Event - Transcept hoping for a dream approval

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With the PDUFA date for its lead product on October 30, hopefully Transcept Pharmaceuticals’ management team will not be experiencing too many wakeful nights over the prospects for the approval for their sleep disorder drug, Intermezzo.

Unlike the majority of sleep aids currently on the market, which focus on trying to get insomniacs to sleep, Intermezzo targets people who have no trouble falling asleep, but suffer from nocturnal waking. At present there are no approved products for this specialist indication, making it a very attractive niche opportunity. Zacks investment research has placed a $500m peak sale value on the drug and estimates royalties to Transcept of $97m by 2014.

The benefits of the drug are that as a sublingual treatment, it is designed to dissolve under the tongue in about two minutes, and can be taken without water, meaning that patients do not have to further disturb their sleep by getting up. Its duration of effect, between three to four hours, also means that it can be taken as needed with few lingering after effects the next day.

In terms of efficacy the product should stand a good chance of approval, the phase III trials showed that patients fell asleep on average 14 minutes after administration, with an impressive 90% of trialists dropping off within 30 minutes.

Long tradition

As the drug is a low dose sublingual reformulation of Sanofi-Aventis’ best seller Ambien (zolpidem), with a long track record of safety data, concerns on this front are minimal. Additionally, confidence about Intermezzo’s passage in front of the regulator can be gained by the FDA's approval in May of Orexo's Edluar, another low dose sublingual version of zolpidem for sleep initiation.

Intermezzo’s chances of commercial success have been significantly enhanced by the $145m US licensing deal it signed in August with private US company Purdue Pharma, which included a chunky $25m upfront fee and gave Transcept the option to co-promote the drug in the psychiatry market a year after launch. Given the group’s ambitions to become a fully integrated pharma company it is an option that Transcept will almost certainty take up (Transcept rolling in cash after Purdue deal with more on the horizon, August 4, 2009).

The expected $30m milestone it should receive on approval will not only increase Transcept's already healthy cash balances of $98.4m as of June 30, but help make this plan a reality. Wisely, Purdue has attached a penalty to the payment to guard against delays, with the figure declining by $2m a month if there has been no green light from the regulator by the end of June 2010.

If Transcept, which gained its NASDAQ listing from a reverse merger into Novacea earlier this year, does get approval then the payment of the milestone and prospect of double digit royalties could see the shares, which have already tripled since their debut in February to $14.83, rise even further (EP Vantage Interview – Transcept capitalising on Novacea’s cash opportunity, April 7, 2009).

Competition

In terms of competition for this market, Transcept appears to be significantly ahead. Other treatments in development include NovaDel Pharmaceuticals’ ZolpiMist, a low dose oral spray formulation of zolpidem, which in December received approval for sleep onset and is currently in phase II trials for middle of the night waking.

At a much earlier stage is Alexza Pharmaceuticals' AX-007, an inhaled low dose version of zaleplon.

However, the product that could provide the biggest threat to Intermezzo is Somaxon Pharmaceuticals’ Silenor, which has a PDUFA date of December 4. The product has a slightly different mode of action being a histamine H1 receptor antagonist; in February 2009 it received a complete response letter because the company decided not to include safety data over QT intervals in its submission, despite having the data,
causing the FDA to give a red light ([Somaxon reeling from Silenor rejection, February 27, 2009](#)).

If Silenor does get approval, Transcept’s partner Purdue will have to work hard to fully capitalise on its slender four week, first-to-market advantage.