
Vivus 4Q15 - Qsymia (phentermine/topiramate extended-release) revenues grew 10% YOY and sequentially flat at \$14M; Company continues working with FDA to redesign CVOT ACQLAIM - March 9, 2016

Executive Summary

- This afternoon, Vivus provided its [4Q15 update](#) in a call led by CEO Mr. Seth Fischer. Qsymia (phentermine/topiramate extended-release) sales grew 10% year-over-year (YOY) and remained flat sequentially at \$14 million in 4Q15.
- Total-year revenue for Qsymia totaled \$55 million for 2015, a 20% YOY growth.
- Regarding the overall obesity class, Qsymia, Arena/Eisai's Belviq (lorcaserin), and Orexigen/Takeda's Contrave (naltrexone/bupropion extended-release) totaled \$34.9 million in 4Q15, a 31% YOY increase; year-end revenues totaled \$153 million, a 58% YOY increase.

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Notably, management provided an update on its plans to discuss redesigning its CVOT ACQLAIM with the FDA. According to the company, the advising epidemiology and cardiology experts believed that Qsymia's safety profile to date does not demonstrate overt CV risk and that an additional CVOT would not provide additional information. We learned that Vivus recently provided this update to the FDA as part of its quarterly communication but that no further meetings have yet been determined, although the company expressed strong commitment to resolve the issue with the Agency. As the CVOT regulatory framework in diabetes drugs evolves (now with positive [LEADER](#) results), we will be curious to see how this issue develops regarding obesity drugs, with the added layer of the market's limited resources. While we do not expect the FDA to lift this requirement at this time, this is speculation only. That said, we do not know how Vivus could afford the CVOT given the low cash balance of \$242 million at year end.

Regarding the overall obesity class, Qsymia, Arena/Eisai's Belviq (lorcaserin), and Orexigen/Takeda's Contrave (naltrexone/bupropion extended-release) totaled \$34.9 million in 4Q15, a 31% YOY increase; year-end revenues totaled \$153 million, a 58% YOY increase. However, it is important to note that Contrave only launched halfway through 4Q14, leading us to believe that the increased revenue is due to the additional sales from Contrave. Ultimately, 2015 saw revenue growth for the market of nearly 60% and growth for Vivus of just 20%, from a smaller base.

- **Management also announced that Vivus will continue its specialty sales force pilot program targeted toward liver disease specialists** after having assessed its results - while there were no details on the findings, we would suspect they must have been relatively positive (perhaps as specialists are more willing to prescribe than PCPs).

-- by Melissa An, Sarah Odeh, and Kelly Close