CLOSER LOOK

MEMORANDUM

Takeda moves out of Contrave; Orexigen announces acquisition of US rights to Contrave (naltrexone/bupropion extended-release) and new agreement with Valeant in Europe - March 15, 2016

Executive Highlights

- This morning, Orexigen announced a "strategic" acquisition of all US rights to Contrave (naltrexone/bupropion extended-release), upon the company and Takeda agreeing to terminate the Amended and Restated Collaboration Agreement. To fund Contrave's commercialization, Orexigen has sold $165 million in convertible senior secured notes.
- In addition, Orexigen has announced a commercialization and distributorship agreement with Valeant Pharmaceuticals for 19 Central and Eastern European countries; Orexigen expects Valeant to launch Mysimba (Contrave in US) in the 12 EU countries in 2H16 and Valeant is also anticipated to apply for marketing authorization in the non-EU countries.

This morning, Orexigen announced a "strategic" acquisition of all US rights to Contrave (naltrexone/bupropion extended-release) as well as a commercialization and distributorship agreement with Valeant Pharmaceuticals for 19 Central and Eastern European countries. Regarding the acquisition of rights, Orexigen first published a press release, emphasizing that it is "jointly announcing" the acquisition with its partner Takeda, and that both companies agreed to terminate the Amended and Restated Collaboration Agreement (details in our 2Q15 report) for Contrave (subject to the parties' receipt of clearance under the Hart-Scott-Rodino Antitrust Improvement Act). Although the companies did not say, we imagine that Takeda drove the decision - see our September, 2010 report about the original agreement in which Orexigen received $50 million plus "up to $1 billion" in sales-based milestones that did not materialize. To fund commercialization of Contrave in the US, Orexigen has sold $165 million in convertible senior secured notes in a private placement to an investor syndicate led by funds managed by The Baupost Group, a fund we do not know, but who emphasizes "value" investing and is a "super secretive" hedge fund, according to Business Insider - here's a recent piece about the firm. That seems like a major bet by Baupost at a time of significant uncertainty. Orexigen has framed the news in a positive light, stating that this acquisition will "greatly increase long-term potential corporate profitability" and "create multiple paths to greater value creation for its shareholders." In the announcement, management also stressed that the timing of this acquisition is "particularly advantageous," as it follows the "heavily resourced commercial launch" by Takeda. Management thus highlighted that Contrave has a solid base from which to implement a "targeted, data-driven commercial plan."

In a separate press release, Orexigen also announced that Valeant Pharmaceuticals will commercialize Mysimba (Contrave in US) in Central and Eastern Europe. Given Valeant's reputation of late, we did not see this as an auspicious announcement, though it is some movement - probably not the best partner. Still, specifically, the distribution agreement includes 12 countries where Mysimba has been approved in the EU (Greece, Slovenia, Slovakia, Czech Republic, Hungary, Croatia, Lithuania, Estonia, Poland, Latvia, Bulgaria, and Romania) as well as several non-EU countries where Valeant will apply for marketing authorization (Serbia, Bosnia and Herzegovina, Albania, Macedonia, Montenegro, Kosovo, and Turkey). Interestingly, these do not include the major EU markets of Germany, Spain, France, etc. Timeline-wise, Orexigen expects Valeant to launch in the 12 EU countries in 2H16, so fairly quickly. Under the agreement terms, Valeant will be responsible for the 19 countries' commercialization activities and for obtaining regulatory approval in the non-EU countries; Orexigen will retain regulatory affairs responsibilities in EU countries and will supply Mysimba tablets to Valeant at an agreed transfer price.

- **In our eyes, the acquisition news comes as a bit of a surprise, as Orexigen only recently hinted toward eagerness to "co-promote Contrave" alongside Takeda.** While Orexigen seems very positive about this acquisition, we cannot help but assume this resulted from underlying tension from Takeda's formal dispute claiming material breach against Orexigen following the termination of the Light Study (due to compromising the scientific integrity of the trial) as well as, in general, a move away from diabetes and obesity. According to the press release, Takeda will move to increasing its promotional resources and support toward the company's recent launches in the inflammatory bowel disease and major depressive disorder areas. Indeed, the company does not seem to be moving anywhere near diabetes and obesity - its F3Q15 call dedicated zero attention to Contrave, similar to recent quarterly updates from Takeda.
    - **Without Takeda's support and marketing expertise, Orexigen has significant financial burdens to take on, especially as a smaller company.** Takeda's support, as part of the original agreement, included 75% of Contrave's post-approval development activity costs as well as potential support for the new CVOT. We thought Orexigen gaining funds through selling convertible senior secured notes to be notable, which implied at least one investor's confidence in the Contrave, but as the obesity market has recently been extremely weak, we see substantial pressure on Orexigen.
- **Orexigen's new agreement with Valeant was an interesting direction to turn. Some would say it was a logical next step with Orexigen's recent heavy focus on an ex-US partnership strategy though Valeant is certainly not a popular leader at present.** The international focus was heavily emphasized in both the 3Q15 and 4Q15 calls, where enabling 2H16 EU launches and partnering Contrave/Mysimba in rest-of-world territories were listed as two focus areas for 2016 for the company. From a public health standpoint, as long as Valeant invests appropriately, we are glad to see the path forward for greater access to obesity pharmacotherapies outside of the US, as these regions have very limited treatment options for a growing unmet need of obesity. As a reminder, Mysimba and Novo Nordisk's Saxenda are the only two obesity drugs approved by the European Commission aside from orlistat in 1998. To our knowledge, Saxenda has not yet been launched in the European region, meaning Mysimba could be the first to launch in this market. While we see Europe as a region of serious unmet need, much of the uptake and success will naturally depend on reimbursement - see our coverage of last year's ECO to hear KOLs' low expectations on this in the future.
- **Orexigen and Takeda agreed to a 180-day transition period following the closing of the acquisition transaction.** During this time period, Takeda will continue to market Contrave in the US and Orexigen will be entitled to continue to earn royalties on net Contrave sales. Both companies will also share clinical development costs as stated by the July 2015 Collaboration Agreement during this period. At the end of this transition period, Orexigen is then entitled to 100% of net sales and responsible for all expenses.

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