Closer Look

MEMORANDUM

# Orexigen 3Q15 - Contrave (naltrexone/bupropion extended-release) revenues decline 20% to $13 million; Orexigen interested in co-promoting product and expresses enthusiasm for partnering efforts and European Mysimba launch; Light Study analysis completed - November 25, 2015

**Executive Highlights**

- Contrave (naltrexone/bupropion) revenues totaled $12.8 million (as recorded by Takeda) in 3Q15, of which Orexigen received $2.6 million in royalties; revenues thus declined 20% sequentially, marking its first decline since launch.
- Management also shared that it is "eager to co-promote Contrave" alongside Takeda in the hopes of building new value for shareholders, although no further details were provided.

*We're back with expanded coverage of Orexigen's 3Q15 financial update, which was recently held in a call led by CEO Mr. Michael Narachi. Contrave (naltrexone/bupropion* extended-release*) revenues totaled $12.8 million (as recorded by Takeda) in 3Q15, of which Orexigen received $2.6 million in royalties. This result translates to Contrave's revenues declining 20% sequentially, marking its first decline since launch. Total prescription volume grew 10% sequentially to 190,201 prescriptions - we suspect this contradicting growth is likely due to the product's patient savings programs. Notably, the company also shared that it is "eager to co-promote Contrave" alongside Takeda in the hopes of building new value for shareholders, although no further details were provided. Management additionally expressed what sounded like renewed attention on the partnering process, as management outlined a "market by market" approach with specific focus on geographic regions including Europe, Latin America, and Australia. Regarding recently acquired partner Kwang Dong Pharmaceuticals, the announcement stated that the company has filed an NDA in South Korea. Otherwise, much of the call focused on confidence in Mysimba's launch efforts in Europe, as management detailed reasons including motivated patients, a different competitive landscape, and a greater obesity specialty concentration. On the R&D front, we learned that the analysis of the Light Study has been completed, after the company terminated the study in May. Management stated that they believe the results to be generally consistent with the 50% interim data; if findings support Contrave's safety profile, Orexigen expects final results to be published in a peer-reviewed journal.*

**Questions and Answers**

**Q: Regarding the European plans, it seems like there could be a series of press releases. But could you help us understand what might be the venue or format of how you would inform us on what's next? Or is there a certain trigger like a collaboration that you're looking to get done or just complete your work in terms of setting out those plans?**

A: You're right, there would be a series of substantial events that lead up to and then through the ultimate commercialization in Europe. But regardless of those specific triggers like transactions or pricing announcements, we do plan to provide a distinct update. As you can imagine, there's lots of information coming in. You can see how much information we've gathered just since our last call. So we think it will be important to plan in a venue coming early in 2016, perhaps on our call - we haven't figured out exactly when - but there will be an opportunity for us to give you an updated view of exactly how this will take shape, what kind of alliances. And as I mentioned, that will go hand in glove with our plans to update revenue and expense guidance for 2016. From everything we're envisioning, we plan to be able to execute with our current

estimates of revenue and expense. So we feel like our financial position is strong. So I just want to make sure that that's clear, and that's why we'll put those two things together early next year.

**Q: I wanted to ask if you could speak to the cardiovascular outcomes trial that is planned to start early in 2016. Could you perhaps provide a little more information on the design and sizing of that trial?**

A: That study is generally going to be similar to the Light Study in overall sample size, but perhaps a little larger. We will likely have a little higher baseline of end rate in order to capture events a bit more quickly. Generally speaking, it is exactly in keeping with the post-marketing requirement, which is to exclude an upper bound of the 95% confidence interval of 1.4, so essentially excluding with certainty a 40% increase in risk. That's the PMR and the final hurdle that we have to do in terms of exclusion of CV risk. And then in addition to that, the primary analysis is an applicable analysis for superiority and will be integrated into the statistical analysis plan. Takeda will be executing that trial and we're in the planning stages with them. I think that that execution will initiate in terms of patient enrollment early next year.

**Q: I had a question on this quarter's net sales. So when we were looking at the quarter-over-quarter growth of IMS, 10%, it seems like it would have implied a sales number that's in the mid-teens like around 17% maybe. Was there anything different this quarter in terms of gross to net, sampling, inventory that led to a reported number of about $13 million?**

A: So first of all, let me say we're limited in what we can say on this topic for competitive reasons and based on our contractual agreement with Takeda and the need for confidentiality on it generally. But I can tell you we're definitely watching it closely. The way we're trying to think about this issue is really the profitability per patient and the total dollars per prescription, which is a function of the net sales per script but also persistency and compliance. And so that's really the focus of our plans and actions. We certainly believe there is room for these dimensions to improve over time, but as you'd understand, it wouldn't be good to announce any specific tactics prior to the time we execute them.

**Q: I guess it looks like net sales went down this quarter. So I guess going forward, how should we think about success of the launch in terms of IMS or reported revenues, and to what degree do you expect growth on IMS to actually track revenues in the near to mid-term?**

A: So in terms of looking at overall prescriptions, I think what we're seeing is strong overall growth of the market, which is great, and nice steady growth of the brand. Over time, we expect through a set of plans and actions for that gross to net to improve. But I think that's about all I can kind of say in terms of the current relationship.

