EDISON

BioPorto Diagnostics

Earnings update

COVID-19 test to enter the clinic

Healthcare equipment & services

With its Q320 earnings, BioPorto announced that its COVID-19 antigen test it has under development would be entering the clinic. The gathering of samples is expected to start imminently and to be complete by the end of December 2020. The company believes that this timeline supports the potential commercialisation of the product in early 2021, if the results of the study are compelling.

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	(70.4)	(0.31)	0.0	N/A	N/A
12/21e	82.5	(31.2)	(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.

Sample collection to start imminently at UC Davis

BioPorto is currently developing an antigen-based rapid assay for COVID-19 using antibodies developed in collaboration with the University of Southern Denmark in combination with the company's generic Rapid Assay Device (gRAD) platform. The site of the new study will the University of California, Davis, where patient sample collection is expected to begin before the end of November 2020. Based on guidance provided by the FDA, the study will include a target of 150 patient samples, of which at least 30 will need to be COVID-19 positive.

NGAL RUO growth steady

The company reported Q320 revenue of DKK4.7m, of which DKK2.7m is attributable to research use only (RUO) sales of the NGAL Test, including DKK1.8m from US NGAL sales. RUO sales are down sequentially, primarily due to the uncommonly large RUO sales in Q220 (DKK5.0m), but the NGAL Test continues its upward trajectory, up 18% year-on-year in Q320 and 58% year-to-date (DKK9.8m).

Slight delay to PAEDIATRIC NGAL

BioPorto also provided an update on its ongoing NGAL development efforts and noted that its ongoing pivotal NGAL study for paediatric acute kidney injury (AKI) is progressing steadily, albeit with some delays due to the pandemic. The second wave of infections is affecting enrolment at the children's hospitals where the study is taking place, and the company has delayed the expected submission of the marketing application for the product until Q121 (from H220).

Valuation: Increased to DKK939m

We have increased our valuation to DKK939m from DKK896m, but it is lower per share, DKK3.52 from DKK4.48. This is on account of the company's DKK93.6m (net) rights offering completed in October (66.6m new shares). We have also adjusted our clinical timelines to account for the COVID-19 delay, which reduced our valuation for the NGAL Test in the ICU to DKK618.5m from DKK671.9m.

19 November 2020

Price	**DKK3.05**
Market cap	**DKK813m**
	DKK6.63/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	(10.3)	39.7	13.3
Rel (local)	(8.3)	31.3	(9.5)
52-week high/low	DKK4.23		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 submission	Q121
Adult NGAL submission	2021

Analyst

Nathaniel Calloway +1 646 653 7036

healthcare@edisongroup.com

Edison profile page

BioPorto Diagnostics is a research client of Edison Investment Research Limited

COVID-19 test in the clinic

On 18 November 2020 BioPorto announced that it is initiating a new clinical program for its COVID-19 rapid diagnostic test. The protocol for the study is based on FDA guidance on the development of tests to detect the SARS-CoV-2 virus and will have a target enrolment of 150 individuals, of whom at least 30 will need to be infected with the virus. The study should be very quick given that it only requires the collection of samples from patients presenting at the hospital. The study is expected to begin by the end of November and to be completed by the end of 2020.

On the company's conference call, management stated that once the results from the study are in, it believes that it can analyse the findings and submit an application for emergency use authorization (EUA) as early as Q121. The review times for EUA applications vary but can be as short as days or weeks. The company has some manufacturing capacity for the test in house, so some small-scale commercialisation could begin immediately afterwards. At the moment, the company is looking at targeting smaller markets initially, where current testing capacity is inadequate. This includes settings where rapid diagnosis is necessary but immediate access to the infrastructure for rapid nucleotide amplification tests (NATs) is not available, such as field triage or surveillance. We expect the company to provide more information regarding its commercial plan for the test if the current study is successful.

The marketability of the test will largely depend on the statistical performance in the upcoming clinical study. The product will not necessarily need to outperform NATs such as the RT-PCR testing, which has become the standard of care for routine screening. However, there are two antigen-based, point-of-care tests that have already received an EUA and multiple other products in development that are targeting a similar niche. For our purposes we are only including visually read (as opposed to instrument read) tests, similar to the gRAD platform. A selection of products with strong performance are presented in Exhibit 1.

