

Otonomy, Inc. (OTIC)

Overweight

P2b OTO-104: Maybe Not Stat Sig, But Still Looks Solid To Us

CONCLUSION

OTIC held a conference call after the close to discuss the P2b results of OTO-104 in Meniere's disease. While the trial barely missed the primary endpoint of reduction in vertigo frequency with P value of 0.067, we believe the results indicate an active drug which should have a viable path forward. The company will request a meeting with the FDA and plans to initiate 2 parallel P3 trials with at least one commenced by end-2015. We believe the P2b data (along with P1b data reported last year) demonstrate the benefit of OTO-104 in reducing vertigo and thus with proper trial designs, OTIC has a strong chance to succeed in the upcoming P3 trials. As such, we reiterate our OW rating with a PT of 46. We believe any weakness in the shares represents a compelling buying opportunity.

- **What have we learned?** % reduction in vertigo frequency (61% vs. 43%, $p = 0.067$, $n = 144$) during Month 3 from baseline is largely in line with the data from the P1b trial (73% vs. 42%, $p = 0.086$, $n = 30$), which we view as very reassuring of a true clinically meaningful benefit. OTO-104 showed increased benefit with higher baseline vertigo frequency, which is highly encouraging and may be used for selecting right pts for the upcoming P3 trials.
- **What is next?** OTIC will hold a post-P2 meeting with the FDA. The company plans to complete planned and post-hoc analyses, which should inform trial design and patient selection for the P3 trials. OTIC already indicated that they would use the same primary endpoint (% reduction in vertigo frequency during Month 3) for the P3 trials, which certainly makes sense for us.
- **AuriPro opportunities:** We see substantial value in the more advanced AuriPro program, which has a Dec 25th PDUFA data for its lead indication, i.e. treatment of middle ear effusion in pediatric patients who undergo TTP surgery. The company also continues its efforts on Auripro expansion into new indications, which may provide meaningful upside from what we currently model.

RISKS TO ACHIEVEMENT OF PRICE TARGET

Development candidates may face clinical, regulatory or commercial setbacks.

COMPANY DESCRIPTION

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

PRICE: US\$31.05

Price as of the close May 21, 2015

TARGET: US\$46.00

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

Joshua E. Schimmer, MD

Sr Research Analyst, Piper Jaffray & Co.
212 284-9322, joshua.e.schimmer@pjc.com

Jerry Yang, Ph.D.

Research Analyst, Piper Jaffray & Co.
212 284-9331, jerry.n.yang@pjc.com

Steven P. Breazzano, Ph.D.

Research Analyst, Piper Jaffray & Co.
212 284-6114, steven.p.breazzano@pjc.com

Changes	Previous	Current
Rating	—	Overweight
Price Tgt	—	US\$46.00
FY15E Rev (mil)	—	US\$0.0
FY16E Rev (mil)	—	US\$13.0
FY15E EPS	—	US\$(2.98)
FY16E EPS	—	US\$(3.76)
52-Week High / Low	US\$41.99 / US\$15.19	
Shares Out (mil)	24.2	
Market Cap. (mil)	US\$751.4	
Avg Daily Vol (ooo)	179	
Book Value/Share	US\$7.26	
Net Cash Per Share	US\$7.37	
Debt to Total Capital	0.0%	
Div (ann)	US\$0.00	
Fiscal Year End	Dec	

Price Performance - 1 Year



Source: Bloomberg

YEAR	REVENUE (US\$ m)						EARNINGS PER SHARE (US\$)					
	Mar	Jun	Sep	Dec	FY	FY RM	Mar	Jun	Sep	Dec	FY	FY P/E
2014A	0.0	0.0	0.0	0.0	0.0	NA	(5.07)	(3.86)	(1.23)	(0.46)	(5.46)	NM
2015E	0.0A	0.0	0.0	0.0	0.0	NA	(0.52)A	(0.64)	(0.80)	(1.01)	(2.98)	NM
2016E	—	—	—	—	13.0	57.8x	—	—	—	—	(3.76)	NM

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Key Events For OTIC				
Program	Disorder	Type	Event	Expected Timing
AuriPro	TTP	Regulatory	FDA Approval	2H 2015
	AOMT	Clinical	P2 results	2015/2016
	New Indication	Clinical	Initiate trials in additional indications	2015
OTO-104	Ménière's disease	Clinical	Initiate the first P3 trial	2H 2015
		Clinical	Initiate the second P3 trial	1H 2016
OTO-311	Tinnitus	Preclinical	File IND and initiate P1b study	2015
		Competitive/ validating	Auris Medical P3 data for AM-101	1H 2016

