

## Quick Take

### Horizon Pharma — Outperform (1)

**HZNP: \$3.47**

### Quick Take: Horizon Gets Paragraph IV; YAWN: “Par” For The Course

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#### Take Home Points

- Paragraph IV certification has always been anticipated and is most likely “weak” on its claims
- DUEXIS has strong Orange Book listed patents that we believe are defensible
- DUEXIS launch is still young, but prescriber response has been very strong and positive
- LODOTRA PDUFA getting closer: July 26, 2012. We are bullish on chances of approval

Yesterday after the market close, Horizon Pharma announced that it had received a Paragraph IV certification from Par Pharmaceuticals, Inc. advising that Par has filed an Abbreviated New Drug Application (ANDA) with the FDA for a generic version of DUEXIS. Horizon is evaluating the Paragraph IV certification currently to determine the next course of action. If the company elects to initiate a patent infringement suit within 45 days of receiving the notice, the approval of the ANDA cannot be granted until the earlier of 30 months or a decision from the infringement case.

#### DUEXIS Has Composition of Matter and Method of Use Patents Issued

Horizon currently has two patents issued and Orange Book listed with claims that cover DUEXIS. Both patents, entitled “Stable compositions of famotidine and ibuprofen” (patent number 8,067,033) and “Methods and Medicaments for Administration of Ibuprofen” (patent number 8,067,451), were issued on November 29, 2011 and are set to expire in 2026.

Additionally, there are currently pending claims to methods of use for the treatment of patients with ibuprofen-responsive conditions and the TID administration of famotidine and ibuprofen.

Recall that Horizon spent much time and effort to create the DUEXIS formulation. This was not straightforward as ibuprofen tends to “eat away” at famotidine when in contact. DUEXIS’ unique formulation separates these two layers and allows for immediate release.

#### Paragraph IV Certification Requires Bioequivalence

Paragraph IV certification has become a routine business tactic and path of FDA filing for generic companies. It can be filed any time before the patent is set to expire. In recent years, Paragraph IV certification filings have been on the rise and generic companies tend to file as early as possible to secure the first-to-file status as a successful outcome allows for 180 days of market exclusivity before the FDA will approve another generic.

Orange book is the FDA’s list of Approved Drug Products with Therapeutic Equivalence Evaluations. Par Pharmaceutical, Inc. has not advised Horizon of whether it has complied with the FDA requirements for proving bioequivalence.

**Please see addendum of this report for important disclosures.**

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**The DUEXIS Duo**

DUEXIS is Horizon's proprietary single-tablet combination of ibuprofen (800mg) and famotidine (26.6mg) for the treatment of pain and inflammation associated with rheumatoid arthritis (RA) and osteoarthritis. Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) and famotidine is a histamine H<sub>2</sub>-receptor antagonist. By combining the two, DUEXIS provides a simple solution that offers GI protection along with pain relief in a fast, effective and convenient manner. DUEXIS is FDA approved for TID administration to provide all day relief of chronic pain due to RA and OA while reducing the risk of developing upper gastrointestinal ulcers, which can result from long-term ibuprofen use. DUEXIS was approved by the FDA in April 2011 and was launched in December 2011.

**Still Early Days, But DUEXIS Launch Is Signaling Success**

While it is still very early in the launch cycle, Horizon has hit the ground running. The company held their launch meeting with reps on January 24<sup>th</sup>. The company has reported that DUEXIS has 70% access with regard to commercial plans, which we believe is a very strong number and that 90% of an initial 120 doctors detailed were able to identify a patient that would be a candidate for DUEXIS and 76% would use samples for the patient. This is also a very strong and important number, in our opinion, as it shows the physicians intent to treat the patient with DUEXIS. We continue to follow scripts closely and continue to see strong upward trending. We believe over the next few quarters, DUEXIS will make strong in-roads into the prescribing community. We reiterate our Outperform rating on shares.

## Addendum

### STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
HZNP	Horizon Pharma

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(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

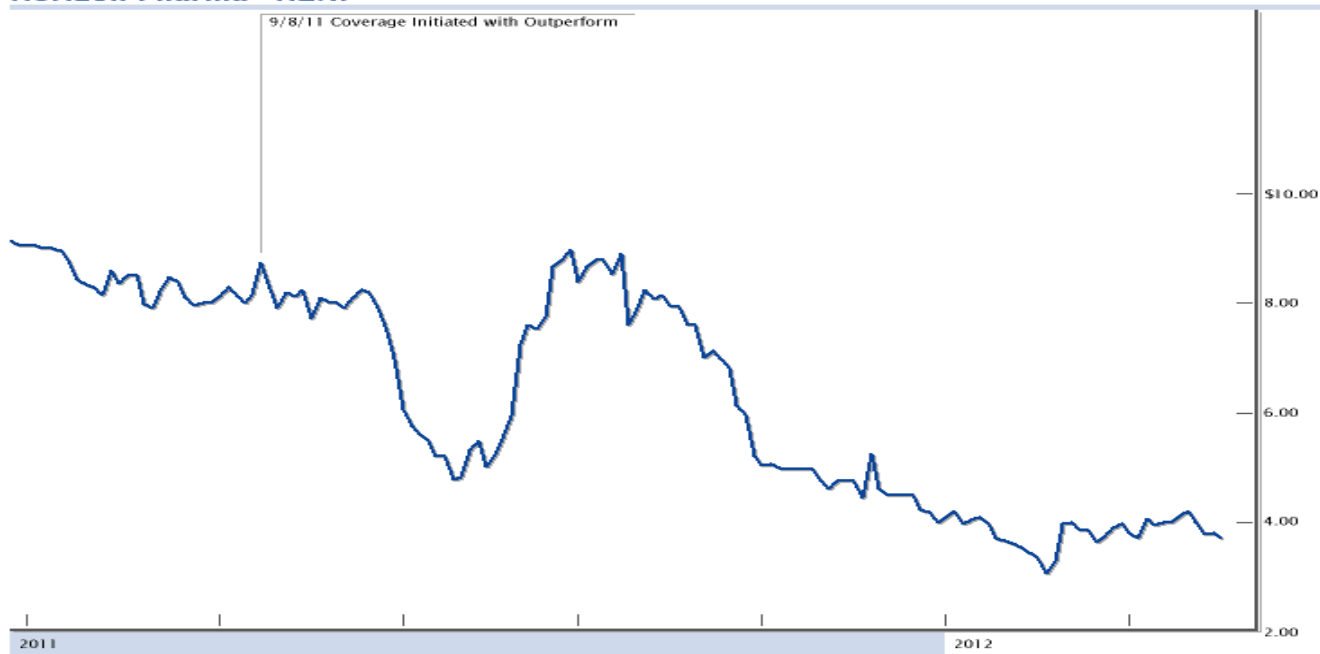
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**Horizon Pharma - HZNP**



Pricing data provided by Reuters America. Chart as of 2/16/12 in USD.