Closer Look

MEMORANDUM

Vivus 2Q14 - Qsymia posts revenue of $11 million, up from $9 million in 1Q14 and $5.5 million in 2Q13 - August 14, 2014

Executive Highlights

- Qsymia posted revenues of $11 million in 2Q14, an increase from 1Q14's $9 million and 2Q13's $5.5 million; the number of Qsymia prescriptions experienced 14% growth.
- Reimbursement for Qsymia grew slightly from 36.7% of scripts to 37.4%, though management seemed optimistic about the direction of the payer landscape.

Last Thursday, Vivus reported its 2Q14 financial update in a call led by CEO Mr. Seth Fischer. Below are our top five highlights from the presentation, followed by Q&A.

1. Qsymia revenues increased to $11 million in 2Q14, up from $9.1 million in 1Q14 and $5.5 million in 2Q13.

2. The number of Qsymia prescriptions increased to 138,000 in 2Q14 from 1Q14's 121,000 prescriptions; this trend signifies a reassuring change from the 2% drop in prescriptions between 4Q13 and 1Q14.

3. Qsymia experienced a small growth in the percentage of scripts covered by third party payers, and management highlighted many of the discount programs offered to expand accessibility and patient persistence.

4. Management vaguely noted that the EMA and FDA have both given Vivus "helpful feedback" on the modified protocol for Qsymia's CVOT.

5. No updates were provided on Qsymia's partnering efforts..

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TOP FIVE HIGHLIGHTS

1. Qsymia revenue increased to $11.0 million in 2Q14, up from $9.1 million in 1Q14 and $5.5 million in 2Q13. These numbers signify a 21% sequential increase and a doubling of year-over-year revenue. Management credited Vivus' "efficient commercial efforts" in holding Qsymia market share stable despite the enhanced competition within the obesity field - this is a different tone than Vivus used to take on the matter of competition, as the company used to indicate that a rising tide of resources in the underdeveloped market would raise all boats. We do think if Novo Nordisk's liraglutide for obesity is approved that more visibility on fighting obesity will help all the compounds in the field.

- **As a reminder, Vivus records Qsymia revenue on a sell-through method,** which means revenue is recognized only when a prescription is dispensed. Vivus had shipped $22.2 million of Qsymia to the wholesaler in 2Q14, which is significantly higher than the $10.5 million shipped in 2Q13. It is our understanding that Eisai records revenue at the time of delivery to the wholesaler, suggesting that Qsymia revenue (as measured by distribution to the wholesaler) in 2Q14 was 54% higher than that of Belviq's $9.9 million.

Table 1: Qsymia revenue (as measured at the time of prescription dispersal)

	2Q13	3Q13	4Q13	1Q14	2Q14
Revenue (USD millions)	$5.5	$6.4	$7.7	$9.1	$11.0
Sequential Growth	-	16%	20%	18%	21%

2. The number of Qsymia prescriptions increased to 138,000 in 2Q14, up from 1Q14's 121,000 prescriptions and 2Q13's 81,000 prescriptions. This boost in scripts was reassuring to see, since the quantity had declined slightly in 1Q14. Net revenue per prescription (including free trial offer scripts) was $80, as compared to $76 in 1Q14 and $68 in 2Q13 - Vivus' goal is to reach $100 by year-end 2014.

- **Orexigen explained that it continued to focus its marketing efforts on the most productive prescribers within the anti-obesity market throughout 2Q14.** Management expressed confidence in their current field sales alignments (which were shifted in 1Q14), commenting that they frequently examine deployments and resource allocation, making adjustments whenever necessary.
- **In the call, Vivus detailed how its messaging to providers focuses on the high need patient.** Management explained that representatives depict what 10% weight loss can accomplish. This information helps potential prescribers understand what specific patient types will benefit and also helps existing prescribers consider treating additional patients with Qsymia.
- **Vivus has the smallest sales force in the obesity market, with only 150 representatives.** For context, Eisai has 600 representatives for Belviq while Orexigen has a planned sales force of 900 representatives for Contrave.

Table 2: Qsymia script rates

	2Q13	3Q13	4Q13	1Q14	2Q14
Prescriptions	81,000	109,000	124,000	121,000	138,000
Growth from Prior Quarter	37%	35%	14%	-2%	14%

3. Coverage for Qsymia improved slightly in 2Q14 and management continued to express confidence in the future of the payer landscape. Coverage for Qsymia underwent a small increase to 37.4% of scripts dispensed (excluding free trial offer prescriptions) in 2Q14 from 36.7% in 1Q14. Though this was not the sizable increase in access we hoped to see for patients, management expressed confidence that the payer landscape is evolving in a way that will improve their contracting and reimbursement. Prior to 1Q14 Vivus had been reporting reimbursement as the percentage of commercial lives so it is challenging to determine the more long-term trend in coverage.

