# Horizon Pharma, Inc. [1,3]

Unsurprising Paragraph IV Challenge but Likely to be Successfully Defended

## MARKET OUTPERFORM HZNP $3.72

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| | |
|---|---|
| Price | $3.72 |
| Target Price | $16.00 |
| 52-Wk Range | $3.05 - $9.34 |
| Shares Out. (M) | 19.147 |
| Market Cap. (M) | $71 |
| Average Daily Vol. (000) | 0.07 |
| Float (M) | 18 |
| LT Debt (M) | 19.2 |
| Cash (M) | 33.0 |
| Enterprise Value (M) | $40.5 |
| Cash/Share | 1.72 |

| FY Dec | | 2010A | 2011E | 2012E |
|---|---|---|---|---|
| Revenue (M) | 1Q | -- | $1.8A | $2.5 |
| | 2Q | -- | $1.3A | $7.8 |
| | 3Q | -- | $0.3A | $12.1 |
| | 4Q | -- | $1.1 | $27.7 |
| | **FY** | **$2.4** | **$4.5** | **$50.2** |
| | | **2010A** | **2011E** | **2012E** |
| EPS | 1Q | -- | ($5.13)A | ($1.07) |
| | 2Q | -- | ($7.78)A | ($0.66) |
| | 3Q | -- | ($1.30)A | ($0.46) |
| | 4Q | -- | ($1.11) | $0.29 |
| | **FY** | **($8.91)** | **($6.94)** | **($1.74)** |
| | P/E | NM | NM | NM |
| | Previous FY | -- | NC | NC |
| | **CY** | **($8.91)** | **($6.94)** | **($1.74)** |
| | PE | NM | NM | NM |

*NC indicates no change to previous estimate. NE indicates no previous estimate.*
*Source: Company reports and JMP Securities*

## INVESTMENT HIGHLIGHTS

- **Paragraph IV filing from Par "par for the course," looking to an out-of-court settlement at worst; reiterate Market Outperform rating and $16 price target on Horizon Pharma.** Horizon announced yesterday evening that it has been notified of a Paragraph IV filing that challenges the IP on Duexis with an ANDA submission to the FDA. Horizon has 45 days to file a countersuit which would push out the generic approval to the earlier of 30 months or non-infringement of the Duexis patents. Despite this being a faster-than-usual filing (orange book listing of Duexis' patents occurred in Dec '11), we anticipate that Horizon is prepared to pursue a countersuit within 45 days. Moreover, we expect the IP for Duexis to hold up for reasons outlined in our initiation report (published 09/07/11) including non-obviousness and nuances in the composition of matter claims, and would anticipate an out-of-court settlement as most likely. We assign at most 10% likelihood to Horizon losing IP protection on Duexis, which would then result in legal process and exclusivity until roughly 2019. That said, despite this news likely weighing on the stock in the short run, we believe this results in a compelling opportunity for value-oriented and experienced investors who have seen Par and other PIV challengers settle in the majority of cases. We derive our $16 price target from 4x estimated U.S. revenues and 7x estimated EU royalties for Duexis and Lodotra in 2017 discounted back at 30%.
- **Duexis' non-obviousness previously tested.** The original filing for one of the two Orange Book-listed Duexis patents, #8067451 "Methods and medicaments for administration of ibuprofen," was not originally approved, in part on an interpretation of the Vimovo patents. This decision was later overturned and the non-obviousness of the Duexis patent was upheld. Prior art had taught against the release of acid-blocking agents at the same time as the NSAID, with the belief that the GI-protectant needed time to act. The positive clinical results which led to Duexis' approval clearly show this is not the case, in our view. Duexis concomitantly and effectively releases ibuprofen due the drug's novel formulation which protects famotidine from reacting with ibuprofen. This novel formulation is protected by the second Orange Book-listed patent, #8067033 "Stable compositions of famotidine and ibuprofen." Both Orange Book-listed patents expire in July 2026. We believe that, without a barrier between the drugs, the prevention of degradation of famotidine by ibuprofen is impossible and that Par will lose on the basis of this observation, as well as process.

**FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO THE JMP FACTS AND DISCLOSURES SECTION**

- **Scenario analysis indicates significant value even in worst case.** A scenario analysis we first conducted for our initiation report suggests that Horizon retains significant value even should the Duexis patents be successfully challenged (Figure 1). For example, assuming Duexis IP is invalidated, leaving only three years of exclusivity from NDA approval (with likely an added ~4 years due to the legal process) while Lodotra's patents were upheld, we would still derive a per share value of ~$16, a ~330% premium to yesterday's close. Note that based on even our possibly conservative IP scenarios, we arrive at a per share valuation in excess of our multiple-based valuation share price target.
- **Recent physician diligence highlights Duexis' unique clinical advantages.** Based on our recent and ongoing physician diligence, we have enhanced conviction on the value-add of Duexis in the clinic. One quote from a KOL we recently spoke to appropriately sums up the Duexis value proposition, in our view: "science catching up to common sense." While most physicians know patients should take GI-protection with NSAIDS, the reality is that few patients comply for various reasons, including under appreciation of the risks involved. In the opinion of our physician, ibuprofen works well and is the NSAID that is "reached for most" in the clinic and drug store, but patients should concomitantly take GI-protectants. In his opinion, Duexis enables the necessary protection to be realized.
- **Paragraph IV filings are commonplace.** Cadence (CADX, MO, $7 PT) received one in July 2011 for Ofirmev and Pozen (Not Covered) in Sept 2011 for Vimovo to name a couple examples. Both Cadence and Pozen/Astra Zeneca filed infringement suits in time to provide 30 months of exclusivity. Presumably legal negotiations continue in these cases. Pfizer's (PFE, NC) Celebrex was subjected to a Paragraph IV in March 2008 and Pfizer went to trial against Teva. A generic Celebrex remains unavailable in the U.S. at this time. Also, Par itself has recently been rebuffed in a spurious challenge on Avanir's (AVNR, MO, $7 PT) Nuedexta.

**FIGURE 1: IP Scenario Analysis**

| Scenario | Duexis U.S. IP Protection To | Years | NPV | Lodotra U.S. IP Protection To | Years | NPV | Probability | Weighted Share Price |
|---|---|---|---|---|---|---|---|---|
| 1 | April 2014 (36 month exclusivity) | 7 | $13.39 | YE 2015 (36 month exclusivity) | 7 | $2.46 | 5.0% | $0.94 |
| 2 | April 2014 (36 month exclusivity) | 7 | $13.39 | 2025 | 14 | $3.12 | 5.0% | $0.97 |
| 3 | July 2026 ('282 patent) | 15 | $20.19 | YE 2015 (36 month exclusivity) | 7 | $2.46 | 5.0% | $1.28 |
| 4 | July 2026 ('282 patent) | 15 | $20.19 | 2025 | 14 | $3.12 | 85% | $22.33 |
| | | | | | | | **Weighted Price Objective:** | **$25.53** |

*Source: JMP Securities LLC*

## INVESTMENT RISKS

Regulatory risk. The FDA, and/or other ex-U.S. regulatory agencies, could reject any of the firms', or its partners', future regulatory filings or require additional studies prior to granting approval.

Commercial risk. If successfully developed and approved, Horizon's products may face competition both from approved products and also potentially from new product candidates in development by biotechnology and pharmaceutical companies. The company may also face IP risk from competing brand or generic products or product candidates.

Balance sheet risk. The expenses associated with drug development and commercialization are high. Horizon may return to the capital markets to secure additional financing to fund current or future development programs or marketing efforts. Horizon had approximately $33MM in cash and equivalents at the end of 3Q11 that we believe will be sufficient to fund operations into 2Q12. We have projected a raise of ~56MM in 2Q12 at $15/share. However, the company may also complete one or multiple ex-U.S. partnerships for Duexis which would reduce the need for equity financing.

