

## No Joy for Obesity Drug Developers

### Updates from Vivus, Amylin, and Arena

Drug name: **Pramlintide/metreleptin**

Developers: **Amylin** (AMLN) and **Takeda**

Probability of Approval: **0%(F)**,  
decreased from 47%(B)

Drug name: **Qnexa**

Developers: **Vivus** (VVUS)

Probability of Approval: **49%(F)**,  
unchanged

Estimated Approval Date: **August 2012**

2018 Worldwide Revenue Estimate  
(assumes approval): **\$862 million**

Drug name: **Lorcaserin**

Developers: **Arena** (ARNA) and **Eisai**

Probability of Approval: **43%(F)**,  
unchanged

Estimated Approval Date: **November 2012**

2018 Worldwide Revenue Estimate  
(assumes approval): **\$671 million**

- Data from **Qnexa's** (Vivus; VVUS) phase III program released at the American Association of Diabetes Educators (AADE) yesterday **do not change our cautious outlook for the drug.**
  - Patients treated with full dose Qnexa during the 56-week EQUIP and CONQUER trials showed statistically significant improvements in quality of life versus placebo, as measured by two surveys.
  - More color will come from the FORTRESS study, a retrospective observational study of fetal outcomes of offspring of women exposed to topiramate, in the fourth quarter.
  - Qnexa's inThought Approvability Index (IAI) remains **49%(F)**. We estimate approval in **August 2012** and forecast 2018 worldwide sales of **\$861 million** if approved.
- Also in obesity drug news, Amylin (AMLN) and Takeda have discontinued development of **pramlintide/metreleptin**. The decision is largely attributed to the requirement for unwieldy injections multiple times per day.
- Finally, results from the Pathology Working Group's (PWG) re-adjudication of female rat mammary tumor diagnoses show that adenocarcinomas were no longer numerically higher after treatment with Arena (ARNA) and Eisai's lorcaserin than in the control group.
  - These results do not change our outlook for lorcaserin. Lorcaserin's IAI is **43%(F)**, with a **November 2012** estimated U.S. approval date and, if approved, 2018 worldwide sales potential of **\$671 million**.

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