

VIVUS, Inc

New Qsymia REMS Is a Critical Step in the Right Direction; Now Will Sales Follow? - ALERT

We are reiterating our OW rating on VVUS following this afternoon's announcement that the FDA has approved the Qsymia REMS modification allowing access through certified retail pharmacies (as opposed to just certified mail-order pharmacies). We regard this as a clear positive (and necessary) development for VVUS, as we've been saying for some time that driving sales would be a function of 1) increasing drug accessibility (modifying the REMS and improving the reimbursement landscape), and 2) increasing physician/patient education/experience (through Feb 15, Qsymia had been prescribed to >27K unique pts with a prescriber base of almost 12K). Both of these will be key to building this market, and today's news is a big step on the accessibility front. We anticipate continued positive follow-through from this for two main reasons; 1) investor skepticism made this a "show me" event (despite management optimism), and 2) from an investment standpoint, obesity names are currently driven by perception and sentiment. Now that VVUS has the new REMS in place the perception that this could facilitate a significant acceleration in sales should increase, thereby facilitating a much needed boost in sentiment. While we remain optimistic that this launch can and will all come together, we anticipate the jury could remain out until more clear-cut evidence is available (i.e., there is an uptick in actual scripts and sales).

- **Along with reimbursement, Qsymia's limited distribution system was a significant barrier to patient accessibility.** The specialty distribution system and exclusive availability through mail-order pharmacies have made it tougher to get access to Qsymia to date. The procedure also differed by regional guidelines, and in some states (for example, NY), a script could not even be faxed in by physicians but actually had to be mailed in, further slowing the process. While the existing certified mail-order pharmacies will remain in place, today's announcement will increase Qsymia's availability by reducing the prescribing burden for docs and wait times for patients to receive the drug. We believe that amending the REMS to allow access through regular retail channels (as well as payors beginning to make coverage policy announcements) will go a long way to helping restore some optimism in Qsymia's outlook.
- **VVUS expects Qsymia to be available at certified retail pharmacies within 90 days.** We would also note that the timing of this REMS modification is in line with company guidance of mid-April. VVUS had submitted a REMS amendment to the FDA to expand its distribution capabilities (announced on October 17), and a decision was expected within six months of submission (so by mid-April).
- **This should also serve as a credibility boost for the company.** VVUS management has long exuded confidence in achieving this modification to the REMS. In fact, as recently as the 4Q12 conference call, VVUS said it had received initial feedback from the FDA and remained very confident. However, we believe some investor skepticism remained, making this a "show me" event.

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Overweight

VVUS, VVUS US

Price: \$11.16

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Biotechnology

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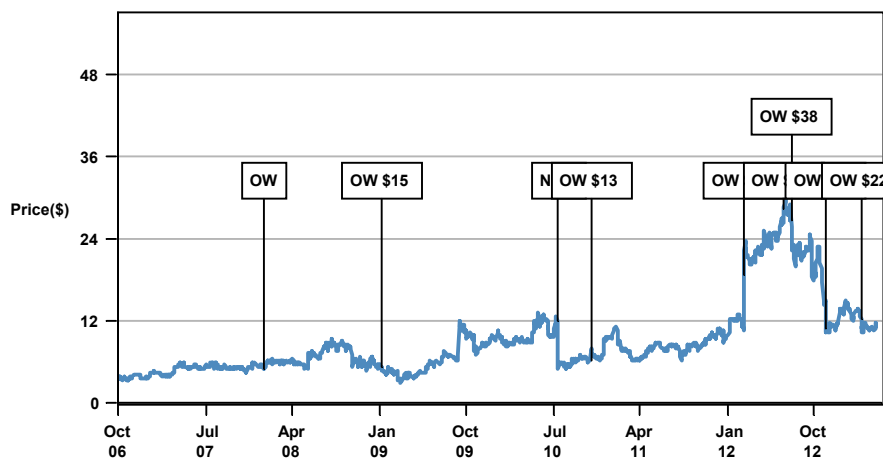
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VIVUS, Inc (VVUS, VVUS US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
03-Jan-08	OW	5.04	-
06-Jan-09	OW	5.32	15.00
16-Jul-10	N	12.11	6.00
29-Oct-10	OW	6.13	13.00
23-Feb-12	OW	18.73	30.00
27-Jun-12	OW	28.33	35.00
18-Jul-12	OW	26.46	38.00
06-Nov-12	OW	10.96	25.00
26-Feb-13	OW	12.41	22.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends. Initiated coverage Jan 03, 2008.

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