Closer Look

MEMORANDUM

Arena 2Q15 - Belviq (lorcaserin) revenues up 22% YOY though down 6% sequentially to $12.1 million; FDA provides company with feedback on phentermine/lorcaserin combination - August 12, 2015

Executive Highlights

- Arena just provided its 2Q15 update in which management reported that Eisai recorded Belviq (lorcaserin) revenues of $12.1 million (of which Arena received $4.3 million) in 2Q15, up 22% year-over-year (YOY) but down 6% sequentially.
- Management stated that they have recently received feedback from the FDA on the phentermine/ lorcaserin combination and that the company is extending market research efforts on the smoking cessation indication for Belviq.
- During 2Q15, the obesity market grew 101% YOY and 12% sequentially to $42.1 million in 2Q15. The majority of the growth stemmed from Orexigen's launch of Contrave (naltrexone/bupropion), which generated $16 million in 2Q15, taking up 38% of market share.

Arena provided its 2Q15 update in a call led by CEO Mr. Jack Lief last week. Management reported that Eisai recorded Belviq (lorcaserin) revenues of $12.1 million (of which Arena received $4.3 million) in 2Q15, up 22% year-over-year (YOY) though down 6% sequentially. IMS Health estimates placed total Belviq prescriptions for the quarter at 183,000 in the US, representing 66% YOY growth and 9% sequential growth (implying reduced pricing and growth in discounting, which we suspect is likely due to Eisai's savings program). During Q&A, management also stated that the gross to net discount was 53% in 2Q15. In addition, management noted that Ildong Pharmaceuticals estimated ~1.8 million Belviq tablets were prescribed in South Korea in 2Q15, representing ~29,000 one-month prescriptions (one tablet is to be taken twice daily), ~16% of the US's total Belviq prescriptions - as a reminder, Belviq was approved in South Korea this past February. As adult obesity rates in Korea are only 4% in adults (according to OECD), we find this market an interesting one to choose as a second approval - we assume that Arena's confidence in Ildong Pharmaceuticals' marketing experience with obesity products (as stated in the press release) may have driven this choice, although Orexigen has also followed this trend with Contrave (naltrexone/ bupropion), perhaps indicating an easier regulatory route in South Korea.

Notably, management stated that the company and Eisai have just received feedback from the FDA on the phentermine/lorcaserin combination. While management emphasized that they cannot yet disclose any details on this feedback, they noted that the company will be evaluating this input in the near future. As background, proposed actions on this combination have ranged from label changes to a new fixed-dose combination - with all of the ongoing interest surrounding combinations, having the chance to develop a new combination obesity drug could have significant potential, although the challenges of the obesity market (i.e. low reimbursement and awareness) will undoubtedly still pose issues. Even so, having another treatment option for physicians will hopefully increase awareness for the need to treat obesity and the urgency of payers to recognize the need to cover these medications and increase access. On the smoking cessation indication, Arena stated that it is expanding market research efforts, which will be anticipated to complete in 4Q15. Although management provided no updates on the once-daily extended release formulation of lorcaserin (Belviq XR), they highlighted that the company plans to file an NDA later this year for the product, which we learned in 1Q15. Overall, Arena's sequential decline is not positive news on balance but the support of its partner Eisai and the promise of the smoking cessation and the combination

with phentermine may work for the company going forward. Q&A is shown below, including details on the company's plans with the phentermine combination and additional geographical regions being considered.

- **During the call, the company mentioned its supporting efforts to increase patient access, as Arena continues to work on approval in additional regions.** Similar to 1Q15, the call mentioned that Arena and Eisai are continuing to work with health authorities in Mexico and Brazil to gain marketing approval in these territories. Obesity is a major problem is Mexico of course (more than one in three adults there is obese according to OECD); interestingly, some gains there have been made with the advice of the Mayor Michael Bloomberg of New York City.
- **Looking at the entire obesity market, as Vivus, Arena, and Orexigen have all reported for 2Q15, the obesity market has grown 101% YOY and 12% sequentially to $42.1 million in 2Q15.** With the exception of Novo Nordisk (which did not report individual Saxenda [liraglutide 3.0 mg] revenues), the obesity market's revenues doubled from 2Q14's $20.9 million, although this growth includes the new addition of Contrave. Sequentially, the market grew 12% from 1Q15's $36.9 million, of which Contrave was on the market for both 1Q15 and 2Q15. The majority of this YOY growth stemmed from Orexigen's launch of Contrave (naltrexone/bupropion), which generated $16 million in 2Q15, taking up 38% of market share. With the launch of both Contrave and Saxenda, we expect the obesity market to see some significant growth; however, as sequential growth has been relatively slow, we hope that this market expansion will generate critically needed noise with regards to reimbursement and the need for more treatment options within obesity.

