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Ardelyx Inc. (ARDX - OUTPERFORM): Tenapanor Meets Primary Endpoint in IBS-C, Data Compare Favorably with Linzess, Reiterate OUTPERFORM

Price: $16.86 **12-Month Price Target: $31**

- **Tenapanor (at a dose of 50 mg BID) met its primary endpoint of an increase in the complete spontaneous bowel movement (CSBM) responder rate in its Phase IIb trial in patients with constipation-predominant irritable bowel syndrome (IBS-C).** At the 50 mg dose, it also demonstrated a statistically significant improvement in a combined endpoint of CSBM response and a reduction in abdominal pain. The double-blind, placebo-controlled study enrolled 371 patients who were administered placebo or 5, 20 or 50mg doses of tenapanor twice-daily for 12 weeks. The high-dose of tenapanor met the primary endpoint of overall CSBM responder rate in 60.7% of patients vs. 33.7% of placebo patients ($p<0.001$) in the ITT population. The overall responder rate, defined as a patient who was an overall CSBM responder and who experienced at least a 30% decrease in abdominal pain from baseline in the same week for 6 of the 12 weeks, was achieved in 50% of patients receiving tenapanor vs. 23.6% receiving placebo ($p<0.001$). Tenapanor also significantly improved patient-satisfaction scores and other secondary endpoints related to abdominal and IBS-C symptoms.

- **The results appear competitive with the leading approved IBS-C therapy, Linzess.** In its two Phase III trials, Linzess demonstrated a CSBM responder rate of 48.6% and 47.6% (vs. 29.6% and 22.6% for placebo) and an overall responder rate of 33.6% and 33.7% (vs. 21.0% and 13.9% for placebo). We note the similarities in endpoints, with both the tenapanor and Linzess studies defining a CSBM responder as a patient having an increase (from baseline) of one or more CSBM during 6 of 12 weeks of study and an abdominal pain responder defined as having at least a 30% reduction in abdominal pain scores from baseline. Although the top-line results with tenapanor are numerically better than what Linzess has demonstrated, we note that the Linzess studies were larger, with over 400 patients in the Linzess arm in each study. The Phase IIb study for Linzess, although it had a similar patient size as the Phase IIb study for tenapanor, used CSBM frequency as its endpoint and is therefore not directly comparable from an efficacy standpoint. Looking at safety, we note the overall discontinuation rate for the 50mg dose was 4.5%, similar to the 3.3% rate for placebo (or about one additional drop-out for the tenapanor dose, assuming ~ 90 patients in each arm). The most common AE with 50mg tenapanor was diarrhea, observed in 11.2% of patients vs. 0% for placebo patients. In comparison, Linzess caused diarrhea in 11-18% of patients (vs. 1% for placebo) in its Phase IIb study and 20% of patients (vs. 3%) in its two Phase III trials. Discontinuation rates for Linzess in its Phase III trial were also higher, at 8-9%, and 27-29% of patients dose-reduced or suspended dosing.

- **We expect ARDX and partner AstraZeneca to advance 50mg BID tenapanor into a Phase III trial in 2015.** The study could also evaluate higher doses of tenapanor for increased efficacy, considering the safety and tolerability the 50mg dose exhibited in the Phase IIb study. ARDX is discussing plans for a Phase III trial with partner AstraZeneca. We note that ARDX has an option to co-promote tenapanor in the US, and retains the option to partially fund the Phase III program for an increased royalty rate.

- **We continue to view ARDX has having one of the most attractive risk/rewards ratios in the small-cap biopharma space.** With AstraZeneca financing the complete development of tenapanor, and with additional potential in large indications like ESRD (Phase IIb enrollment continues, data expected in H1:15) and CKD (Phase IIa enrollment continues, data expected H2:15), we would be buyers of ARDX shares.

- **Reiterate OUTPERFORM rating and $31 price target.** Our price target of $31 is derived by applying a 6 multiple to ARDX's share of 2022 tenapanor sales in the US, added to a 15 multiple of the royalty ARDX is expected to receive in 2022 for ex-US sales of tenapanor.

  Risks to the achievement of our price target include clinical or regulatory failure for tenapanor and failure to achieve sales or earnings estimates.

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Company	Disclosure
Ardelyx Inc.	1,3,5,7

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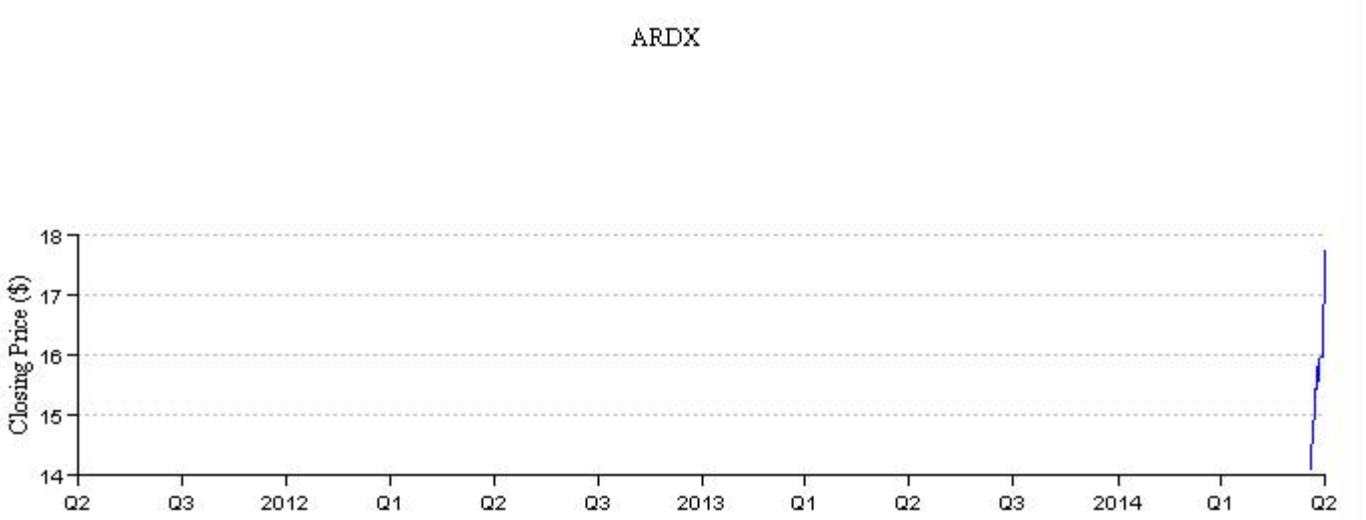

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