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Relypsa (RLYP - OUTPERFORM): ASN Preview: Presentations Support Patiromer Approval; Awaiting FDA Acceptance of Patiromer NDA; Reiterate OUTPERFORM and $57 PT

Price: $19.29 **12-Month Price Target: $57**

- **Patiromer presentations at the American Society of Nephrology Meeting (ASN Nov. 11-16, 2014 Philadelphia) include three posters.** Patiromer poster presentations include:
  1. FR-PO792: " Patiromer Lowers Serum K+ and Prevents Recurrent Hyperkalemia in Patients with Diabetes and CKD on RAAS Inhibitors: Subgroup Results of a Phase 3 Trial",
  2. FR-PO810: " Patiromer Reduced RAASi Dose Discontinuations in CKD Patients with Moderate-to-Severe Hyperkalemia",
  3. SA-PO153: "Patiromer Induced a Rapid Onset of Action and Sustained K+ Lowering throughout the Dosing Period in CKD Patients with Hyperkalemia".

  In summary, we believe the combination of results from these posters bode well for the approval of Patiromer for the treatment of hyperkalemia.

- **Recent News: On October 22 2014, Relypsa announced the submission of a new drug application (NDA) to the FDA for US commercialization of patiromer.** The FDA has 60 days to respond to an NDA submission, suggesting to us that potential FDA acceptance could occur by year-end**.** The company previously estimated an FDA advisory committee (if necessary) could potentially occur in Q2:15, followed by potential approval in late 2015, and we continue to project U.S. launch by year-end 2015. With regulatory and commercial success, we project gross peak annual U.S. sales for patiromer could reach about $1.4 billion.

- **We anticipate some upside with FDA acceptance of the patiromer NDA submission by year-end.** FDA acceptance of an NDA submission reduces regulatory risk, in our view, and we believe investors are likely to value this anticipated announcement. With highly positive clinical results supporting the NDA, we anticipate FDA approval around Q3 2015 is highly likely.

Figure 1: Milestones (*our estimates; **Bloomberg estimates)

Timing	Milestone	Estimated Probability	Estimated Upside / Downside
Nov 11**	Q3 Financials	--	--
Q4:14	**Patiromer NDA Submission**	**70:30**	**±0-10%**
Q2:15*	**Potential FDA Advisory Committee Meeting for Patiromer (If necessary)**	**50:50**	**±0-20%**
Q3:15	**Potential FDA Approval of Patiromer**	**90:10**	**±0-40%**
Q4:15*	**Potential US Launch of Patiromer**	**90:10**	**±0-10%**
2014/2015	**Potential Patiromer Partnership(s)**	**50:50**	**±0-20%**

Source: Company data, Wedbush Securities, Inc.

- **Next: We anticipate release of Q3 financials around November 11th (Bloomberg estimate) as well as FDA acceptance of the patiromer NDA submission by year-end.**

- **We reiterate our OUTPERFORM rating and our 12-month price target of $57.** Our price target is calculated based on sum of- parts for each drug/indication combination using a 30% annual discount from our peak annual revenues projections and 1-10x multiple, depending on stage of development to reflect risk followed by a 365-day projection for time value.

INVESTMENT THESIS *Relypsa is an emerging pharmaceutical company focused on the development and commercialization of cutting-edge treatments for renal, cardiovascular, and metabolic disorders. Its polymer drug discovery platform was in-licensed from Ilypsa, Inc., a subsidiary of Amgen (AMGN). Patiromer is the lead drug candidate emerging from this platform and is a non-absorbed, optimized potassium-binding polymer which is dosed twice daily as an oral suspension powder to normalize hyperkalemia in patients with chronic kidney disease (CKD) and/or heart failure (HF). Hyperkalemia (HK), a chronic condition characterized by excessive potassium, typically occurs in CKD and HF patients due to the body's inability to properly clear potassium. Furthermore, renin-angiotensin-aldosterone system inhibitors (RAASi), the standard-of-care for CKD and HF, can actually cause hyperkalemia themselves. Due to the lack of effective, safe, and tolerable treatments for hyperkalemia, treatment guidelines recommend reducing or discontinuing RAASi therapy if hyperkalemia develops—despite their protective effects on the kidney. This situation has created an unmet medical need for CKD and HF patients. In our view, patiromer has the potential to be best-in-class and the first breakthrough treatment for hyperkalemia since 1958. Compared to the only currently approved treatment for hyperkalemia, Kayexalate (an absorbed polymer), the physical and chemical properties of patiromer confer several advantages, including better binding capacity, tolerability and compliance. In fact, Kayexalate has never shown statistically significant reductions in serum potassium levels in prospective clinical trials. In addition, its poor tolerability profile makes it unsuitable for chronic administration. In contrast, patiromer was shown to be effective at lowering serum potassium levels into the normal range while also reducing the incidence of recurrent hyperkalemia with chronic dosing in the Phase 3 and Phase 2b programs. Given the clinical profile of patiromer, we believe it has the potential to fill an unmet need for CKD and HF patients with mild or moderate-to-severe hyperkalemia as well those on a suboptimal dose of a RAASi due to recurrent hyperkalemia. In the U.S., we estimate there are about 2.4 million CKD and HF patients who would be immediately eligible for patiromer treatment, with additional opportunities to further expand and grow the market. The company filed the NDA for Patiromer on October 24, 2014, setting the stage for potential approval and launch in H2:15. With a small specialty sales force of about 100 reps, we project peak annual sales of patiromer could reach about $1.4 billion in the U.S. alone.*

