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Adolor Stock Catalysts for 2011 and 2012

by: Smith On Stocks

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Introduction

I recently published an introductory [report](#) on Adolor ([ADLR](#)) entitled "Adolor: A Small Stock to Watch." The company recently reported 4Q, 2010 and this note discusses those results as well as pointing out key catalysts in 2011 and 2012.

Keys to Stock Performance in 2011 and 2012

- Steady progress in sales of Entereg throughout the quarters of the year.
- Results from two phase II proof of concept trials with ADL5945 that should be available in 3Q or 4Q, 2011
- Partnering deal on ADL5945 if phase II trials are successful could occur in 1H, 2012
- Phase III trial of ADL5945 could start in mid-2012 if two previous catalysts are positive.
- At the American Society of Colon and Rectal Surgeons Annual Meeting during May 14 to 18, a retrospective analysis of Entereg will be presented that shows that it reduces hospital stays when compared to standard of care.
- There is an unpredictable catalyst in that Glaxo ([GSK](#)) might elect to give Entereg back to Adolor. Its sales potential of \$100 million is a rounding error within Glaxo's \$46 billion sales base. This might initially be construed as negative for Adolor, but I think it would be a major positive.

Possible Stock Performance

Adolor is selling at a market capitalization of \$67 million. It is a rarity among small biotechnology companies in that it has an approved drug, Entereg. I am projecting 2011 sales of \$36 million for Entereg and peak sales of \$100 million. At that level, the product might create \$25 million of annual cash flow for Adolor.

Progress with Entereg could lead to steady gains in the stock price. However, the key to the Adolor investment outlook is success in two phase II trials now underway with its second drug in development, ADL5945. This drug addresses a much larger market opportunity as there is currently no oral drug approved for chronic opioid induced constipation. In my opinion, this could be a bigger value driver than Entereg. Predicting success in the phase II trials is difficult based on existing data. I can't offer odds on success.

The company is reasonably well capitalized. It has \$47 million of cash and a burn rate of about \$25 million per year. Hence, it has about two years of cash. I think that the stock could have a very significant move if the phase II trials on ADL5945 are positive and lead to a lucrative partnering deal.

Entereg Continues to Make Steady Progress

Entereg is a product that is marketed in hospitals for opioid induced constipation in bowel resection patients. This is a niche market that may represent an addressable market of perhaps \$300 million potential. It is co-marketed with Glaxo and profits are split 50/50.

Progress with Entereg has been steady since its introduction in 2008. Sales in 2008, 2009 and 2010 have been \$1.2 million, \$14.6 million and \$25.4 million. The year over year increase for 2010 versus 2009 was 75%. In 4Q, 2010 Entereg sales increased sequentially by 12% to \$7.3 million. Based on 4Q sales the annualized run rate is \$29.2 million. The company does not give revenue guidance, but I am projecting 2011 full year sales of \$36.6 million, a 44% rate of increase. At \$30 million of sales, Entereg should reach cash flow breakeven and thereafter will begin to generate cash.

Adolor has conducted a retrospective matched cohort comparative analysis study analyzing certain outcomes data,

including length of stay, for several thousand bowel resection patients who received Entereg as compared to a rigorously matched set of control patients, bowel resection patients, who did not receive Entereg.

I would emphasize that this is not a controlled prospective study that is necessary for regulatory action on labeling. Management states that bowel resection patients who had received Entereg had a length of stay that was shorter than non-Entereg patients. The resultant earlier discharges create cost savings for the hospital. An abstract discussing the results of this study has been accepted as a presentation at the 2011 American Society of Colon and Rectal Surgeons Annual Meeting in Vancouver during May 14 to May 18. , and a full manuscript has been submitted for publication in a peer-reviewed journal. This data could bolster the acceptance of Entereg in the market.

ADL5945 Phase II Proof of Concept Trials

Adolor is conducting two confirmatory proof of concept trials with ADL5945 in obstructive bowel disease. The first trial is evaluating two doses of 5945 at 0.1 milligram and 0.25 milligrams, given twice-daily versus placebo over a four-week double-blind treatment period. This study is expected to enroll approximately 120 patients or 40 patients in each arm. The second study is similarly designed, but will evaluate only a 0.25 milligram dose given once daily versus placebo. There will be a total of 80 patients with 40 in each arm. Results from both of these trials will probably be released in 3Q or 4Q, 2011.

Adolor is competing with four companies to develop an orally effective product for the opioid induced constipation market. Progenics has an intravenous product approved with Relistor. In terms of clinical development the partnership of Nektar with Astra Zeneca ([AZN](#)) appears to be in the lead, but I have seen no indication that they have entered phase III. Alkermes has just announced a phase III. If the phase II trials of ADL5945 are successful, it is possible that a partnership deal could be signed late 2011 or early 2012 and a phase III trial could start in 1H, 2012. This would put Adolor on a comparable timeline to development as Nektar and Alkermes and possibly ahead of Progenics which seems to be struggling to come up with an oral formulation of Relistor.

Financial Situation

The company had \$47 million in cash at the end of 4Q, 2010. They have reduced their burn to \$25 million per year which gives them about two years of cash. Management hopes that a partnering deal for ADL-5945 could bring in a significant upfront payment that would put them in a strong cash position which could sustain them through to profitability arising from Entereg sales. Of course, this is contingent on a lot of unknowns foremost of which is whether the data will be positive. Behind this is whether the data will drive a partnering deal and what the terms of that deal might be.

Disclosure: I have no positions in any stocks mentioned, and no plans to initiate any positions within the next 72 hours.



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