EDISON

BioPorto Diagnostics

Clinical update

Retrospective paediatric AKI study initiated

Pharma & biotech

BioPorto announced that it would be initiating a pilot study for the detection of paediatric acute kidney injury (AKI). The study will be a retrospective analysis of urine collected from paediatric ICU patients in an earlier study. We expect the results from this analysis to potentially support an additional 510(k) application for this population if The NGAL Test is approved for adults. The results are expected in H119.

Year end	Revenue (DKKm)	PBT* (DKKm)	EPS* (DKK)	DPS (DKK)	P/E (x)	Yield (%)
12/16	20.7	(22.4)	(1.57)	0.0	N/A	N/A
12/17	25.2	(33.7)	(2.03)	0.0	N/A	N/A
12/18e	29.6	(37.2)	(2.09)	0.0	N/A	N/A
12/19e	52.7	(28.1)	(1.50)	0.0	N/A	N/A

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

Low-cost pathway to adding indications

The study will examine the urine from paediatric patients who were previously enrolled in a study in 2014. Urine will be used in this case (as opposed to serum in the pivotal adult AKI study) as children have much lower rates of urinary tract infection, which can interfere with test results. The samples have already been tested using the company's NGAL ELISA test as part of the previous study (but not the turbidimetric NGAL test under current investigation), so the company has a high degree of insight into the results. Given the samples are in hand, we expect the total cost to be very low, at less than DKK4m.

Study could be pivotal after adult approval

In most situations, the retrospective nature of the study would limit its capacity to serve as a pivotal study. However, we believe this study could potentially support paediatric approval if The NGAL test is first approved for adults. We expect the FDA to be amenable, given the limited capacity to perform clinical studies in this small population and the agency's mandate to address paediatric indications.

Paediatric AKI population small, but important

The addressable market for this new indication is significantly smaller than for the adult indication. There are many fewer admissions of paediatrics to the ICU than adults, with only 4,000 beds in the US. We estimate approximately 240,000 patients per year. However, there is a significant need: 26.9% of paediatric ICU patients have AKI, 11.6% with severe AKI, the latter of which have a 77% increased risk of death.

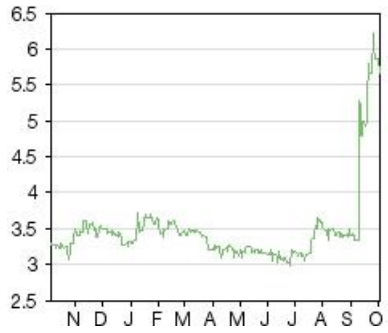
Valuation: Increased to DKK1,105m or DKK7.10/share

We have increased our valuation to DKK1,105m or DKK7.10 per basic share from DKK1,078m or DKK6.93 per basic share. We have added the paediatric ICU indication as a testing market with a valuation of DKK27.0m. We have also added the cost of the study to our model, but this does not affect our financing schedule (DKK60m in 2018).

3 October 2018

Price	**DKK5.66**
Market cap	**DKK880m**
	DKK6.38/US$
Net cash (DKKm) at 31 June 2018	22.5
Shares in issue	155.5m
Free float	83.8
Code	BIOPOR
Primary exchange	NASDAQ Copenhagen
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	65.5	79.4	74.7
Rel (local)	71.8	75.3	81.7
52-week high/low	DKK6.2	DKK3.0	

Business description

BioPorto is a diagnostic company focused on the development and marketing of antibodies and other products for research and diagnostics. This includes a portfolio of products marketed for research use and The NGAL Test, which the company has submitted to the FDA for the prediction of acute kidney injury.

Next events

FDA decision on NGAL Test	H218
Launch of NGAL Test in US	Late 2018
Paediatric AKI results	H119

Analysts

Nathaniel Calloway	+1 646 653 7036
Maxim Jacobs	+1 646 653 7027

healthcare@edisongroup.com

Edison profile page

BioPorto Diagnostics is a research client of Edison Investment Research Limited

A retrospective study for a paediatric AKI application

BioPorto announced that it would be performing a study of patient samples to support an application to the FDA for the risk use with AKI in paediatric patients (ie to assist a doctor in predicting AKI risk). The company will specifically be examining a set of patient samples that were collected in paediatric ICU patients in 2014 and comparing responses from The NGAL Test to medical records. These samples were previously interrogated with the company's ELISA NGAL test, so the content of the data set is already understood.

