

# **AuriPro Pushes Forward Clinically Into Second Indication**

Market size of AuriPro could increase significantly with less clinical risk

This morning Otonomy announced the initiation of a Phase II label expansion study for AuriPro to treat pediatric patients with acute otitis media with tympanostomy tubes (AOMT).

We believe label expansion could significantly increase the market size of AuriPro. Recurrent ear infections frequently occur in pediatric patients. Epidemiologic studies demonstrate that after TTP (tympanostomy tube placement) surgery, the proportion of children developing one or more episodes of otorrhea reached 74.8% after 12 months and 83.0% after 18 months. We believe the use of AuriPro post TTP surgery (i.e., AOMT) could roughly translate to a potential increase of approximately 75% of our market share forecast for AuriPro where it is indicated for use **during** TTP surgery. The current standard of care is the use of antibiotic drops, such as Ciprodex, which requires four drops being administered in the child's affected ear(s) twice daily for seven days. We believe AuriPro's single administration which covers the full course of treatment is far more convenient and will have a much higher adoption and compliance rate. Ciprodex had 2014 annual sales of \$368M. In our financial model we have not included the market opportunity of AuriPro in AOMT, which we believe could provide additional upside potential.

#### We believe the clinical success rate of AuriPro in AOMT is high. 1)

AuriPro successfully completed two Phase III studies treating middle ear effusion during TTP surgery. We believe the pathophysiology of AOMT is very similar, if not the same as middle ear effusion during TTP surgery. 2) Ciprodex is approved for AOMT, but its off-label use in treating middle ear effusion during TTP surgery is effective and is widely used. We believe AuriPro can be as effective in treating these two indications as Ciprodex. 3) The trial design of AOMT is similar to that of the middle ear effusion during TTP surgery. The AOMT study is a one-month, open-label clinical trial expected to enroll 30 pediatric patients in the U.S. The presence of otorrhea will be assessed for up to two weeks. In the two Phase III trials of AuriPro in treating middle ear effusion during TTP surgery, the cumulative proportion of otorrhea is a secondary endpoint which was measured for two weeks. This endpoint was met with statistical significance (p=0.038 and p<0.001) in both Phase III trials.

**Top-line data potentially released in 2H15.** Otonomy has not guided as to the date for releasing the top-line data, nor has it reported the number of clinical sites currently enrolling or to be opened. However, the Phase III trial of AuriPro in treating middle ear effusion during TTP surgery for over 500 patients took approximately eight months from dosing the first patient

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Price: \$32.46



to reporting top-line results. We believe the time frame for AOMT should be similar or shorter with top-line data readout in 2H15.

We would continue to be strong buyers of Otonomy shares and are eying the top-line data readout of the Phase IIb trial of OTO-104 for Ménière's disease in 2Q15.



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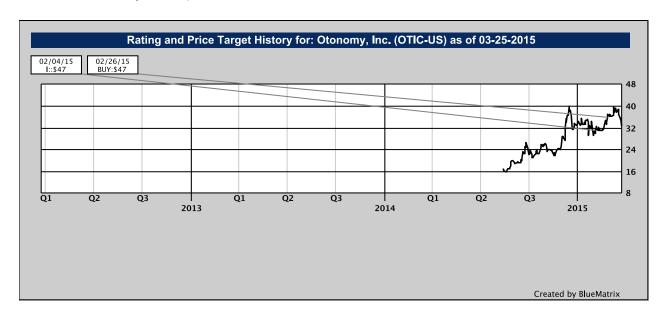
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