Medicis facing Reloxin makeover as Solodyn concerns persist

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The 25% decline in Medicis's stock price over the past six months can be attributed to investors’ real concerns over the impact of potential generic entrants on its leading acne treatment, Solodyn, which generated almost half of the company’s sales in 2007.

However, EvaluatePharma's NPV Analyzer suggests that the market is taking a very pessimistic stance towards the situation. With a healthy cash pile of almost $800m and a competitor to Botox waiting for FDA approval, even the threats to Solodyn do not warrant the company's depressed valuation.

Patent concerns overhang stock

Solodyn, launched in 2006, is a type of antibiotic, called minocycline hydrochloride, commonly used to treat acne. The Medicis product, however, has been formulated for extended release, and is the only once-daily minocycline on the market. This attractive differentiation has lead to swift uptake; the drug generated sales of $98m in its first year of launch, and the consensus for 2012 is $317m.

Minocycline lost patent protection almost 20 years ago, so Solodyn patents cannot be listed in the FDA Orange Book, because the product is classed as an old antibiotic. This means that when a generic version is filed with the FDA, if the company chooses to sue for patent infringement, it is not entitled to a 30-month stay, a level of protection that Orange Book-listed patents are afforded.

In addition, even though the NDA filing was supported by two phase III efficacy trials, Solodyn did not qualify for three year new product exclusivity, again because it is classed an old antibiotic.

Despite the lack of an Orange Book listing, Medicis states it has protection to 2018 based on the dissolution rate patent (‘838); this has been issued and could form the basis of a court case once the FDA approves a generic.

Impax generic filing

The robustness of this stance was tested by Impax, which submitted an ANDA for its minocycline hydrochloride extended-release tablets in October 2007. The generics firm filed a lawsuit the following January, requesting a court declaration stating that its product did not infringe the ‘838 patent, but it was dismissed in April. This was seen as mildly positive for Medicis.

In a stalling tactic, Medicis in March lodged a citizen petition requesting that the FDA does not approve any generic versions of Solodyn without requiring in-vivo bioequivalence testing for each strength of the drug. The basis of the petition seems plausible given the fact Solodyn is not bioequivalent to any other minocycline product.

This attempt by Medicis to delay generic competition may offer short-term respite; if granted generics would be required to do costly and lengthy head-to-head non-inferiority trials. If it fails, however, generic competition could enter the market fairly swiftly. And because no patents are listed in the Orange Book, generic challengers are not required to inform Medicis of their intention to launch, which could mean further unforeseen competition exists.

Modelling Solodyn scenarios

A worst case scenario would see the FDA rule against the citizen petition and approve the generic, within the typical 15 months from filing time frame, suggesting a potential January 2009 launch.

Based on current consensus forecasts, EvaluatePharma’s NPV Analyzer suggests Medicis’ market capitalisation should be closer to $1.8bn, rather than the current $1.1bn valuation. However, these forecasts are based on a best case scenario for Solodyn, with the ‘838 patent holding to 2018.
EvaluatePharma’s NPV Analyzer models the following scenarios:

<table>
<thead>
<tr>
<th>Scenario</th>
<th>NPV Analyzer Market Cap (NPV + net cash)</th>
<th>Share Price</th>
<th>Scenario valuation vs. current share price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Best Case: Solodyn Patent Holds 2018</td>
<td>$1,794m</td>
<td>$31.81</td>
<td>+57%</td>
</tr>
<tr>
<td>Worst Case: Generics from 1 Jan 2009 (Exclude entire Solodyn Product NPV of $636m)</td>
<td>$1,158m</td>
<td>$20.53</td>
<td>+2%</td>
</tr>
<tr>
<td>Current Market Cap. (as of 9 May 2008)</td>
<td>$1,139m</td>
<td>$20.20</td>
<td></td>
</tr>
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</table>

**Best case/worse case**

A protracted legal battle over Solodyn’s 2018 patent, delaying the competition, would be positive for the company, a scenario that the market is not currently factoring in. The NPV Analyzer suggests that the share price could gain up to 57% if the 2018 patent holds.

On the other hand, Medicis stock will undoubtedly react negatively to generic entrants. But it is worth remembering that removing Solodyn’s NPV entirely indicates a valuation in-line with current levels, suggesting the share price should recover, in that eventuality.

Also, the possibility that Medicis will file a new formulation of the drug in the near future cannot be ruled out. A company representative told EP Vantage that they are “evaluating new forms”. Any additional disclosure on new formulations would be positive, as it would increase the probability that the Solodyn franchise can be maintained.

**Looking beyond Solody**

Beyond the immediate concerns of Solody, Medicis investors could receive a significant boost if the company’s most important pipeline product, Reloxin, gets approved. It would be the only direct competitor to Allergan’s Botox in the near $500m facial aesthetics market. Allergan previously had to divest Reloxin following its March 2006 acquisition of Inamed.

Even with the US economic downturn, the current consensus forecast for Reloxin looks modest at $55m in 2009 and $98m in 2010.

The quicker than expected refiling of Reloxin in March, after an initial application rejection in January, has set up the following two milestones:

<table>
<thead>
<tr>
<th>Product</th>
<th>Event</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dysport (Ipsen only)</td>
<td>FDA Decision Date (PDUFA) on Dysport (botulinum toxin type A) for the Treatment of Cervical Dystonia</td>
<td>03/10/2008</td>
<td>03/10/2008</td>
</tr>
<tr>
<td>Reloxin</td>
<td>FDA Decision Date (PDUFA) on Reloxin (botulinum toxin type A) in Aesthetics</td>
<td>16/01/2009</td>
<td>16/01/2009</td>
</tr>
</tbody>
</table>

*Source: EvaluatePharma Alpha: Calendar of Events*

If the FDA were to give Ipsen’s Dysport, the same product as Reloxin but for cervical dystonia, approval in October 2008 this would surely improve the odds on the approval for the more lucrative Reloxin in aesthetics, in January 2009.

In February, the FDA announced a safety review of botulinum toxins. Although a concern for investor risk perception, the product has a well established safety profile.

**Solid player in a long term growth sector**

Although the generic threat to Solody is real, Medicis is a solid player in the high-growth US non-invasive cosmetic market. With its biggest-selling product Restylane already established in the dermal filler market, a Reloxin approval would transform it into a serious contender to Allergan’s dominance in this field.

And in the worse case scenario of Solody generics in 2008 and a delay to Reloxin’s FDA approval, Medicis would surely become a takeover target, with a rather attractive $795m cash pile.