RISKS TO THE ATTAINMENT OF OUR 12-MONTH PRICE TARGET

1) Clinical – There is risk that results from the ongoing Phase 1 onset-of-action study are negative, but we view this is unlikely.; 2) Regulatory – Although the Phase 3 program was successful and conducted under a special protocol assessment (SPA), the FDA may fail to approve patiromer in a timely fashion, if at all.; 3) Manufacturing – Relypsa relies on third-party suppliers to manufacture patiromer and there is risk that those parties may not meet their obligations. In addition, they may not be able to successfully scale up manufacturing in a timely and cost efficient manner.; 4) Commercial – As with all new product launches, initial sales of patiromer could be slower than anticipated and call into question its ultimate sales potential. Furthermore, patiromer could face competition from potential new drugs for hyperkalemia including ZS Pharma's late-stage candidate, ZS-9.; 5) Financing – The company ended Q2 2014 with about $160.4MM in cash and investments. We project runway into Q4 2015—when we estimate potential FDA approval of patiromer. Therefore, we believe Relypsa will likely need to raise additional funds in order to commercially launch patiromer (and/or work with a strategic partner for primary care and/or exUS commercialization) and to ultimately reach profitability which we model to occur in 2018.

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Company	Disclosure
Relypsa	1,3,4,5

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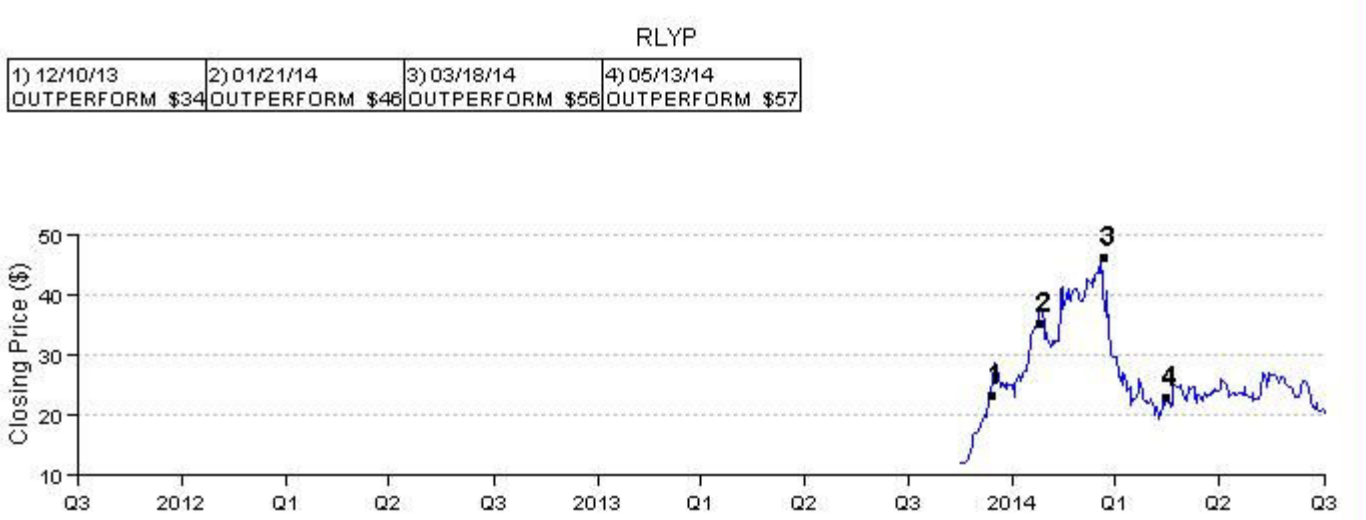

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