## COMPANY DESCRIPTION

Horizon Pharma is a specialty pharmaceutical company focused on the development and commercialization of novel drug formulations for the treatment of pain and inflammatory indications, particularly arthritis. The company has two approved products, Duexis in the U.S. and Lodotra in Europe. The primary near/mid-term drivers for Horizon are successful execution on the launch of Duexis in the U.S. (planned for 4Q11) as well as U.S. approval of Lodotra (NDA filing expected in 3Q11). Horizon has partnered Lodotra in Europe and Asia, with Mundipharma and Merck/Serono, and intends to secure a partner for Duexis for ex-U.S. geographies.

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**Publicly Traded Companies Covered by JMP and Mentioned in This Report (as of February 17, 2012):**

| Company | Disclosures |
|---|---|
| Avanir Pharmaceuticals, Inc. | (1) |
| Cadence Pharmaceuticals, Inc. | (1) |
| Horizon Pharma, Inc. | (1,3) |

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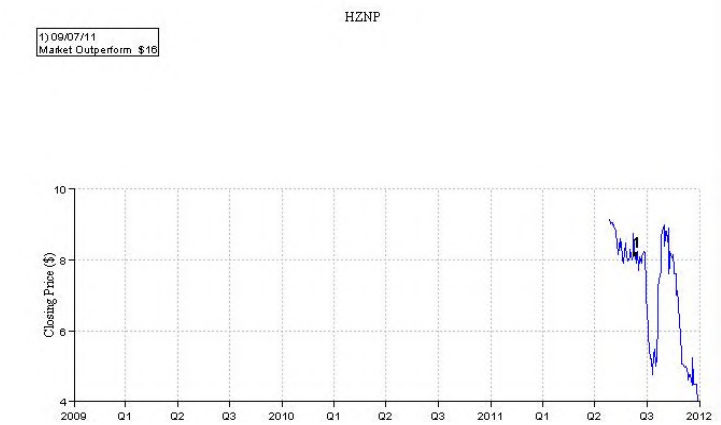
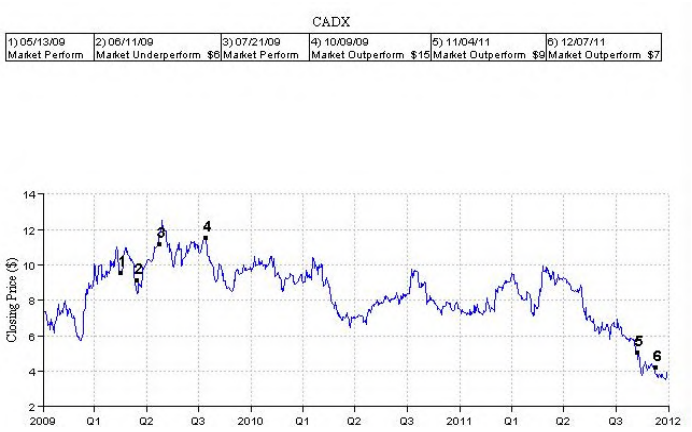
| JMP Rating | Regulatory Equivalent | # Co's Under Coverage | % *of Total* | Regulatory Rating | # Co's Under Coverage | % *of Total* | # Co's Receiving IB Services in Past 12 Months | *% of Co's With This Rating* |
|---|---|---|---|---|---|---|---|---|
| Market Outperform | Buy | 226 | *65%* | Buy | 226 | *65%* | 43 | *19%* |
| Market Perform | Hold | 117 | *34%* | Hold | 117 | *34%* | 11 | *9%* |
| Market Underperform | Sell | 6 | *2%* | Sell | 6 | *2%* | 0 | *0%* |
| TOTAL: | | 349 | *100%* | | 349 | *100%* | 54 | *15%* |

**Stock Price Chart of Rating and Target Price Changes:**
Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: Jovus and JMP Securities.

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