

Sagent Pharmaceuticals (SGNT) Obama's Exec Order: SGNT Beneficiary

BUY

Price target \$28.00

Price \$25.69

Key Takeaway

President Obama signed an executive order yesterday to help ease the nation's current drug shortages, highlighting an untapped opportunity for Sagent (SGNT), our favorite small/mid-cap idea. With several shortage products already pending FDA approval, and a new manufacturing facility awaiting FDA inspection, Sagent should benefit from any FDA efforts to accelerate shortage approvals.

Obama weighs in. Yesterday, in a surprise, President Obama signed an executive order to address the growing number of drugs in short supply (mostly generic injectables), and announced support of bipartisan legislation (HR.2245, S.296) that strengthens the FDA's ability to prevent drug shortages. Key elements of President Obama's executive order include: requiring companies to improve the reporting of potential shortages, increasing FDA staffing at FDA's Drug Shortages program, and working with the US Department of Justice to investigate potential price gouging (which hurts consumers). Most concretely for SGNT, the executive order also *"requires FDA to expand its current efforts to expedite review of new manufacturing sites, drug suppliers, and manufacturing changes to help prevent shortages."* While it remains unclear whether the White House action will positively impact SGNT in the near term, any accelerated FDA approvals could be upside.

The growing drugs shortage puts lives at risk. The US is facing an increase in the number of key drugs that are in short supply, posing a major problem for the FDA and a significant risk to the health and safety of the US population. According to gov't statistics, for the period of 2005-2010, the # of prescription drugs in the US reported as being in short supply almost *tripled*, and while many drug shortages have actually been avoided (137 between Jan. 1, 2006 and Sept. 26, 2011), the # of drugs on the FDA's critical shortage list (CSL) has only *increased*. FDA's website (<http://www.FDA.gov/Drugs/DrugSafety/default.htm>) reveals ~75 drugs that are on the current CSL; 56 are injectable products, while 14 are generic injectable oncology products (our proprietary table is available on request). As SGNT is a niche generic pharmaceuticals company focused on sterile injectable drugs (and particularly those that are for cancer), the drugs shortage issue plays nicely into Sagent's sweet spot, and has potential to drive upside to our current model.

What's it mean for Sagent? Of Sagent's 11 approvals thus far in 2011, three include those for CSL products -- levofloxacin (an anti-infective), paclitaxel (for cancer), and most recently, vecuronium (for muscle spasms). As common practice, SGNT does not disclose exactly what's in its pipeline (for competitive reasons), but at last count, it currently has 59 ANDAs pending approval, 33 of which are at least two years into their review. Several of these ANDAs are for shortage products, with one coming from the company's new Chengdu facility in China (now on-line but awaiting final FDA clearance). Chengdu is a state-of-the-art manufacturing facility, which SGNT intends to use in the manufacture of *at least nine* additional shortage products. An FDA approval of Chengdu is not expected before 2013, but we believe that the president's Executive Order could accelerate the timing of such an inspection.

We see upside. Recall that while the market for many drugs on the CSL can sometimes be small (e.g., the US vecuronium market is only ~\$10M), given limited competition and healthy pricing, the financial impact could be significant for a small company like Sagent. Given limited information, it's difficult for us to quantify exactly what the potential impact on SGNT could be, but we note that: 1) revenue from any new products from Chengdu represent pure *upside* to our current forecasts; and 2) any new shortage products (particularly, those that are oncology-specific in nature) have the potential to meaningfully boost the company's overall gross margin.

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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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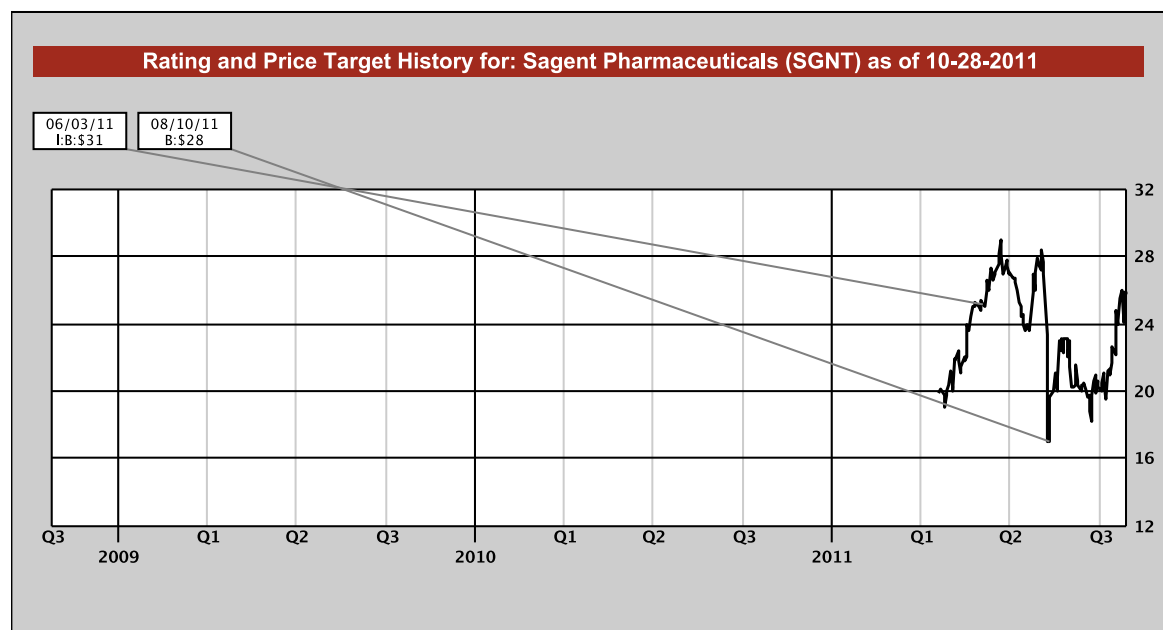
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