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Relypsa (RLYP - OUTPERFORM): Additional Manufacturing Supports Potential Patiromer Launch, In Our View; Reiterate OUTPERFORM And $57 PT

Price: $21.91 **12-Month Price Target: $57**

- **Relypsa announced that it has agreed to a multi-year manufacturing and supply deal with DSM Fine Chemicals**. Under this agreement, DSM Fine Chemicals will supply the active ingredient for patiromer, supporting current contract manufacturer Lanxess. Relypsa reiterated their plan to submit a New Drug Application (NDA) to the FDA for patiromer in Q3. Relypsa's initial NDA for patiromer will list Laxness as the sole manufacturer of patiromer. Following FDA approval of patiromer, the company plans to submit a supplemental NDA listing DSM Fine Chemicals as an additional manufacturer.

- **The agreement between Relypsa and DSM Fine Chemicals de-risk the manufacturing of Relypsa's lead drug, patiromer.** We believe having a second supplier reduces the risk that potential demand, if approved, would exceed supply and create an unfavorable commercial situation—especially since we believe Patiromer is likely to be first to the market among potential next-generation hyperkalemia treatments. We have previously highlighted the potential risk of manufacturing on gross peak sales and view this deal as a positive, since it mitigates that risk.

Figure 1: MILESTONES (*our estimates)

Q3:14	**PATIROMER NDA SUBMISSION**
Q2:15*	**POTENTIAL FDA ADVISORY COMMITTEE FOR PATIROMER (*IF NECESSARY)**
Q3:15	**POTENTIAL FDA APPROVAL OF PATIROMER**
Q4:15*	**POTENTIAL U.S. LAUNCH OF PATIROMER**
2014/2015*	POTENTIAL PATIROMER PARTERSHIP(S)

Source: Company data, Wedbush Securities, Inc.

- **Management continues to deliver, in our view.** The company will file an NDA for patiromer in Q3 2014. The FDA has 60 days to respond to an NDA submission and the company anticipates potential FDA acceptance in Q4 2014. The company estimates an FDA advisory committee (if necessary) could potentially occur in Q2:15, followed by potential approval in Q3:15 and U.S. launch in Q4:15. With regulatory and commercial success, we project gross peak annual U.S. sales for patiromer could reach about $1.4 billion.

- **We reiterate our OUTPERFORM rating and $57 12-month price target.** 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. 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 12-month price target 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 Q1 2014 with about $78.9MM 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.

Analyst Certification
I, Liana Moussatos, Ph.D., 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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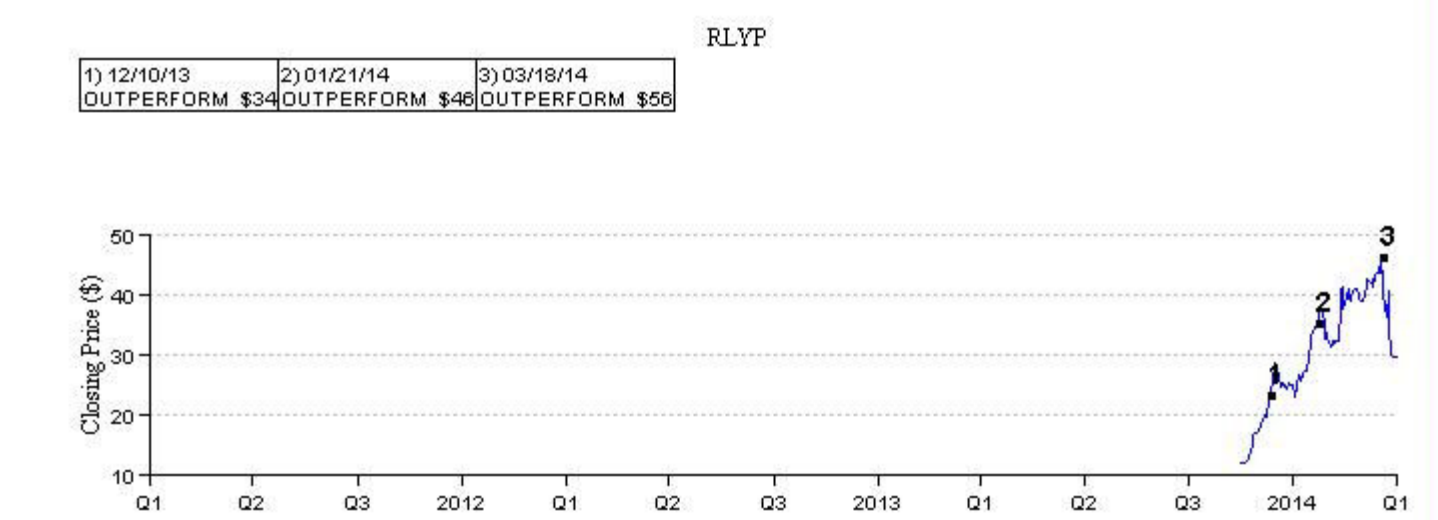

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