

# Ardelyx

**Pharma & biotech**
**19 November 2014**

## Gut reaction is positive

Phase IIb data in constipation-IBS for phosphate-sodium absorption inhibitor tenapanor was positive at the highest dose and a decision to proceed to Phase III is expected by year end. Further data will be presented at the Digestive Disease Week meeting in May 2015. Data from Phase II trials in other key indications, which would significantly expand the market opportunity for tenapanor, are expected in Q115 (ESRD) and H215 (CKD) and could provide positive momentum. A replacement for CSO Dominique Charnot, who steps down at year end, is also awaited.

## Tenapanor in IBS encouraging, further data in 2015

Ardelyx's platform designs and rapidly screens first-in-class, non-systemically absorbed small molecule therapeutics for diseases that involve specific gastrointestinal receptors. Tenapanor is the lead candidate in the NHE3 (a sodium transporter) inhibitor programme, which was licensed worldwide to AZN in 2012. Last month saw positive Phase IIb data in constipation-predominant irritable bowel syndrome (IBS-C) at the 50mg dose (5-20mg doses missed the primary endpoint) and Ardelyx is meeting with partner AZN to decide the next steps. Tenapanor's lead indication is the treatment of hyperphosphatemia in end-stage renal disease (ESRD), where it is in Phase IIb trials (data Q115). It is also being studied in chronic kidney disease (CKD) in type 2 diabetes (Phase IIa data H215).

## GI receptor mining could prove to be a rich seam

Tenapanor potentially has the advantages of lower pill burden, lower side effects and improved compliance compared to phosphate binders currently used in hyperphosphataemia. Around 700,000 ESRD patients on dialysis take phosphate binders in the US, Europe and Japan, and Ardelyx estimates the market could reach \$2.3bn by 2015. There are larger numbers of diabetic patients with late-stage CKD (1.8m patients in US, 2.3m Europe/Japan), though phosphate binders are not approved for CKD in the US.

## Valuation: Unlocking further value in 2015

Ardelyx's EV is c \$282m, including cash of \$112m as of end-September. The stock has risen c 50% from its \$14 IPO price in June 2014, mainly driven by positive IBS-C data for tenapanor. As part of the \$870m deal with AZN, Ardelyx could earn a further \$70m in development milestones in 2015 for tenapanor, on top of the \$75m received to date. The deal also potentially gives Ardelyx high single-digit to high-teens royalties on sales and the right to co-promote in the US.

### Consensus forecasts

Year end	Revenue (\$m)	PBT (\$m)	EPS (\$)	DPS (\$)	P/E (x)	Yield (%)
12/12	5.4	(9.8)	(11.32)	0.0	N/A	N/A
12/13	28.9	(6.4)	(5.82)	0.0	N/A	N/A
12/14e	34.9	1.3	0.10	0.0	213.0	N/A
12/15e	74.2	22.4	1.61	0.0	13.2	N/A

Source: Company reports, Bloomberg

**Price \$21.3**
**Market cap \$394m**

### Share price graph



### Share details

Code	ARDX
Listing	NASDAQ
Shares in issue	18.5m

### Business description

Ardelyx, founded in 2007 and based in Fremont CA, is a clinical-stage biopharmaceutical company focused on the discovery and development of minimally-systemic, small molecule drugs that work exclusively in the gastrointestinal (GI) tract to treat cardio-renal, GI and metabolic diseases. It has collaborations with AstraZeneca (tenapanor in Phase II in three indications) and Sanofi (in preclinical).

### Bull

- Two partnered programmes validate the ability of ARDX's technology to generate GI drugs.
- Hyperphosphataemia treatment market offers a significant opportunity to drugs with improved side-effect and compliance profiles.
- Q314 cash of \$112m covers current operating burn for c five years.

### Bear

- AZN may decide not to continue developing specific indications of tenapanor; a decision on IBS-C is expected by end 2014.
- Over-dependence on AZN and Sanofi until own pipeline matures or additional partners acquired.
- Tenapanor will face competition in ESRD and CKD treatment, including that from existing phosphate binders (generic sevelamer launched April 2014) and those in development (eg Keryx's Zerenex).

### Analysts

Dr Charlotte Hetzel	+44 (0)20 3077 5700
Dr Philippa Gardner	+44 (0)20 3681 2521
Dr Mick Cooper	+44 (0)20 3077 5734

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

**EDISON QUICKVIEWS ARE NORMALLY ONE OFF PUBLICATIONS WITH NO COMMITMENT TO WRITING ANY FOLLOW UP. QUICKVIEW NOTES USE CONSENSUS EARNINGS ESTIMATES.**

Edison, the investment intelligence firm, is the future of investor interaction with corporates. Our team of over 100 analysts and investment professionals work with leading companies, fund managers and investment banks worldwide to support their capital markets activity. We provide services to more than 400 retained corporate and investor clients from our offices in London, New York, Frankfurt, Sydney and Wellington. Edison is authorised and regulated by the Financial Conduct Authority ([www.fsa.gov.uk/register/firmBasicDetails.do?sid=181584](http://www.fsa.gov.uk/register/firmBasicDetails.do?sid=181584)). 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 Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. [www.edisongroup.com](http://www.edisongroup.com)

#### DISCLAIMER

Copyright 2014 Edison Investment Research Limited. All rights reserved. This report has been 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 Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. 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") (c) FTSE [2013]. "FTSE(i)" 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.