- **In the call, Vivus highlighted its efforts to lower out-of-pocket costs for patients and its recent changes to the Qsymia discount offers.** Vivus currently provides a discount of up to $75 off any amount of co-pay above $60 for covered patients and a cash discount of $75 for patients who are paying cash. Both of these offers cover all doses and are effective for up to 12 prescriptions. The company is also keeping the "Free to Start" program, which provides the first 14 days of Qsymia starting dose free of charge to patients. Management noted that these programs will broaden the availability of savings and extend the time period of saving, which will hopefully increase Qsymia utilization and patient persistence.

- **Vivus also works at the provider level, supporting prescribers with reimbursement assistance services.** Market research done by Vivus showed that many prescribers find it challenging to understand prior authorization procedures and to secure reimbursement for such medications. Therefore, Vivus has provided services to lessen the burden for prescribers and their administrative staff. Messaging also purposely raises providers' awareness of the availability of Qsymia as a prescription benefit.
- **Due to the REMS modification in mid-2013, Qsymia is now offered at over 40,000 pharmacies.** This modification eliminated the regulatory barriers to obtaining Qsymia at local certified retail pharmacies and thus the drug is currently available at various pharmacies, which includes major retail chains, independent pharmacies, mass merchandisers, and food stores.

4. Management commented that they have received "helpful feedback" from both the EMA and FDA regarding the company's modified CVOT, AQCLAIM. As noted in Vivus' 1Q14 update, Vivus modified the design of Qsymia's CVOT for the FDA in order for the trial to meet the EU's pre-approval requirements. Vivus since submitted the modified protocol to the FDA, and received feedback from the FDA. Vivus noted that in response to the FDA's feedback, it is working to ensure that the planned interim analysis will continue to uphold the study's integrity (see our coverage on the FDA hearing on CVOT interim data disclosure here) and will support the regulatory pathways in both the US (post-approval assurance of safety) and EU (pre-approval).

5. No updates were provided on Qsymia's partnering efforts, but management noted that they continue to be open to establishing commercial alliances for Qsymia on a global or regional basis if it creates value for stockholders. In the call, Vivus commented that it could not provide information on timing or structure of a partnership, but promised to report updates in the case of any material developments.

- **The weak emphasis on partnering efforts continues a trend we have seen since the company's 4Q13 call.** Vivus' prioritization of finding a partner seems to have lessened, which may be due to Qsymia's less than stellar market success. However, as we noted in our 1Q14 report, we believe that the ROI for a partner remains high since Qsymia works very well in some patients and addresses a massive unmet need.

QUESTIONS AND ANSWERS

Q: What could you tell us about how you're potentially able to leverage the independent studies like the one recently published by Duke regarding Qsymia being good value for money?

A: Based on the fact that it's a third-party trial, we really are not able to leverage it from a sales and marketing standpoint, although we are very pleased with the very broad pickup of that study. There are many different periodicals that have picked up on that study. And certainly, as we move forward in managed markets, it's important information for them to look at from a pharmacoeconomic standpoint.

Q: What can you say about the potential or the average duration of therapy?

A: What we've seen so far is that the average duration of therapy is fairly consistent with what we saw in mail order and in retail. It's approximately four months.

Q: What is the percentage of scripts covered by insurance in 2Q14?

A: The actual number of scripts covered in 2Q14 - the ones actually paid for by a third party - is 37.4%.

Q: Can you just give us your thoughts currently on timing of initiation for a claim? It sounds like even though you've gotten feedback from the FDA, there may be a couple things you want to finalize with the protocol, so will this initiate in 3Q14?

A: In our plan right now, we're doing all the work up to get to patient initiation of that trial. We do believe that there's a very important hearing on Monday [August 11] with the FDA [Editor's note: see our coverage of the hearing here], specifically around CVOTs' interim analyses, which we know is going to be very important to

our submission in Europe so that we do not sacrifice the integrity of the study. But our plan is to move ahead and begin that trial. The timing exactly is hard for me to state right now, but in the near term.

-- by Melissa An, Hannah Deming, and Kelly Close