There are several differences between this planned paediatric study and the studies in adult AKI that the company has previously performed. First, and most significantly, the study will be retrospective in nature. This methodology carries a number of considerations. For example, retrospective studies have a lower degree of statistical rigour because their design introduces more bias than prospective studies. For this reason, most regulatory bodies require prospective clinical studies to support approval for diagnostics. However, we believe that the FDA and other regulators will likely be more amenable to a retrospective study in this case. To begin with, there are practical concerns around performing a prospective trial on paediatric AKI in the ICU. The number of clinical sites required and associated expense would be prohibitive. This is not uncommon for paediatric indications and the agency has a mandate to facilitate reasonable accommodation in this area. By comparison, we expect this retrospective study to be low cost (estimated at less than US$1m). Additionally, given the timing of this study, the results should be available after the approval of The NGAL Test in adults. It would be more difficult to convince the FDA to approve without a supporting prospective clinical study in adults.

Another practical differentiator between this study and the pivotal adult trial is that it will use urine NGAL, whereas the adult study used serum NGAL. There are a number of different considerations regarding when it is best to use urine or serum. Urine NGAL provides a more direct readout of kidney function, but urinary tract infections (UTIs) frequently give false positives. The pivotal adult study used serum NGAL precisely to avoid this confounding factor, given how common UTIs are in adults, particularly women. UTIs are much less common in children, which enables the use of urine in this population with less concern and less invasiveness. Because the product will use urine instead of serum, the company will need to file a new 510(k) application for the product following completion of the study.

The paediatric AKI testing market

As with other estimates of AKI prevalence, there has been significant variability in the rates of AKI in paediatric ICU populations. One of the most recent and comprehensive studies published in the *New England Journal of Medicine* found that 26.9% of patients admitted to 32 different paediatric ICUs had AKI.[1] 11.6% of these patients had severe AKI, which was associated with a 77% increase in the risk of death, underlying the need for effective detection and intervention in this setting. However, the rate of AKI in children associated with hospital stays is small given the lower underlying rate of paediatric ICU admissions. Only an estimated 5% of ICU beds in the US are dedicated to paediatrics, or around 4,000 in total.[2] We estimate approximately 240,000 admissions per year, based on reported occupancy of 59 patients per bed per year.[3]

[1] Kaddourah A, et al. (2017) Epidemiology of Acute Kidney Injury in Critically Ill Children and Young Adults. *New Eng J Med* 376, 11-20.

[2] Society of Critical Care Medicine.

[3] Folafoluwa o, et al. (2005) A National Survey of Pediatric Critical Care Resources in the United States. *Pediatrics* 115, e382.

Because of these factors, we believe that revenue from the paediatric market will be incremental compared to the much larger adult markets. However, given the low cost of pursuing this approval, we believe the development is justified on its own. However, there are additional factors apart from revenue from paediatrics that we consider valuable. Approval in paediatrics will allow a unified treatment algorithm where all ICU admissions are treated similarly. We believe this has the potential to aid adoption. Moreover, there is significant value in the goodwill in treating this population. Finally, there is the potential for an approval in paediatrics to translate into a future approval for neonates. Neonates are hospitalized at significantly higher rates, accounting for 73% of all hospital admissions in patients under 18,[4] and approximately 20,000 ICU beds.[2] There is increasing awareness of AKI in this population and the associated risks: rates of AKI in very low birth weight infants have been measured as high as 40%.[5]

Valuation

We have increased our valuation to DKK1,105m or DKK7.10 per basic share from DKK1,078m or DKK6.93 per basic share. This increase is associated with the addition of the paediatric ICU detection market. Our models are similar to the adult ICU market, adjusted for the lower underlying admission rate. We model approval for this indication in 2019 and first sales in 2020. Our probability of success is 45% as we see approval in the adult population first as the biggest hurdle (50% probability of success) with a 90% chance of success if that indication receives approval. Otherwise, our valuation remains unchanged.

Exhibit 1: Valuation of BioPorto

Program	Market	Prob. of success	Peak Revenue ($m)	Valuation (DKKm)
The NGAL Test	ICU	50%	188.1	732.6
	ED	30%	179.0	341.0
	Post-surgery	30%	57.3	101.6
	Research	100%	2.6	21.8
	Paediatrics	45%	15.0	27.0
Other products	Research	100%	3.9	33.1
Unallocated costs				(174.8)
Total				1,082.3
Net cash and equivalents (Q218) (DKKm)				22.5
Total firm value (DKKm)				1,104.8
Total shares (m)				155.51
Value per share (DKK)				7.10
Dilutive warrants (m)				11.6
Total diluted shares				167.1
Value per diluted share (DKK)				6.84

Source: BioPorto reports, Edison Investment Research

Financials

We had added the clinical cost associated with the paediatric study, which we estimate at only DKK3.8m. Otherwise our model remains unchanged. We do not expect this expense to contribute significantly to the company's funding requirement, which we currently record as DKK60m in illustrative debt in 2018.

[4] Healthcare Cost and Utilization Project.