Exhibit 1: Selection of rapid point-of-care COVID-19 tests

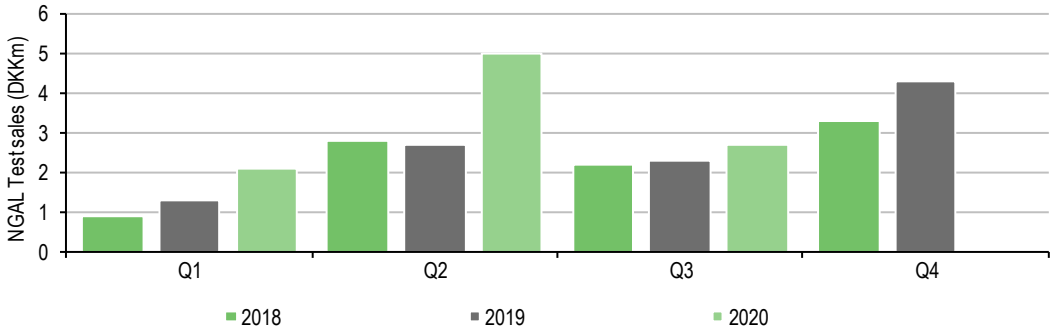
Test	Company	EUA?	Sensitivity	Specificity
BinaxNOW	Abbott	Yes	97.1%	98.5%
CareStart	Access Bio	Yes	88.4%	100.0%
Panbio	Abbott	No	91.4%	99.8%
Respi-Strip	Coris BioConcept	No	91.2%	99.4%
Rapid COVID-19 test	Healgen	No	96.7%	99.2%

Source: Company websites, FDA

Commercial and clinical update

We continue to closely track the trajectory of the RUO sales of the NGAL Test in order to gauge the interest in the technology. Sales of the NGAL product continue to grow on a year-on-year basis (Exhibit 2) to DKK2.7m (18% growth year-on-year), albeit are down from the exceptionally high Q220 sales (DKK5.0m). RUO sales for the product in the US were DKK1.8m, which is flat from Q319. Total companywide revenue was down year-on-year (DKK4.7m in Q320 vs DKK6.6m for Q319), but this attributable to the company's decision in 2019 to wind down some of its non-proprietary products in favour of internal development and the NGAL Test. The company maintained its guidance of DKK30m sales for 2020 (and a DKK73m operating loss), which implies DKK14m in sales in Q420. We remain more conservative in our estimates and forecast DKK23m in total sales in 2020 (down from DKK26m previously).

Exhibit 2: The NGAL Test, research use only sales



Source: BioPorto reports.

The company also provided an update on its ongoing pivotal study of the NGAL Test for paediatric AKI. The study is currently ongoing at children's hospitals in the US. However, the recent increase in COVID-19 cases in the US has slowed the pace of enrolment, resulting in a delay in the completion of the study from H220 to Q121. BioPorto expects to complete the data analysis and submit a De Novo application to the FDA in Q121. The company is waiting on this submission and the response from the FDA to initiate its clinical program for adult AKI, so this delay may have impacts on that program as well, albeit a small delay.

Finally, the company announced that it is moving forward with plans to commercialise its dipstick NGAL test (NGALds), essentially an application of NGAL to the gRAD platform. The goal of this product is to similarly provide a rapid, point of care solution for the testing for kidney damage, a testing paradigm that currently does not exist. The company noted that it plans to self-declare a CE mark by the end of 2020 for the product and begin commercialisation 'in select countries through established distribution channels.' We can envision this product being used in a range of scenarios, such as in regions underserved by hospitals, where testing for AKI typically occurs. We will be excited to learn more about the product and more detail of the commercial plans in the future.

Valuation

We have increased our valuation to DKK939m from DKK896m, although it is lower on a per share basis: DKK3.52 from DKK4.48. This is a result primarily of the rights offering that was concluded in October 2020, with net proceeds of DK93.6m (66.6m new shares). Additionally, we have rolled forward our NPV, and these effects are offset by adjustments to our timelines to account for the delay in the submission of the paediatric NGAL test. This reduced our valuation for the NGAL test in the ICU setting to DKK618.5m from DKK671.9m.

We currently do not include the COVID-19 rapid test in our valuation. Given the uncertainties regarding this market we are not valuing any diagnostic product without first seeing its performance statistics. We expect to make this determination shortly after the release of such details following the completion of the ongoing clinical study.

Exhibit 3: Valuation of BioPorto

Program	Market	Prob. of success	Peak revenue ($m)	Valuation (DKKm)
The NGAL Test	ICU	50%	176.6	618.5
	ED	30%	167.1	304.3
	Post-surgery	30%	54.1	87.3
	Research	100%	4.1	7.1
	Paediatrics	50%	15.4	11.2
Other products	Research	100%	1.2	1.1
Unallocated costs				(208.8)
Total				820.7
Net cash and equivalents (Q320 + offering) (DKKm) excluding lease obligations				118.1
Total firm value (DKKm)				938.8
Total shares (m)				266.6
Value per share (DKK)				3.52
Dilutive warrants (m)				6.5
Total diluted shares (m)				273.1
Value per diluted share (DKK)				3.52

Source: BioPorto reports, Edison Investment Research

Financials

As we mentioned above the company completed a rights offering of 66.6m new shares for DKK93.6m net proceeds in October. Based on our forecasts, this should remove the financial overhang for the company as it should be sufficient in our view to finance the company into 2022 (although company guidance is that the firm is funded until Q421), when we predict that the company should begin profitability. We previously included DKK20m in illustrative debt to cover the overhang. Other changes to the financial forecasts include lower revenue for 2021 (DKK82.5m from DKK102.3) primarily on account of the clinical delays. There is still a high degree of uncertainty regarding the timing for the submission of the adult NGAL test, which has an oversized impact on revenue estimates. We are currently forecasting a marketing application in mid-2021 and approval in H221, but we may further adjust this depending on the timing of any of the intervening events. We note that the company has not provided guidance for this submission timing aside from the year '2021'. Other changes to our forecasts include some rebalancing of costs between SG&A and R&D with little net impact.

