AuriPro's Third Indication is a Free Call in our Valuation

Buy

Price: $26.11

Application Expands from Inside Eardrum to Outside Eardrum

This week Otonomy announced the initiation of a Phase II label expansion study for AuriPro to treat pediatric patients with acute otitis externa (AOE), commonly referred to as swimmer's ear. We believe Otonomy is targeting more severe AOE cases which are treated by ENT specialists.

What is AOE?

AOE, a common infection that affects approximately 2.4 million people in the U.S. every year, is the diffuse inflammation of the external ear canal. Nearly all (98%) AOE infections in the U.S. are caused by bacterial infections with the most common pathogens being *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Topical and occasionally oral antimicrobials are used for the treatment of AOE. A majority of AOE are treated by primary care physicians (PCP). And according to the most recent AOE Clinical Practice Guideline published by the American Academy of Otolaryngology, specialist (e.g., ENT doctors) referral is uncommon (3%) for AOE.
Recall that the lead indication for AuriPro is middle ear effusion in pediatric patients undergoing tympanostomy tube placement (TTP) surgery and the second indication is acute otitis media with tympanostomy tubes (AOMT).

Similarities among these three indications include:

- All are caused by bacterial infections
- Treating physicians are ENT specialists (Otonomy is likely targeting a subset of AOE patients treated by ENT specialists)

Differences among these indications include:

- TTP and AOMT are indications in the middle ear (inside the tympanic membrane or eardrum) and AOE is in the external ear canal (outside of eardrum)
- Otonomy is targeting pediatric patients (six months to 17 years of age) for the TTP and AOMT indications, but a wider age range (six months to 80 years of age) for AOE

What is the study design?

The study is an open-label Phase II clinical trial expected to enroll approximately 75 patients in the U.S. In the one-month study period, the trial aims to characterize safety and procedural factors associated with AuriPro administered AOE patients, which will be randomized to receive a single administration of AuriPro ranging in volume from 0.1mL to 0.4mL.

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SEE PAGE 3 FOR REQUIRED DISCLOSURE INFORMATION

We remain cautiously optimistic with regard to the clinical and commercial prospects for the AOE program. Ciprofloxacin, the active ingredient of AuriPro, is a generic antibiotic and a component of Ciprodex (Ciprofloxacin 0.3%, dexamethasone 0.1%) and Cipro HC (Ciprofloxacin 0.2%, hydrocortisone 1.0%), which are ear drops frequently used for AOE. As AuriPro is targeting AOE patients failing treatment with antibiotic ear drops, it is not clear to us as how much of an efficacy difference AuriPro could demonstrate in the patient population that fails or does not respond to Ciprodex or Cipro HC. On the commercial front, the total addressable market for AOE treated by ENTs (3% of 2.4M incidence in the U.S.) could be significantly smaller than TTP (approximately 670K incidence) or AOMT (approximately 500K incidence). Additionally, convenience and patient compliance, a major benefit offered by AuriPro, could be more appealing to pediatric patients addressed by the TTP and AOMT programs, than a more general population addressed by the AOE program. This could cloud patient adoption and commercial prospects for AuriPro among the AOE population. That said, **the AOE program (also the AOMT program) is a free call option in our valuation as we have NOT included it in our financial model**. Should the program demonstrate clinical and/or commercial benefit, it presents additional upside potential for our valuation of OTIC shares.

Upcoming for Otonomy, the AOMT Phase II study (discussed in a previous note here) has completed as indicated at ClinicalTrials.gov, and data could be available in 2H15. We look forward to the PDUFA date of Dec 25, 2015 for AuriPro in treating middle ear effusion during TTP surgery. We await more details on OTO-104's Phase III trial design and clinical development time-line for the treatment of Ménière's disease in 2H15.

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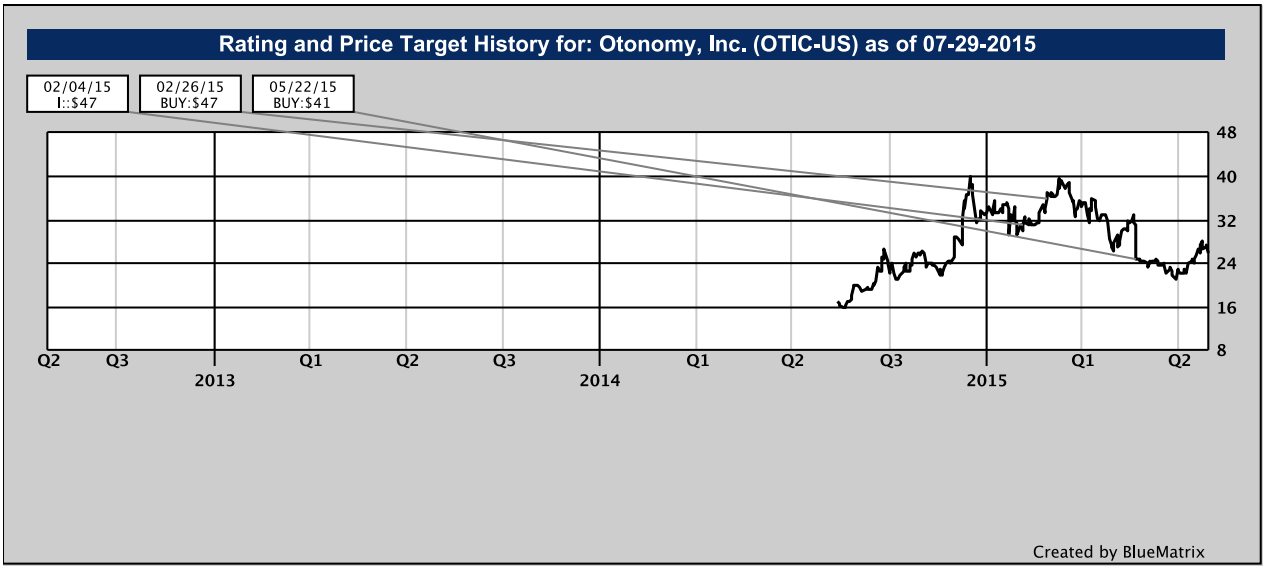

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