to achieve total revenue of USD 15-25M by 2026, which may potentially make the company cash flow positive by 2026.

Valuation and risks. Our 12-month price target is derived from an estimated market value of the firm at \$280M, which includes a discounted cash flow (DCF) analysis-based asset value of \$280M for the NGAL Test and other products (ELISA kits and antibodies), using a 15% discount rate and 1% terminal growth rate. Assuming 410M shares outstanding at the end of 2024, this yields a value of approximately \$0.68 per share, or roughly DKK5 per share. Probabilities of clearance assigned are 100% for the pediatric NGAL Test and 70% for the adult NGAL Test. Risks include but are not limited to: (1) failure to obtain regulatory clearance for the NGAL Test; (2) failure of NGAL Test to achieve commercial success due to market size, penetration rate, and/or competition; and (3) dilution risk.

Table 1. BioPorto A/S (BIOPOR.CO)—Historical Income Statements, Financial Projections

FY end December 31 DKK in thousands, except per share data

		2022A			2023E							
	2021A	1QA	2QA	3QA	4QA	2022A	1QA	2QA	3QA	4QE	2023E	2024E
Revenue												
NGAL revenue	12,092	3,729	3,329	2,664	5,135	14,857	4,822	4,572	5,842	4,200	19,436	27,000
Other products and license revenue	12,162	2,773	5,177	2,607	3,555	14,112	3,219	3,176	2,767	2,500	11,662	13,000
Total revenue	24,254	6,502	8,506	5,271	8,690	28,969	8,041	7,748	8,609	6,700	31,098	40,000
Expenses												
Cost of sales	9,213	2,556	2,454	1,064	3,853	9,927	2,733	2,783	2,514	2,144	10,174	12,800
Research and development	30,258	8,021	9,826	10,662	6,429	34,938	6,048	8,802	4,666	4,800	24,316	19,200
Sales and marketing	17,381	4,044	5,090	5,135	6,950	21,219	5,910	4,508	4,655	4,700	19,773	20,000
General and administrative	32,657	10,099	11,273	8,379	12,078	41,829	10,300	9,543	7,196	7,250	34,289	29,000
Lease impairment / Restructuring costs					2,583	2,583		2,967	1,278		4,245	-
Total expenses	89,509	24,720	28,643	25,240	31,893	110,496	24,991	28,603	20,309	18,894	92,797	81,000
Gain (loss) from operations	(65,255)	(18,218)	(20,137)	(19,969)	(23,203)	(81,527)	(16,950)	(20,855)	(11,700)	(12,194)	(61,699)	(41,000)
Other income/expense												
Financial income	2,461	185	979	1,712	(1,691)	1,185	22	35	1,156		1,213	-
Financial expenses	(1,046)	(249)	(226)	(520)	(210)	(1,205)	(273)	(146)	(74)		(493)	-
Total investment income and other	1,415	(64)	753	1,192	(1,901)	(20)	(251)	(111)	1,082	-	720	-
Loss before provision for income taxes	(63,840)	(18,282)	(19,384)	(18,777)	(25,104)	(81,547)	(17,201)	(20,966)	(10,618)	(12,194)	(60,979)	(41,000)
Provision for income taxes	6,727	1,252	2,293	1,900	179	5,624	1,141	1,317	1,020	854	4,332	2,870
Net income (loss)	(57,113)	(17,030)	(17,091)	(16,877)	(24,925)	(75,923)	(16,060)	(19,649)	(9,598)	(11,340)	(56,647)	(38,130)
Net loss per share (basic)	(0.21)	(0.06)	(0.05)	(0.05)	(0.07)	(0.24)	(0.05)	(0.06)	(0.03)	(0.03)	(0.16)	(0.10)
Net loss per share (diluted)	(0.21)	(0.06)	(0.05)	(0.05)	(0.07)	(0.24)	(0.05)	(0.06)	(0.03)	(0.03)	(0.16)	(0.10)
Weighted average number of shares outstanding (basic)	267,423	268,905	334,680	334,680	334,693	318,541	334,680	339,271	379,657	379,671	358,320	398,423
Weighted average number of shares outstanding (diluted)	267,423	268,905	334,680	334,693	334,693	318,541	334,680	339,271	379,657	379,671	358,320	398,423

Source: Company reports and H.C. Wainwright & Co. estimates.