[5] Carmody JBet al. (2014) Recognition and reporting of AKI in very low birth weight infants. *Clin J Am Soc Nephrol* 9, 2036–2043

Exhibit 2: Financial summary

DKK000s	2016	2017	2018e	2019e
31-December	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Revenue	20,720	25,155	29,561	52,707
Cost of Sales	(5,027)	(6,907)	(8,095)	(11,295)
Gross Profit	15,693	18,248	21,466	41,412
Sales	(18,041)	(18,545)	(19,033)	(21,409)
R&D	(9,669)	(21,930)	(27,533)	(35,479)
Administrative	(13,030)	(14,267)	(15,923)	(16,719)
EBITDA	(22,596)	(33,134)	(37,632)	(28,803)
Normalised operating profit	(22,596)	(33,134)	(37,632)	(28,803)
Amortisation of acquired intangibles	(182)	(329)	(329)	(329)
Exceptionals	0	0	0	0
Share-based payments	(2,061)	(2,856)	(2,856)	(2,856)
Reported operating profit	(24,839)	(36,319)	(40,817)	(31,988)
Net Interest	148	(570)	462	711
Joint ventures & associates (post tax)	0	0	0	0
Exceptionals	0	0	0	0
Profit Before Tax (norm)	(22,448)	(33,704)	(37,170)	(28,092)
Profit Before Tax (reported)	(24,691)	(36,889)	(40,355)	(31,277)
Reported tax	2,099	4,821	4,160	3,229
Profit After Tax (norm)	(20,538)	(29,297)	(33,336)	(25,190)
Profit After Tax (reported)	(22,592)	(32,068)	(36,195)	(28,048)
Minority interests	0	0	0	0
Discontinued operations	0	0	0	0
Net income (normalised)	(20,538)	(29,297)	(33,336)	(25,190)
Net income (reported)	(22,592)	(32,068)	(36,195)	(28,048)
Basic average number of shares outstanding (m)	131	145	160	168
EPS - basic normalised (ore)	(157)	(203)	(209)	(150)
EPS - diluted normalised (ore)	(157)	(203)	(209)	(150)
EBITDA Margin (%)	-109.1	-131.7	-127.3	-54.6
Normalised Operating Margin	-109.1	-131.7	-127.3	-54.6
BALANCE SHEET				
Fixed Assets	3,069	2,623	3,158	2,622
Intangible Assets	1,959	1,629	1,223	894
Tangible Assets	400	263	1,204	997
Investments & other	710	731	731	731
Current Assets	47,572	62,981	90,103	66,417
Stocks	3,941	3,434	2,661	3,713
Debtors	4,662	6,380	7,289	12,996
Cash & cash equivalents	35,641	47,080	72,412	41,966
Other	3,328	6,087	7,741	7,741
Current Liabilities	(5,146)	(8,653)	(9,751)	(10,927)
Creditors	(1,169)	(3,412)	(5,523)	(6,699)
Tax and social security	(242)	(182)	0	0
Short term borrowings	0	0	0	0
Other	(3,735)	(5,059)	(4,228)	(4,228)
Long Term Liabilities	(1,204)	(883)	(61,040)	(61,040)
Long term borrowings	0	0	(60,000)	(60,000)
Other long term liabilities	(1,204)	(883)	(1,040)	(1,040)
Net Assets	44,291	56,068	22,470	(2,929)
Minority interests	0	0	0	0
Shareholders' equity	44,291	56,068	22,470	(2,929)
CASH FLOW				
Op Cash Flow before WC and tax	(22,596)	(33,134)	(37,632)	(28,803)
Working capital	839	2,325	918	(5,582)
Exceptional & other	(239)	(595)	462	711
Tax	2,336	2,005	2,888	3,229
Net operating cash flow	(19,660)	(29,399)	(33,363)	(30,445)
Capex	(357)	(38)	(1,148)	0
Acquisitions/disposals	0	0	0	0
Net interest	0	0	0	0
Equity financing	20,858	40,921	0	0
Dividends	0	0	0	0
Other	(67)	(45)	(157)	0
Net Cash Flow	774	11,439	(34,668)	(30,445)
Opening net debt/(cash)	(34,867)	(35,641)	(47,080)	(12,412)
FX	0	0	0	0
Other non-cash movements	0	0	0	0
Closing net debt/(cash)	(35,641)	(47,080)	(12,412)	18,034

Source: BioPorto reports, Edison Investment Research

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. Edison is authorised and regulated by the Financial Conduct Authority. Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Pty Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

DISCLAIMER

Copyright 2018 Edison Investment Research Limited. All rights reserved. This report has been commissioned by BioPorto Diagnostics and prepared and issued by Edison for publication globally. 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. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Investment Research Pty Ltd (Corporate Authorised Representative (1252501) of Myonlineadvisers Pty Ltd (AFSL: 427484)) and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US 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. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and 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 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. This document is provided 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. Edison has a restrictive policy relating to personal dealing. 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. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. 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. 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 (ie 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. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2018. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.

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
295 Madison Avenue, 18th Floor
10017, New York
US

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