

## Otonomy

### Within an Earshot; OTO-104 Phase 2b Miss Adds Greater Uncertainty to Story... Downgrading to Neutral

Today after the close OTIC announced the Phase 2b trial of OTO-104 in Meniere's disease missed its primary endpoint with OTO-104 reducing vertigo by 61% vs. 43% on placebo ( $p=0.067$ ). This is a disappointing update; we thought the trial would be fairly straightforward based on our doc diligence and early data. The trends in both the primary and *pre-specified* secondary endpoints (some of which hit stat sig) may be persuasive enough to see this trial as proof-of-concept and reserve hope headed into Phase 3. Thus, we think weakness on the back of this update could be an opportunity for longer term investors. That said, this development clearly introduces added uncertainty into the program as well as added cost (now 2 additional trials instead of 1). Further, in the next 6-12 months, we have trouble finding drivers for upside (as we await clarity on the path for OTO-104, and AuriPro's Dec 25th PDUFA is a fairly high probability event in our/investors view). Thus we are lowering our YE15 target to \$30 from \$42 and downgrading to Neutral.

- **Despite the primary endpoint miss, OTIC sees clear signs of efficacy in the totality of the data and intends to move forward into Phase 3 later this year.** On the call, management reiterated their belief that the Phase 2b trial design was the right one, and highlighted the *pre-specified* secondary endpoints that did reach stat sig (with all trending in the same direction) as clear signs of efficacy (see slides here for a review of the [data](#)). At this point management remains confident in the 3-month time period and endpoint, and will continue to analyze the data to look for potential ways to optimize the Phase 3 trial design (e.g. patient enrichment as mgmt. noted a prospectively defined subgroup of patients with higher baseline vertigo had increased treatment effect).
- **We see this Phase 2b trial as additional positive POC, but now see heightened risk headed into the Phase 3 trials.** The active ingredient in OTO-104 is the steroid dexamethasone, which is currently widely used off label (in liquid form) in the treatment of inner ear disorders (including Meniere's disease). Real world doc feedback plus trends in the '104 data so far support our continued belief in a treatment effect. That said, we are lowering our probability of success for OTO-104 to 40% from 70% given what we see as increased risk headed into Phase 3 trials. Based on what we have seen to date, it looks like patient enrichment *could* be key, but this could also limit the ultimate label. Further, the company will now have to run 2 trials (which it plans to do in parallel) vs. the 1 additional needed had this trial been positive, which increases our expense assumptions going forward.

#### Otonomy, Inc. (OTIC;OTIC US)

FYE Dec	2012A	2013A	2014A	2015E	2016E (Prev)	2016E (Curr)
EPS Reported (\$)						
Q1 (Mar)	-	(1.04)	(3.65)	(0.52)A	-	-
Q2 (Jun)	-	-	(3.40)	(0.76)	-	-
Q3 (Sep)	-	-	(1.23)	(0.81)	-	-
Q4 (Dec)	-	-	(0.46)	(0.85)	-	-
FY	(3.38)	(7.64)	(5.46)	(2.95)	(2.93)	(3.29)
Bloomberg EPS FY (\$)	-	-4.47	-5.04	-2.97	-	-3.44

Source: Company data, Bloomberg, J.P. Morgan estimates.

#### See page 5 for analyst certification and important disclosures.

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### ▼ Neutral

Previous: Overweight

OTIC, OTIC US

Price: \$31.05

### ▼ Price Target: \$30.00

Previous: \$42.00

#### Biotechnology

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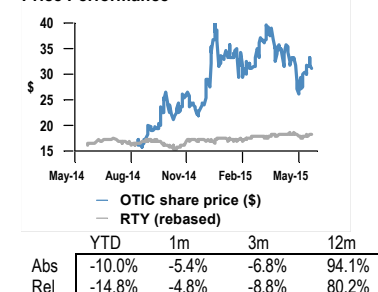
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#### Price Performance



#### Company Data

Price (\$)	31.05
Date Of Price	21 May 15
52-week Range (\$)	41.99-15.19
Market Cap (\$ mn)	749.36
Fiscal Year End	Dec
Shares O/S (mn)	24
Price Target (\$)	30.00
Price Target End Date	31-Dec-15

- **We see limited read-through from OTO-104 to OTO-311 (with blockbuster potential in tinnitus) given different active ingredients.** OTIC plans to file an IND and initiate clinical development of OTO-311 in tinnitus in 2015, which could be a blockbuster indication (and is not currently included in our valuation). Though OTO-104 did not show any impact on tinnitus endpoints in the current Phase 2b trial, we note that OTO-104 contains dexamethasone, while OTO-311 contains the NMDA receptor antagonist Gacyclidine.
- **We remain confident in AuriPro and believe it provides a base for valuation, but success in the pipeline will be critical for upside... downgrading to N as we await clarity on next steps.** Our confidence in AuriPro ahead of its Dec 25<sup>th</sup> PDUFA remains, though we currently model peak sales of only ~\$275M for this product (the potential for label expansion does exist). This contributes ~\$15/share to the valuation (based on 85% prob-of-success), in addition to \$6/shr in current cash. While OTO-104 previously contributed ~\$14/share at 70% prob-of-success, we now model ~\$7/shr contribution (based on lower probability of success and increasing the probability we assign to more conservative commercial scenarios), and we have also lowered the value we assign to the general pipeline/platform by \$3 and increased the discount rate to 11% (from 10%). The net effect of our changes is a decrease in our YE15 target to \$30 from \$42, and we are downgrading shares to Neutral given what we see as a lack of meaningful near term catalysts.