I think it's also important to just note that during the launch and as stability is created, there's some variance in the channels etc. So I think over time, it gets more and more predictable, and also we expect an improving trend on a profit per Rx, or profit per patient. And the tactics of how we get there, obviously we're not going to preannounce, but we expect you to see some evidence of that. I think you've heard us say prelaunch that there is a lot of focus on gross demand in the launch phase. And then later as we get more mature and we get a lot of demand and we get a broad set of prescribers and there is more and more coverage and access, we can work harder on profit per Rx.

**Q: I was wondering if you could provide some commentary on your financial bandwidth to build out a European infrastructure along with bringing in additional product.**

A: Maybe I'll give you a little bit of an overview on that first. Regarding the bandwidth to build out a European infrastructure, some of those centralized functions we can do very efficiently. And with respect to new assets, I think we have to think of those differently. So our current plans, when we say that our balance sheet is strong to fund things in the foreseeable future, we're talking about all of our current plans, all of our current commitments, the income and inflows that we expect. Any new asset acquisition prices or otherwise would fall outside of the strength of our balance sheet we talk about today. I just want to reiterate as well that we should end the year with over $200 million. So our net cash utilized in operations is estimated for this year to be

between $60 million and $65 million. We definitely see that we've got sufficient cash for the foreseeable future.

I think it's also important to recognize that we're not pulling income from this product. We anticipate income from additional partnering transactions and we have dialogue going on right now for rights to the product outside the US, like we did with Korea this year where we received $7 million upfront. And we'll plan to provide additional more detailed guidance on 2016 revenue and expense plans associated with the scope of any European go-to-market strategy early next year.

**Q: I'm trying to just reconcile the script growth to what the sales number was. And I know you can't talk specifically about it, but was it a combination of things? Gross to net, inventory, or something else we don't know about? I'm just trying to figure out why the sales were down sequentially.**

A: Yes, a combination. I think you'd be able to look at our focus on a profit per Rx even as a combination of things? So in addition to things that might happen in-channel etc., the profit per prescription is a function of a number of variables that you could predict, that we don't want to go into in any detail. And then the profit or the annuity per patient prescription is a function of compliance. So we're focused there. I think you're talking about just the reporting here and you're trying to track, because obviously you're getting weekly information or monthly information on IMS data gross demand and then you're only getting quarterly insight into our net sales. So maybe as time goes on, that's going to be a lot more predictable, and in this first year, there is a little bit of lumpiness in that.

**Q: So on the ex-US strategy, it sounds to me like you guys have kind of determined that you're going to go to a retail partnering structure in Europe. So you were saying that soon you're going to actually formally update your strategy. What's going to be new? It seemed to me like you've kind of finalized your strategy there. What sorts of things are you evaluating next?**

A: I think you're probably right in the vernacular of strategy and tactics. I think what you're going to see is some details. I think importantly, we plan to provide much more clarity on our revenue and expense in totality for 2016. And I think over time, you will also see exactly what kind of alliances we're forming and how broad that is across the 31 different markets in Europe and where we're focused. As we track the early days of any commercialization in Europe, we will understand what are predictors of success long before actual revenue starts to come in. So we'll lay out a lot more of how exactly is it going to go, where is it going to go, when is it going to go, and how you can tell if we're winning.

We've determined that it's going to be a market by market approach. We've spent a lot of time and we've gained a lot of information and I hope some of the content here gives you a view of the tip of the iceberg of information that we've been learning. And although the strategy in terms of commercialization is definitely different than perhaps you or we would have expected a year ago, we're actually really pleased with the way the market opportunity looks in Europe and we're eager to put this together and get after it.

**Q: When you consider the European market relative to the United States market over the last few years, would you anticipate a faster ramp in terms of adoption? It may take more work, but is it a better pay off? How would you characterize it relative to the US market?**

A: As I mentioned, because only orlistat is available today, it's a very underdeveloped market. And because of that it makes sense to go at it kind of in this three-phase approach. So I would expect a steady, continuous ramp-up. Ultimately we think there's tremendous potential in Europe. It's a very nice market. But I think you'll see it steadily. And again, you'll see it kind of at different slopes in each of the 31 countries. So I'd characterize this as a steady, continuous growth that you should be able to achieve over the lifecycle of the brand.

**Q: You've hesitated to talk about persistence in the past, but it seems like with refill rates of about 64% or so, you perhaps are putting together some data on that in the States. Can you speak to persistence at this point in terms of taking Contrave in the US or is that not the right way to look at it?**

A: No, we spend a lot of time looking at it. I think on the last call, I was updating you on the refill rates as I did today at 64%, which is in line with the other brands. I think to kind of finish all the adherence and persistency work, we really need to get through the remainder of the year and probably early into next year, as we said before, before I think we have anything thoughtful or meaningful to provide in terms of a comparison. So right now it's steadily moving along. All of the metrics seem to be moving in the right direction in that regard. But I don't have anything more tangible in terms of adherence or persistency.

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