

Sagent Pharmaceuticals (SGNT) Generic Levaquin IS Their Bag, Baby

BUY

Price target \$31.00

Price \$26.51

Key Takeaway

FDA just approved Sagent's 2nd ANDA for generic Levaquin. While already in our model, Sagent appears to be the only generic approved for this pre-mixed "bag" formulation -- presenting the potential for significant upside. Right now we have only \$4.5M in our model for 2011, but with a \$150M brand product and as a sole generic (we don't know about an AG), it could be closer to \$30M, which could raise EPS by \$0.05 in 2011.

Generic Levaquin Bag Approved - Sagent is Alone for Now. FDA has approved Sagent's generic bag formulation of Levaquin (levofloxacin), a widely-used antibiotic that generated \$1.3BN in reported US sales for Johnson & Johnson (JNJ, \$67.92, NC) in 2010. The bulk of this is the oral pill, but IMS shows the injectable at \$154M over the last 12 months -- with the bag being 97% of that, or \$149M. This is Sagent's *second* ANDA for injectable levofloxacin to be approved. On June 20, at the expiration of Levaquin's market exclusivity, FDA approved Sagent's injectable vial formulation. This new ANDA approval is for an injectable pre-mixed bag formulation, and while this comes a few weeks behind the injectable vials, 1) it's the bigger revenue opportunity, and more importantly, 2) no other generics have yet been approved. We do not yet know whether J&J will do an authorized generic on the product.

Old Assumptions. Levofloxacin should fit nicely into Sagent's existing product portfolio of generic injectable antibiotics (which among others, already includes generic injectable Rocephin, Zithromax, Cipro, and most recently, Zosyn). Given the small size of the vial (~\$6M in LTM sales, 4% of the injectable Levaquin market), it's unlikely Sagent will even launch this product. As for the pre-mixed bags, we had previously assumed: 1) as many as 4-5 potential generic competitors; 2) given the number of competitors, a 60% discount off current brand pricing (so a total addressable market opportunity of ~\$60M); and 3) Sagent market share of roughly 15%. Thus, on an annualized basis, this results in a \$9M opportunity for Sagent, but given a launch mid-year, we've currently modeled \$4.5M in revenue contribution from this product in 2011. We also used a very low gross margin assumption of 10%.

Perhaps 5 Cents of EPS Upside. We assume Sagent is the sole supplier of levofloxacin pre-filled bags for at least 3 months (Hospira [HSP, \$54.22, NC] and Bedford both have tentative approval). With \$38M in brand sales per quarter, a smaller 20% price discount (as sole supplier), erosion rate of 50% and 100% market share, it would translate to \$15M in Q3 sales for Sagent. (Normally for a generic launch, the first quarter would also have lots of stocking, making the potential much higher for Q3.) Compared to our original Q3 estimate of \$2.5M, the incremental \$12.5M in revenue at a higher 25% gross margin assumption would yield an incremental \$3M net income (assuming no tax for now), or 3 cents in EPS. Assuming more competition starting in Q4, we see an incremental 2 cents in EPS -- hence a potential 5 cents in upside for 2011. However, we are not formally changing any numbers until we learn more about the competitive dynamics.

Thoughts on the stock. Since the company's IPO in April, SGNT shares have handily outperformed the broader market and healthcare indices (stock is up ~66% since being priced at \$16/share vs. S&P up 3%), and year-to-date, Sagent is one of the best performing IPO of the entire 2011 IPO class. That said, the shares have pulled back from its peak at \$29 in June. And with an additional 38 products (represented in 67 ANDAs) pending approval -- an incredibly rich pipeline for such a small company -- a demonstrated ability to get products approved, and the potential for EPS upside, we remain comfortable with our Buy rating and \$31 PT.

Corey Davis, Ph.D. *

Equity Analyst

(212) 336-7187 cdavis@jefferies.com

Graig Suvannavejh, Ph.D. *

Equity Associate

(212) 284-2170 gsuvannavejh@jefferies.com

Oren G. Livnat *

Equity Associate

(212) 284-2214 olivnat@jefferies.com

* Jefferies & Company, Inc.

Company Description

Sagent Pharmaceuticals is a specialty pharmaceuticals company focused primarily on hospital-based, generic injectable drugs sold in the US. Founded in 2006, Sagent has sourcing, development, manufacturing, and sales and marketing capabilities, and has amassed an extensive, global network of partnerships and collaborations that provide for a low cost business model and a deep pipeline of ANDA opportunities.

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Jefferies makes a market in Sagent Pharmaceuticals.

