BIOBUSINESS BRIEFS

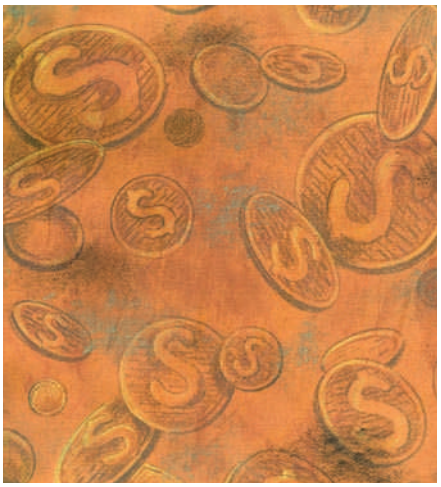
MARKET WATCH

Upcoming market catalysts in Q3 2010

Efforts to develop new anti-obesity drugs will face a critical test when two of the three therapies currently under consideration by the US FDA for regulatory approval — phentermine/topiramate (developed by Vivus) and lorcaserin hydrochloride (developed by Arena Pharmaceuticals) — come before FDA advisory committees in the third quarter.

A panel is expected to convene on 15 July to review phentermine/topiramate, for which the Prescription Drug User Fee Act (PDUFA) date is 28 October. Phentermine/topiramate given once daily showed greater weight loss than currently approved products and other late-stage drugs, with a 1-year placebo-subtracted weight loss of 8.6% for the high dose (15 mg phentermine IR/92 mg topiramate CR) and 6.6% for the mid-range dose (7.5 mg phentermine IR /46 mg topiramate CR). Additionally, weight loss relative to baseline of 13.2% and 10.5%, respectively, was seen for patients completing the trial. Although this weight loss is superior to other therapies, the main issue to be addressed before approval is safety. Topiramate is approved for seizures and migraines, but has some rare side effects, such as cognitive impairment and glaucoma, which could raise concerns in the broad population that would receive an obesity therapy.

The advisory committee meeting for lorcaserin, which has a PDUFA date of 22 October, is scheduled to take place on 16 September. Lorcaserin has demonstrated weaker efficacy than phentermine/topiramate, with placebo-subtracted weight loss ranging from 3.6% to 4%, which does not meet one of the FDA efficacy benchmarks for approval: a mean weight loss at least 5% greater than placebo (*Nature Rev. Drug Discov.* 8, 833–834; 2009). However, the 10 mg twice-daily dose will probably meet the alternative efficacy benchmark, which is based on the proportion of patients losing at least 5% of body weight; a third of patients lost more than 10% of weight relative to baseline. In addition, lorcaserin does not seem to have major safety issues.



Although a positive vote at the advisory committee meeting and approval would represent a large step forward for the company, confidence in the commercial potential of lorcaserin is uncertain given its modest efficacy.

The decision on the efficacy/safety balance of these two therapies may depend on the extent to which panel members see the obesity epidemic as a disease to be treated or as a lifestyle-change people should make. The data generated on the impact on co-morbidities such as diabetes, dyslipidaemia and sleep apnoea will also have a key role in this debate. It is interesting that the FDA did not try and hold both panels at the same time given the similar patient populations. It may be because of the diverse targets that the drugs act on, which means that different physician specialties are needed to evaluate each drug. Given the strong need for obesity therapies, it seems likely that the panels would vote for approval in each case, but a major question is whether the FDA would then follow the panels' advice.

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