## Investment Thesis, Valuation and Risks

### Otonomy (Neutral; Price Target: \$30.00)

#### Investment Thesis

We have a Neutral rating on OTIC based on the potential of its two lead pipeline candidates: AuriPro (sustained exposure antibiotic) and OTO-104 (sustained exposure steroid). AuriPro has successfully completed Phase 3 trials in TTP surgery (ear tube placement); we expect a 1Q16 launch with peak sales of \$250M. OTO-104 recently completed a Phase 2b trial in Ménière's disease with disappointing results. We assume launch in 2018 with peak sales of ~\$500M.

#### Valuation

Our Dec 2015 price target of \$30 is based on a blended average of our proprietary probability-adjusted scenario analysis (50%) and a risk-adjusted NPV model (50%).

#### OTIC Valuation Summary

Otonomy Valuation Summary			
Discount rate	11%		
4Q15 Fully Diluted Shares (mm)	27.0		
<b>Main value drivers</b>	<b>Prob of approval</b>	<b>Peak WW sales est (avg. scenario)</b>	<b>Avg peak yr</b>
US AuriPro	85%	\$ 273	2022
US OTO-104	40%	\$ 497	2023
<b>Valuation methodology</b>	<b>Value / share</b>	<b>Weighting</b>	<b>Adj. value/ share</b>
Real options scenario analysis	\$ 31.88	50%	15.94
Risk adjusted NPV analysis	\$ 28.88	50%	14.44
Total			\$ 30.38
Catalyst/liquidity discount			0%
<b>YE15 Price Target</b>			<b>\$ 30</b>

Source: J.P. Morgan estimates.

#### Risks to Rating and Price Target

OTIC is susceptible to the standard risks that apply to the entire biotech industry, including development, regulatory, commercial, manufacturing, financing, and IP pitfalls. More specific risks to the downside include more clinical setbacks for the key pipeline product OTO-104 and pre-clinical candidate OTO-311, regulatory hurdles, and commercial setbacks. On the upside, quicker-than-expected clinical development of pipeline assets, particularly OTO-104 after its setback, could drive shares higher.

## Otonomy: Summary of Financials

Income Statement - Annual	FY14A	FY15E	FY16E	FY17E	Income Statement - Quarterly	1Q15A	2Q15E	3Q15E	4Q15E
Revenues	0	0	7	-	Revenues	0A	0	0	0
Cost of products sold	0	0	(1)	-	Cost of products sold	0A	0	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(8)	(23)	(35)	-	SG&A	(4)A	(6)	(7)	(8)
R&D	(32)	(48)	(62)	-	R&D	(9)A	(12)	(13)	(13)
Operating income	(40)	(71)	(92)	-	Operating income	(12)A	(19)	(20)	(21)
EBITDA	(40)	(71)	(92)	-	EBITDA	(12)A	(19)	(20)	(21)
Net interest (income) / expense	-	-	-	-	Net interest (income) / expense	-	-	-	-
Other income / (expense)	(3)	0	0	-	Other income / (expense)	0A	0	0	0
Income taxes	0	0	0	-	Income taxes	0A	0	0	0
Net income - GAAP	(43)	(70)	(91)	-	Net income - GAAP	(12)A	(18)	(20)	(21)
Net income - recurring	(43)	(71)	(91)	-	Net income - recurring	(12)A	(18)	(20)	(21)
Diluted shares outstanding	8	24	28	-	Diluted shares outstanding	23A	24	24	24
EPS - excluding non-recurring	(5.46)	(2.93)	(3.29)	-	EPS - excluding non-recurring	(0.52)A	(0.76)	(0.81)	(0.85)
EPS - recurring	(5.46)	(2.95)	(3.29)	-	EPS - recurring	(0.52)A	(0.76)	(0.81)	(0.85)
Balance Sheet and Cash Flow Data	FY14A	FY15E	FY16E	FY17E	Ratio Analysis	FY14A	FY15E	FY16E	FY17E
Cash and cash equivalents	149	160	171	-	Sales growth	-	-	-	-
Accounts receivable	-	-	-	-	EBIT growth	99.7%	78.7%	29.8%	-
Inventories	-	-	-	-	EPS growth - recurring	(28.5%)	(46.0%)	11.5%	-
Other current assets	2	2	2	-	Gross margin	-	-	-	-
Current assets	151	162	174	-	EBIT margin	-	-	(1333.6%)	-
PP&E	1	1	1	-	EBITDA margin	-	-	(1333.6%)	-
Total assets	152	163	175	-	Tax rate	0.0%	0.0%	0.0%	-
Total debt	0	0	0	-	Net margin	-	-	(1327.3%)	-
Total liabilities	3	3	4	-	Net Debt / EBITDA	375.6%	224.3%	186.4%	-
Shareholders' equity	148	160	171	-	Net Debt / Capital (book)	34066.3%	39112.0%	45170.6%	-
Net income (including charges)	(43)	(71)	(91)	-	Return on assets (ROA)	(44.9%)	(45.1%)	(54.2%)	-
D&A	0	0	0	-	Return on equity (ROE)	(46.5%)	(46.0%)	(55.3%)	-
Change in working capital	0	0	0	-	Enterprise value / sales	-	-	83.9	-
Other	1	2	3	-	Enterprise value / EBITDA	NM	NM	NM	-
Cash flow from operations	(41)	(68)	(88)	-	Free cash flow yield	(17.1%)	(9.2%)	(10.3%)	-
Capex	(0)	(0)	(0)	-					
Free cash flow	(42)	(69)	(89)	-					
Cash flow from investing activities	(0)	(0)	(0)	-					
Cash flow from financing activities	153	80	100	-					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.

Note: \$ in millions (except per-share data). Fiscal year ends Dec

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Otonomy (OTIC, OTIC US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
08-Sep-14	OW	19.39	32.00
18-Mar-15	OW	39.03	42.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.  
Initiated coverage Sep 08, 2014.

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