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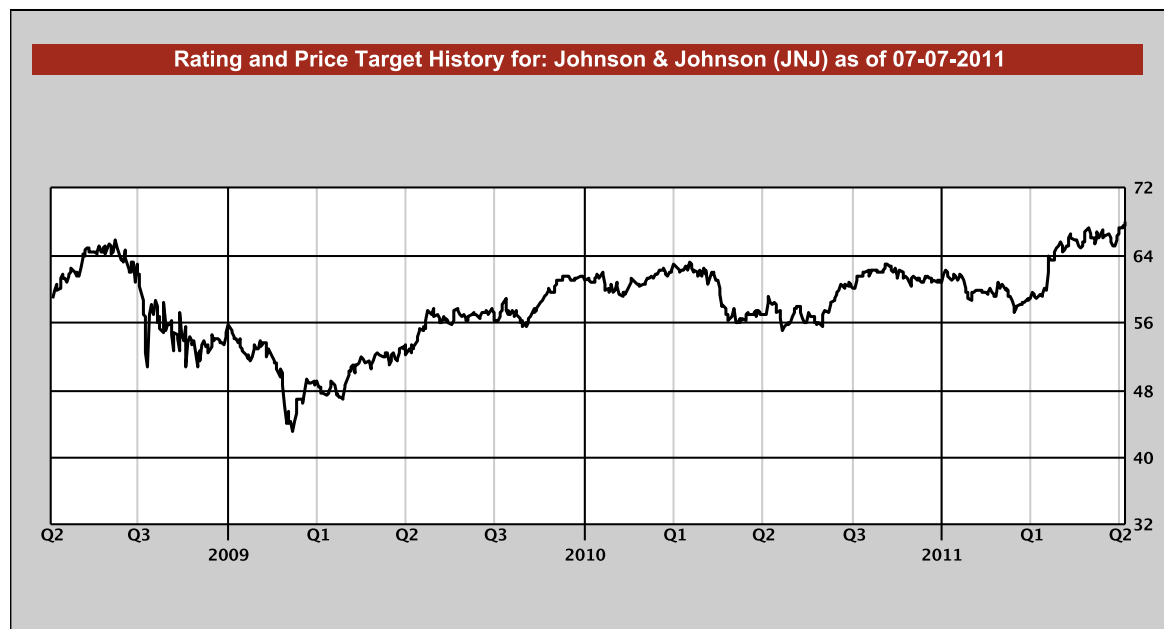
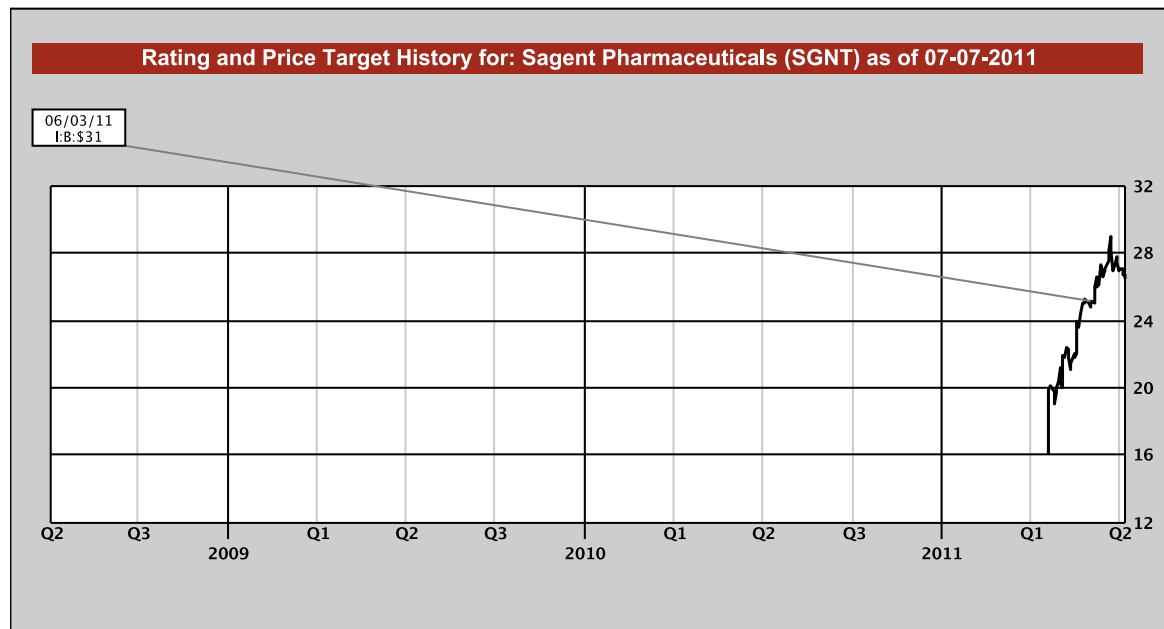
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Other Companies Mentioned in This Report

- Sagent Pharmaceuticals (SGNT: \$26.51, BUY)



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			Count	Percent
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