Intermezzo approval not the end of Transcept thriller

For Transcept Pharmaceuticals, FDA approval of its middle-of-the-night insomnia pill is not the end of the story. The final twist in their thriller is a decision by partner Purdue Pharma due by December 8 on whether to commercialise Intermezzo in the US or hand the rights back.

After watching its $30m approval milestone dribble away following two FDA rejections, executives will be anxious for the credits to roll on this unexpectedly long saga with everyone living happily ever after. A negative decision from Purdue would put Transcept in the unenviable position of having to find a new marketing partner for a sleeping pill that has faced multiple safety questions on its path to market (Intermezzo disappointment another rude awakening for Transcept, July 13, 2011).

Dosing, warnings

Yesterday, the FDA gave a thumbs-up to Intermezzo, a fast-acting, low-dose formulation of zolpidem tartrate, the active ingredient in Sanofi's branded medication Ambien. The aim is to treat insomnia after waking in the middle of the night, and thus the dosage needed to be modulated to take into account the fact that patients would need fewer than the seven to eight hours of sleep recommended on the Ambien label. Intermezzo's label warns against taking it if patients have fewer than four hours of planned sleep remaining.

In a call with investors, Transcept executives said they were pleased that the label did not warn against driving in the morning following a dose of Intermezzo if taken with more than four hours of bedtime remaining, a concern the regulators had expressed in an earlier rejection (Transcept's insomnia drug approval process turns into nightmare, October 29, 2009).

Approval also came after Transcept agreed to a half dosage of 1.75mg for women, in recognition of different metabolic rates.

The decision pleased investors – shares rose 27% to $8.49 yesterday immediately following the in-market announcement of approval, before settling down to close at $7.34, an 11% gain on the day. The hope that Transcept would soon be seeing a $10m fee for handing over intellectual property to Purdue and banking a double-digit royalty stream, estimated at $11.4m in 2014 by Zacks Investment Research, is heartening news for investors.

Given the two previous complete response letters - the second which forced the company to cut its staff to just 17 from 31 even as it was trying to put a second compound, TO-206, into phase II trials in obsessive compulsive disorders - approval must be taken as incredibly good news.

The big momentum

Continuing the momentum, of course, will depend on the final word from Purdue. The private Connecticut specialty pharma group has 10 working days to decide whether to follow through with the deal. Arguing in favour of Purdue taking on Intermezzo is its unique place in the sleep-medicine space, a pill meant to help people to get back to sleep. The Zacks analysts estimate that this will be worth $50m in sales in 2014.

Arguing against is the safety worries that have dogged Intermezzo, along with the disappointing returns for Silenor, Somaxon's new product which fills a similar sleep maintenance niche (Somaxon wins approval for Silenor and hunt for partner begins, March 19, 2010). Its numbers have been unimpressive - $12m in sales in the first nine months of 2011 against full-year consensus estimates of $25m – and its marketing partnership consisted of hiring the OTC sales force of consumer products giant Procter & Gamble. Somaxon's shares have suffered as a result - down 77% so far this year to a two-year low of 73 cents.
Intermezzo could, of course, perform significantly better; however, Silenor’s record does not necessarily lend confidence to such a scenario. Thus Purdue’s decision will be as keenly awaited as the FDA’s and the champagne at Transcept’s offices remains on ice.