AuriPro NDA Accepted For Filing; Time-Line On Track For 4Q15 Action Date

Commercial Launch Still Expected In 1Q16

Buy

Price: $28.58

This morning, Otonomy announced the acceptance for filing of AuriPro's NDA for the treatment of middle ear effusion in pediatric patients undergoing tympanostomy tube placement (TTP) surgery. AuriPro is expected to be Otonomy's first commercial product with a launch expected in 1Q16 if approved.

FDA decision by YE15; no need for AdCom meeting; launch in 1Q16. Otonomy has not yet disclosed the PDUFA date. We expect that the review of the NDA will be a 10-month standard review calculated from the date of the NDA submission which was Feb 26th 2015. This allows us to project the FDA's announcement of an official action by YE15. Otonomy noted that no FDA Advisory Committee meeting would be needed based on its pre-NDA communication with the FDA. We believe there is a high probability for AuriPro to receive FDA approval based on the two successful Phase III trials in a total of 532 pediatric patients. The company expects the commercial launch of AuriPro in 1Q16. If approved, AuriPro will be the first product marketed for the treatment of middle ear effusion during TTP surgery.

AuriPro has a strong potential of being a commercial success. In our financial model we project peak WW revenue of ~$200M for AuriPro. We assume a pricing strategy of $200 to $250 per treatment for AuriPro, comparable to the pricing of Ciprodex at a wholesale acquisition cost (WAC) of $176 and an average wholesale price (AWP) of $211. Ciprodex is the most widely used antibiotic ear drop to treat middle ear effusion during TTP. However, it has not been FDA approved for this indication and it requires a dosing regimen of twice daily for seven days as compared to AuriPro's single administration to cover the whole course of treatment. In April 25th, Otonomy presented the AuriPro Phase III data at the American Society of Pediatric Otolaryngology Conference in Boston. Although the data have been previously announced, we believe the presentation will give AuriPro more exposure to the otolaryngology community, which will drive physician awareness and help increase product adoption if approved. In our financial model, we estimated a peak market penetration of 55% in our base case, and a 25%-30% market penetration in our bear case.

Otonomy has been diligently preparing for the commercial launch. In the fall of 2014, Otonomy hired Anthony Yost as Chief Commercial Officer, who has more than 30 years of pharma commercialization experience and

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had launched more than 20 products. Otonomy plans to launch AuriPro by hiring 40 sales reps to target 2,500 ENT physicians that perform 80% of TTP surgeries in the U.S. The company has not yet disclosed ex-U.S commercialization plans.

Beyond the AuriPro program, it is expected that Otonomy will announce top-line data for the Phase IIb clinical trial for OTO-104 in treating Ménière's disease in mid-2015. We would continue to be strong buyers of Otonomy shares and urge investors to buy on any weakness.

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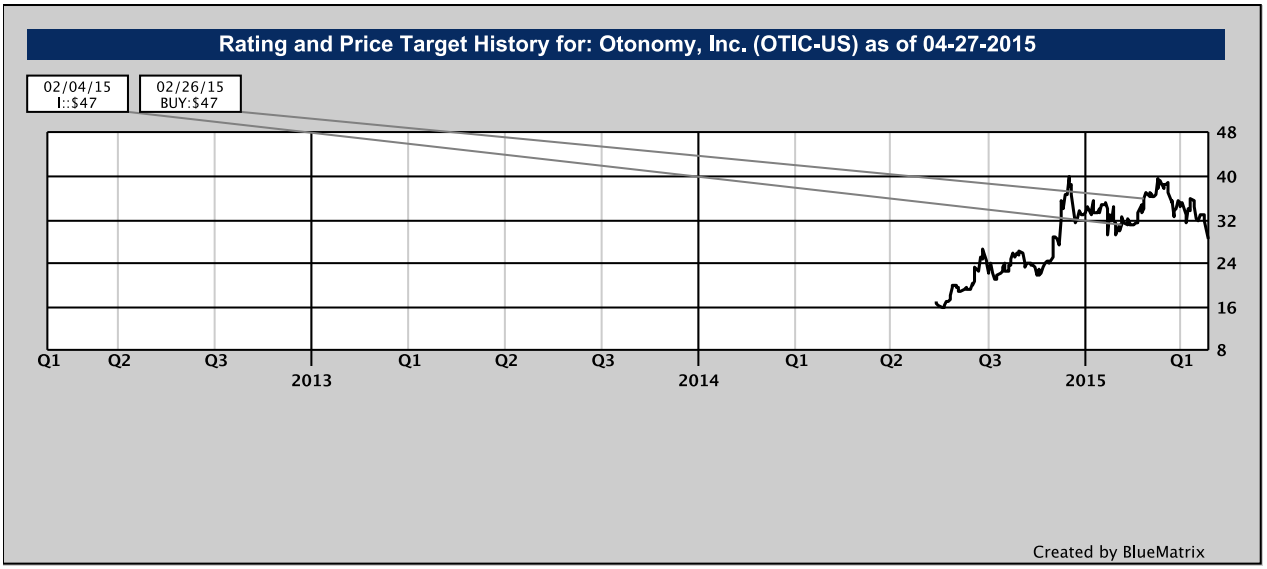

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