Exhibit 4: Financial summary

DKK'k	2018	2019	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Revenue	26,016	26,622	23,477	82,515
Cost of Sales	(8,181)	(9,293)	(10,195)	(13,946)
Gross Profit	17,835	17,329	13,282	68,570
Sales costs	(20,935)	(39,268)	(25,527)	(43,256)
R&D	(18,676)	(24,556)	(34,147)	(34,629)
Administrative	(20,005)	(27,804)	(26,437)	(26,701)
EBITDA	(42,103)	(68,333)	(63,914)	(30,005)
Operating Profit (before amort. and except.)	(42,646)	(71,190)	(68,493)	(31,682)
Amortisation of acquired intangibles	0	0	0	0
Exceptionals	0	0	0	0
Share-based payments	865	(3,109)	(4,335)	(4,335)
Reported operating profit	(41,781)	(74,299)	(72,828)	(36,017)
Net Interest	164	52	(1,925)	506
Joint ventures & associates (post tax)	0	0	0	0
Exceptionals	0	0	0	0
Profit Before Tax (norm)	(42,482)	(71,138)	(70,418)	(31,176)
Profit Before Tax (reported)	(41,617)	(74,247)	(74,753)	(35,511)
Reported tax	3,569	4,605	4,636	2,202
Profit After Tax (norm)	(38,124)	(66,726)	(66,051)	(29,242)
Profit After Tax (reported)	(38,048)	(69,642)	(70,117)	(33,308)
Minority interests	0	0	0	0
Discontinued operations	0	0	0	0
Net income (normalised)	(38,124)	(66,726)	(66,051)	(29,242)
Net income (reported)	(38,048)	(69,642)	(70,117)	(33,308)
Average Number of Shares Outstanding (m)	157	170	210	277
EPS - normalised (DKK)	(0.24)	(0.39)	(0.31)	(0.11)
EPS - diluted normalised (DKK)	(0.24)	(0.39)	(0.31)	(0.11)
EPS - basic reported (DKK)	(0.24)	(0.41)	(0.33)	(0.12)
Dividend (DKK)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	3,563	8,218	14,985	14,353
Intangible Assets	1,374	4,799	11,995	11,363
Tangible Assets	1,437	1,710	1,302	1,302
Investments & other	752	1,709	1,688	1,688
Current Assets	62,638	34,464	114,920	93,432
Stocks	3,631	4,155	3,352	4,585
Debtors	8,036	5,695	2,894	10,173
Cash & cash equivalents	46,709	18,122	101,296	71,297
Other	4,262	6,492	7,377	7,377
Current Liabilities	(9,217)	(14,858)	(29,002)	(35,856)
Creditors	(4,451)	(3,237)	(2,394)	(9,248)
Tax and social security	(141)	(2,306)	(3,348)	(3,348)
Short term borrowings	0	0	0	0
Other	(4,625)	(9,315)	(23,260)	(23,260)
Long Term Liabilities	(787)	(2,502)	(10,275)	(10,275)
Long term borrowings	0	0	0	0
Other long term liabilities	(787)	(2,502)	(10,275)	(10,275)
Net Assets	56,197	25,322	90,627	61,654
Minority interests	0	0	0	0
Shareholders' equity	56,197	25,322	90,627	61,654
CASH FLOW				
Op Cash Flow before WC and tax	(42,103)	(68,333)	(63,914)	(30,005)
Working capital	(631)	4,453	15,804	(1,658)
Exceptional & other	(74)	159	113	506
Tax	4,799	3,557	5,249	2,202
Net operating cash flow	(38,009)	(60,164)	(42,748)	(28,953)
Capex	(1,483)	(1,106)	(1,071)	(1,046)
Acquisitions/disposals	0	0	0	0
Net interest	0	0	0	0
Equity financing	39,319	35,983	129,894	0
Dividends	0	0	0	0
Other	(198)	(3,332)	(2,861)	0
Net Cash Flow	(371)	(28,619)	83,214	(29,999)
Opening net debt/(cash)	(47,080)	(46,709)	(18,122)	(101,353)
FX	0	0	0	0
Other non-cash movements	0	32	17	0
Closing net debt/(cash)	(46,709)	(18,122)	(101,353)	(71,354)

Source: BioPorto accounts, 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 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.

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 Holbom
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