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Relypsa (RLYP - OUTPERFORM): Phase 1 Onset-of-Action Trial Fully Enrolled; Q3:14 NDA Filing for Patiromer Remains On Track; Reiterate OUTPERFORM and \$46 PT

Price: \$32.37 12-Month Price Target: \$46

- Relypsa announced completion of patient enrollment in the ongoing Phase 1 onset-of-action trial and expects results in H1:14. The purpose of the trial is to evaluate the time to onset of the potassium-lowering action of patiromer in chronic kidney disease (CKD) patients with hyperkalemia (HK). The open-label, single arm trial enrolled 25 patients and the study design includes a three-day run-in period to control dietary intake of potassium followed by a 48-hour treatment period and a 7-day post treatment visit for adverse events. The change from baseline in serum potassium levels will be measured at 48 hours and at earlier time points to determine when the onset of potassium-lowering action occurs. The company expects results from the trial in H1:14, and based on the treatment period, we estimate could come in the March/April timeframe. In our view, the Phase 1 study is relatively straightforward and we see minimal clinical risk.
- The Phase 1 onset-of-action study is the final clinical trial necessary to support an NDA filing expected in Q3:14. We estimate an FDA advisory committee (if necessary) would occur in Q2:15, followed by potential approval in Q3:15 and U.S. launch in Q4:15.

Figure 1: ANTICIPATED MILESTONES (*our estimates)

H1:14	PATIROMER PHASE 1 ONSET-OF-ACTION RESULTS
H1:14	COMPLETION OF CMC ACTIVITIES SUPPORTIVE OF NDA
Q3:14	PATIROMER NDA SUBMISSION
Q2:15	POTENTIAL FDA ADVISORY COMMITTEE FOR PATIROMER
Q3:15	POTENTIAL FDA APPROVAL OF PATIROMER (*IF NECESSARY)
Q4:15	POTENTIAL U.S. LAUNCH OF PATIROMER
2014/2015*	POTENTIAL PATIROMER PARTERSHIP(S)

Source: Company reports and Wedbush PacGrow Life Sciences

 We reiterate our OUTPERFORM rating and our 12-month price target of \$46. Our price target is calculated based on sumof-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.

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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 llypsa. 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, reninangiotensin-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. We anticipate the company will file an NDA in Q3:14, 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 attainment of our fair value include: 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 Q3:13 with about \$16.5 million in cash, investments, and equivalents. With net proceeds of approximately \$77.9 million from the initial public offering (IPO), we project cash runway through Q1:15. Therefore, Relypsa will likely need to raise additional funds in order to commercially launch patiromer and to ultimately reach profitability which we model to occur in 2018.



Analyst Certification

I, Liana Moussatos, Ph.D., Richard Lau, CFA, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Company	Disclosure
Relypsa	1,3,4,5,7

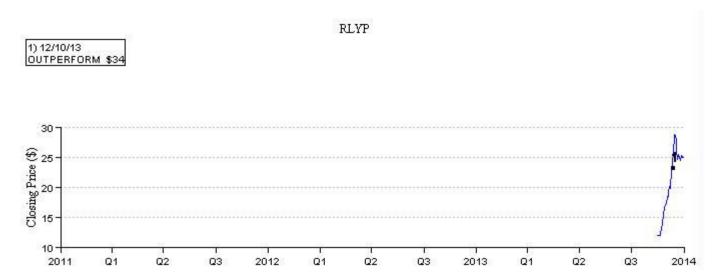
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