

Otonomy, Inc. (OTIC)

Overweight

Eyes On EARS; Tinnitus Program Update Relevant For OTIC

CONCLUSION

This morning, Auris Medical (EARS) announced that it has successfully completed an interim analysis of its P3 TACTT3 trial of AM-101 for treatment of tinnitus (ringing in ears). The recommendation for the study was to continue enrolling patients in the early post-acute phase (3-6 months prior to entry) but stop enrolling patients in the later post-acute phase (6-12 months prior to entry). The prespecified futility endpoint was not met for the study, which is encouraging, but the efficacy signal for the 6-12 month post-onset group did not merit further evaluation. This relevance of this program is that OTIC has its own tinnitus program using a similar mechanism, but which leverages the company's proprietary hydrogel depot delivery system to significantly improve upon convenience. As well, OTIC's NMDA receptor antagonist has shown much higher preclinical potency than EARS'. Reiterate our OW rating on OTIC.

- **Tinnitus is a complex auditory problem** characterized by persistent ringing in the ear; it can be an extremely disabling and uncomfortable sensation and affects an estimated 16M patients in the U.S., with as many as 2M having difficulty with daily function as a result. The precise mechanism and etiology of tinnitus is not well defined, and causes are varied (but often it is idiopathic).
- **OTIC's OTO-311** is an intratympanic gel formulation of the NMDA receptor antagonist gacyclidine. An IND is expected to be filed this year, but newsflow from EARS' NMDA-ra program should help inform prospects for OTO-311. While we consider this program higher risk, we see little to no value ascribed to OTIC for it. This morning's update for the EARS AM-101 program continues its "mixed" flow of data -- encouraging that the interim analysis of the early post-acute phase cohort in the TACTT3 study was good enough to continue enrolling, but also concerning that the late post-acute phase cohort did not show a strong enough signal to continue enrolling.
- **Considering the year ahead for OTIC:** The big event for OTIC this year is the P2b data for OTO-104 for Meniere's coming up in the next few months. This is a binary event, with potential for meaningful upside with success, which seems likely based on the early clinical findings and broad support for use of steroids for this condition in the literature. In the event of failure, we believe downside can be mitigated by OTIC advancing and highlighting the potential utility of AuriPro in indications beyond TTP (tympanostomy tube placement), moderating R&D spend to maximize the value of AuriPro, potentially in-licensing new programs or products to promote to the ENT community, and continuing to pursue OTO-311, learning from EARS' successes and/or failures. We believe these latter factors provide a meaningful floor to OTIC shares.

COMPANY DESCRIPTION

OTIC is developing drugs to treat a variety of ear conditions.

PRICE: US\$36.77

TARGET: US\$46.00

DCF thru 2022, 10.5% discount rate, 3.0% terminal growth rate

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RISKS TO ACHIEVEMENT OF PRICE TARGET

Development candidates may face clinical, regulatory or commercial setbacks.

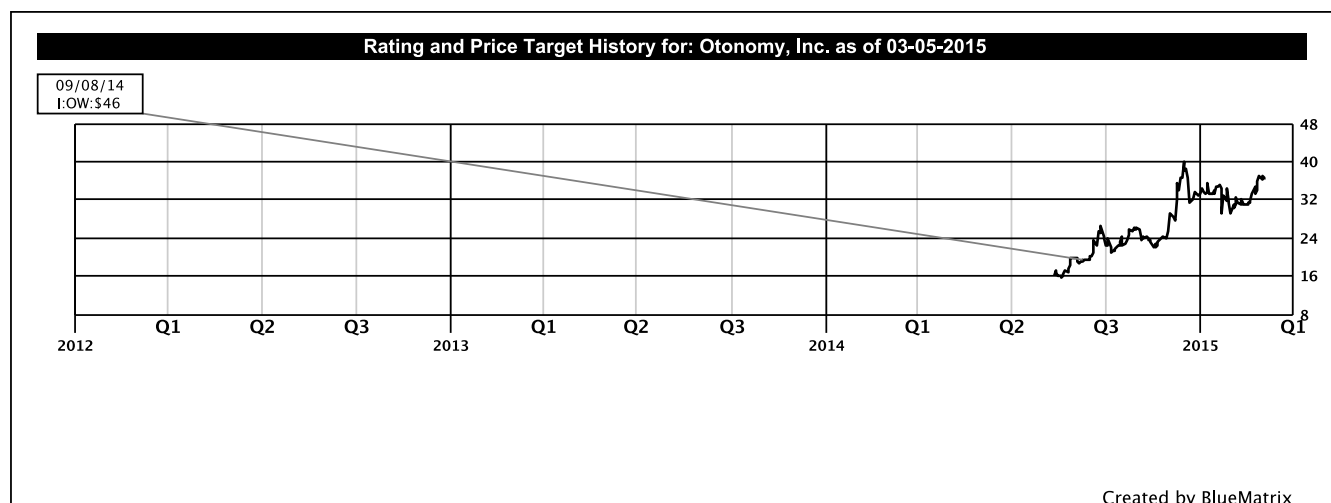
Price Performance - 1 Year



Source: Bloomberg

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BUY [OW]	377	59.56	102	27.06
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