Management Update Allowed Us To Focus On 2015 Events

Buy

Price: $36.33

This is a biotech story that continues to impress

We had the opportunity to sit down with the CEO of Otonomy on Friday to get an update on the NDA filing and other events that investors will be looking for in 2015.

- With the NDA submission for AuriPro now complete, the Company should hear back from the FDA within 60 days (~late April) as to whether the submission will be filed for review. We continue to believe this is academic and that the NDA will be accepted for filing with no issue. With a standard 10-month review, we expect a PDUFA date to be assigned for late December. The Company reiterated that they have been told that an Advisory Committee meeting will most likely not be needed for the review of AuriPro for the tympanostomy tube placement (TTP) surgery indication.
- Ciprodex, which is marketed by Novartis by way of its acquisition of Alcon, is the main competition that AuriPro will face. Interestingly, Ciprodex is a drug with ~$400M in annual sales and is used off-label for TTP surgery. We continue to agree with management that this is the low-hanging fruit when it comes to launching AuriPro. Ciprodex sells at an AWP of $167 and management continues to state that they could price in the $200 to $250 range and receive no push-back from payers as they would have the only FDA approved therapeutic on the market. This drug is ideally suited for otolaryngologists as its administration allows the doctor to be reimbursed from both the CRT code as well as a percentage of the J-code. Target market: 2.3 million units of ear drops prescribed annually in the U.S. for the middle ear.
- As previously announced, the Phase IIb for OTO-104 in Menieres disease was fully enrolled in December 2014 with 154 patients. Management continues to guide for a date read-out in 2Q15. Pricing on this program has a lot more upside as there are currently no treatments approved for this severely debilitating disease. It is important to remember that the ongoing Phase IIb could act as one of the two pivotal trials needed for FDA approval, so the 2Q15 data read-out is a very important inflection point for the story as we believe OTO-104 is the indication that will drive Otonomy to profitability and beyond.
- The finally indication, while early could be a big winner for Otonomy is clinically successful for the treatment of tinnitis (ringing in the ears). OTO-311 (gacyclidine) is a selective and potent NMDA receptor antagonist. The competing drug from Auris requires a daily injection for three days. Given the potency of OTO-311, less frequent administration may be the case given Otonomy's sustained release polymer technology. More to come on the development of this drug in 2015.
- We continue to be bullish on shares of Otonomy and reiterate our $47 price target. By focusing on a niche market where a salesforce of 20 to 80

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can target 4,000 ENT physicians which make up 80% of total prescribers, Otonomy has the potential to be a formidable otology-focused company. Since going public on 8-14-14, shares of OTIC have appreciated 116% as compared to 33% for the NBI during the same time period. Since early February shares of OTIC have appreciated 16.7% as compared to an 11% rise in the BTK, again for the same time period. The reason for this appreciation is clear given that management has continually met or exceeded their defined clinical and regulatory goals and as a result shares have appreciated accordingly. Our price target is maintained at $47 and we would continue to be strong buyers of OTIC.

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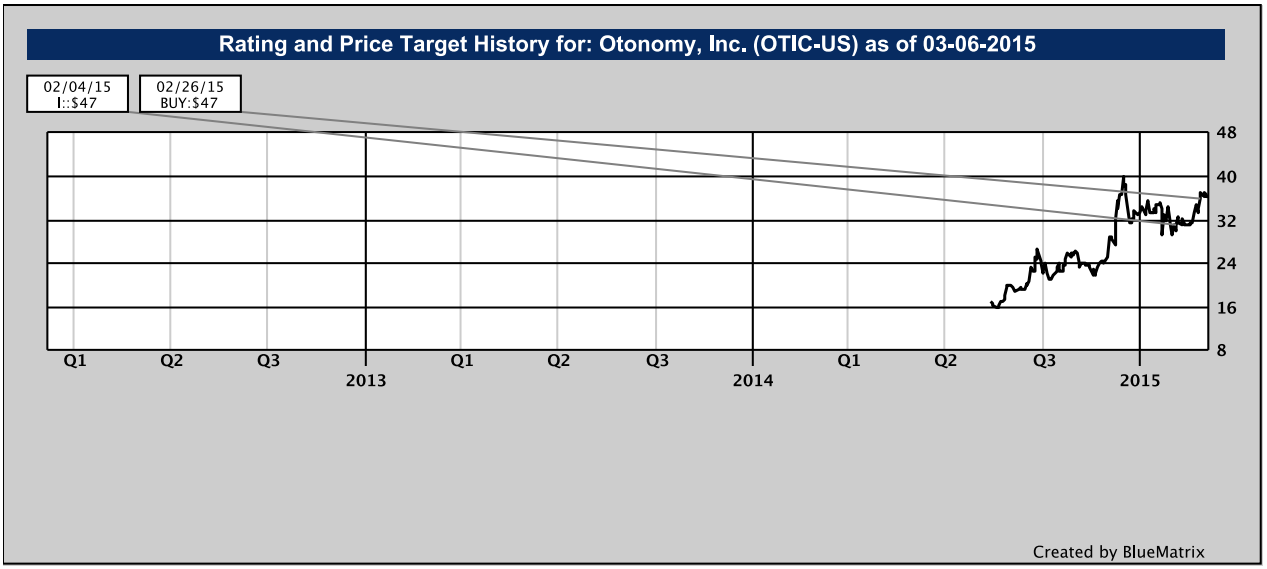

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