Table 2. BioPorto A/S (BIOPOR.CO)—Historical Balance Sheets, Financial Projections

FY end December 31 DKK in thousands, except per share data

		2022A				2023E						
	12/31/21A	3/31A	6/30A	9/30A	12/31A	12/31/22	3/31A	6/30A	9/30A	12/31E	12/31/23	12/31/24
Assets												
Current assets:												
Cash and equivalents	45,523	27,016	107,862	98,946	81,792	81,792	57,732	85,374	69,943	66,003	66,003	81,013
Inventories	2,718	2,222	2,225	3,202	2,558	2,558	2,374	1,755	1,342	1,342	1,342	1,342
Trade receivables	7,177	7,305	8,122	2,506	2,829	2,829	4,087	3,022	5,225	5,225	5,225	5,225
Income tax receivables	6,272	7,540	9,797	11,843	6,444	6,444	7,395	8,968	4,516	4,516	4,516	4,516
Other receivables	738	101,440	1,106	389	1,769	1,769	589	786	1,350	1,350	1,350	1,350
Prepayments	1,769	1,075	1,572	1,018	1,555	1,555	2,280	1,939	1,648	1,648	1,648	1,648
Assets held-for-sale					4,481	4,481	4,402	4,408	3,166	3,166	3,166	3,166
Total current assets	64,197	146,598	130,684	117,904	101,428	101,428	78,859	106,252	87,190	83,250	83,250	98,260
Deposits	1,739	1,759	1,855	1,920	1,933	1,933	1,811	1,884	1,927	1,927	1,927	1,927
Non-current tax receivable									5,500	5,500	5,500	5,500
Rights and software	1,049	1,021	921	844	766	766	689	612	535	535	535	535
Fixtures and fittings, tools and equipment	1,925	2,161	1,999	1,828	1,586	1,586	1,427	1,245	1,075	775	775	(425)
Right-of-use assets	12,345	11,718	11,419	11,075	2,927	2,927	2,509	2,091	1,673	1,673	1,673	1,673
Total Assets	81,255	163,257	146,878	133,571	108,640	108,640	85,295	112,084	97,900	93,660	93,660	107,470
Liabilities and shareholder equity												
Current liabilities												
Current portion of non-current liabilities	2,975	3,070	3,233	3,255	3,197	3,197	3,171	3,320	3,438	3,438	3,438	3,438
Trade payables	4,260	7,233	6,008	3,978	10,457	10,457	5,256	5,742	2,480	2,480	2,480	2,480
Tax payables	84	86		97	80	80	78	78	80	80	80	80
Other payables	17,471	19,241	20,327	26,004	17,237	17,237	15,011	16,253	16,248	16,248	16,248	16,248
Total current liabilities	24,790	29,630	29,568	33,334	30,971	30,971	23,516	25,393	22,246	22,246	22,246	22,246
Lease obligation	10,200	9,583	9,256	9,020	7,448	7,448	6,566	5,635	4,889	4,889	4,889	4,889
Other non-current liabilities	301	137	137	137		-				-	-	-
Total Liabilities	35,291	39,350	38,961	42,491	38,419	38,419	30,082	31,028	27,135	27,135	27,135	27,135
Shareholder's equity												
Share capital	267,754	334,693	334,693	334,693	334,693	334,693	334,693	379,670	379,670	379,670	379,670	427,610
Treasury shares	-					-				-	-	-
Exchange-rate adjustments	(119)	(169)	(878)	(2,299)	(234)	(234)	(247)	(122)	(834)	(834)	(834)	(834)
Retained earnings	(221,671)	(210,617)	(225,898)	(241,314)	(264,238)	(264,238)	(279,233)	(298,492)	(308,071)	(312,311)	(312,311)	(346,441)
Total shareholder's equity	45,964	123,907	107,917	91,080	70,221	70,221	55,213	81,056	70,765	66,525	66,525	80,335
Total liability and shareholder's equity	81,255	163,257	146,878	133,571	108,640	108,640	85,295	112,084	97,900	93,660	93,660	107,470

Source: Company reports and H.C. Wainwright estimates.

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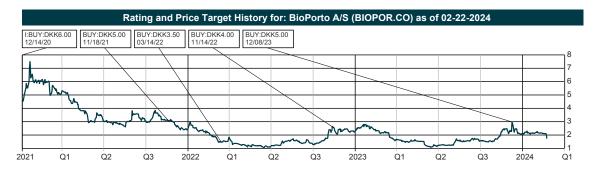
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Distribution of Ratings Table as of February 22, 2024									
			IB Se	IB Service/Past 12 Months					
Ratings	Count	Percent	Count	Percent					
Buy	557	88.13%	144	25.85%					
Neutral	63	9.97%	5	7.94%					
Sell	2	0.32%	0	0.00%					
Under Review	10	1.58%	5	50.00%					

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