Questions and Answers

Q: Can you elaborate on the process that you're going through in deciding what to do for smoking with Belviq? You mentioned you're doing a market analysis, but what are you looking for there and where are you in discussions with the FDA about that?

A: So Eisai and us continue to assess Belviq for smoking cessation by conducting thorough analysis of the current market opportunities and projected market opportunities as you can imagine. It's not just about the efficacy of the drug, but do we need a weight-loss component in this? What are the current therapeutic options? Where are these options going? And is this the best use of our focus right now? And we'll see, we're still in that process and we'll let you know as we have more information about that.

Q: I wanted to follow up a bit on the smoking. So the gating event here is in the evaluation of the market, but have there been any discussions with the FDA in terms of what they would want for a regulatory trial there or are you just putting off a meeting with the FDA until after you finish this market analysis?

A: Yeah. We want to figure out what we want to do first because as you can imagine the FDA wants to see what your plans are and then they'll give you thumbs up or thumbs down on those things or make some suggestions on that. Regarding strategy, we are talking with a number of potential big pharma partners continuously on not just any one product, but most of our products. And clearly, we're committed to improving the value, the overall stockholder value for Arena. And partnering is potentially one way of doing that, but we're open to a variety of possibilities and we'll report as is appropriate. As you can imagine, we don't talk about ongoing discussions.

Q: On the phentermine combination, did you have a separate meeting specifically for that development program? And I know you said you just received the minutes, but at least, can you tell us whether this feedback was positive about a potential combination strategy there?

A: Well, we did receive some information just now. But we can't comment on ongoing discussions with the FDA as it has been our practice. So we will as is appropriate.

Q: But there was a separate specific meeting just for the phentermine combination?

A: Yes. We presented some of our plans. They gave us preliminary feedback and now we're going to be evaluating that with Eisai. But we have not had a chance to talk with Eisai about that.

Q: On the smoking sensation, it looks like the plans for the next step have been pushed out while you're completing your assessment. And on the latest, you have said that there's no study this year. Is it possible that you might not push through this indication when we go into next year?

A: Well, there are a lot of possibilities, so I don't want to speculate on any of these. I think we just have to get through the process. As you've heard, we have a lot of programs that are ongoing right now, and we're focused on generating stockholder value with those programs. So I think Belviq is one of them. I think Belviq has a lot of good features to it. We believe it's a product that addresses the real patient need. Eisai and us believe that there's significant potential for this product and obviously reimbursement is important. There is the Treat and Reduce Obesity Act. Eisai has a sales force of 320 sales reps. There's an ongoing cardiovascular outcome study that I think could be significant in the future opportunities here.

And there's a lot of new territories that are being evaluated. We're very successful in South Korea and that's doing well. But it's still yet to come. Hopefully, we'll hear from Mexico, Brazil, Israel, Taiwan. There's an EU filing coming up at the end of March based on what Eisai has communicated. And keep in mind that there was an 8% increase in scripts over the first quarter.

Q: Can you tell us what is the type of discounting that's currently offered of the gross to net?

A: So in this past quarter, our gross to net discount was 53%. It was a little bit better than Q1. And I think that is due to seeing our new "pay no more than $75" savings program come on board at the beginning of the year and we see our voucher redemptions slightly decrease over that time period as well.

Q: Can you give us progress on the DTC marketing for BELVIQ, and how long you expect to continue the program?

A: So Eisai is spending dollars, significant amounts of money on promotion. They plan to continue the current DTC advertising for the foreseeable future.

Q: I know you don't want to talk about your communication with FDA regarding the phentermine combination, but can you tell us what's the next step? Are you meeting with the FDA or are you going to discuss this with Eisai and decide what to do?

A: We literally just received the feedback from the agency. So we have not had a chance to discuss it with Eisai. So that is the next step we need to look at. We propose a specific development plan. We need to see what the FDA thought about the development plan, what suggestions they have to potentially modify it, have the discussion with Eisai and then decide how to move forward from there.

I know I sound like a broken record, I'm sorry. One of the things that we said with combination is that it really matters on what the requirements are going to be for a combination study. If we have to do a "Belviq-like" study with 8,000 patients and 20,000 echoes in the CVOT, that's going to be pretty onerous. So we'd have to seriously reflect on whether we want to go forward with something like that.

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