Source: Company reports and Piper Jaffray

OTIC Discounted Cash Flow (DCF) and Equity Valuation (\$ M):	
Assumed Discount Rate (%)	10.5%
Discounted Net Cash Flow (2014-'20)	846
Terminal Growth Rate (%)	3.0%
Implied Terminal Year FCF Multiple	13.7x
NPV of FCFF	\$1,145
Terminal Value as % of total	26.1%
Add: Net Cash	201
Shares Outstanding 2017E (million)	29
Price Target	\$46

Source: Company Reports and Piper Jaffray.

OTIC DCF Valuation Analysis					
Discount Rate					
Terminal Growth		10.0%	10.5%	11.0%	11.5%
	2.0%	\$44	\$41	\$37	\$34
	3.0%	\$51	\$46	\$42	\$38
	4.0%	\$59	\$53	\$48	\$43
	5.0%	\$71	\$63	\$56	\$50
	6.0%	\$89	\$77	\$67	\$59

Source: Company Reports and Piper Jaffray.

OTIC Potential Upside Vs Current					
Discount Rate					
Terminal Growth		10.0%	10.5%	11.0%	11.5%
	2.0%	24%	14%	4%	(4%)
	3.0%	42%	29%	17%	7%
	4.0%	65%	48%	34%	21%
	5.0%	98%	75%	56%	40%
	6.0%	148%	114%	87%	65%

Source: Company Reports and Piper Jaffray.

OTIC Annual P&L	2013A	Q1 14A	Q2 14A	Q3 14A	Q4 14A	2014A	Q1 15A	Q2 15E	Q3 15E	Q4 15E	2015E
Total U.S. Product Sales (000s)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
ex-US royalty	\$0	0.0	0.0	0.0	0.0	\$0	0.0	0.0	0.0	0.0	\$0
Total Revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Costs & Expenses:											
Cost of Goods Sold	\$0	0.0	0.0	0.0	0.0	\$0	0.0	0.0	0.0	0.0	\$0
% Product sales	0	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%
R&D	\$16	9.0	8.3	7.4	7.2	\$32	8.6	12.0	13.0	15.0	\$49
% Revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SG&A	\$4	1.6	1.6	2.0	2.7	\$8	3.5	3.0	6.0	9.0	\$22
% Revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total Operating Expenses	\$20	10.6	9.8	9.4	9.9	\$40	12.1	15.0	19.0	24.0	\$70
Operating Income (loss)	(\$20)	(10.6)	(9.8)	(9.4)	(9.9)	(\$40)	(12.1)	(15.0)	(19.0)	(24.0)	(\$70)
Interest and Other Income, Net	\$0	(0.3)	(0.3)	(2.6)	0.1	(\$3)	0.1	0.1	0.1	0.1	\$1
Accretion, convertible preferred	(\$1)	(0.0)	(0.0)	(0.0)	0.0	(\$0)	0.0	0.0	0.0	0.0	\$0
Pretax Income (Loss)	(\$20)	(\$11)	(\$10)	(\$12)	(\$10)	(\$43)	(\$12)	(\$15)	(\$19)	(\$24)	(\$69)
Income Taxes (Benefit)	\$0	0.0	0.0	0.0	0.0	\$0	0.0	0.0	0.0	0.0	\$0
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income, adjusted (GAAP)	(\$20)	(10.8)	(10.2)	(12.0)	(9.8)	(\$43)	(12.0)	(14.9)	(18.9)	(23.9)	(\$70)
Stock option expenses	0	0.3	0.3	0.3	0.9	2	1	1	1	1	2
% Revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Net Income, non-GAAP	(\$20)	-10.6	-9.9	-11.8	-8.9	(\$41)	(12.5)	(15.4)	(19.4)	(24.4)	(\$72)
Diluted EPS (Non-GAAP)	(\$4.51)	(\$4.95)	(\$3.76)	(\$1.20)	(\$0.42)	(\$5.24)	(\$0.54)	(\$0.66)	(\$0.83)	(\$1.03)	(\$3.06)
Diluted EPS, GAAP	(\$4.47)	(\$5.07)	(\$3.86)	(\$1.23)	(\$0.46)	(\$5.46)	(\$0.52)	(\$0.64)	(\$0.80)	(\$1.01)	(\$2.98)
Diluted Shares Outstanding (MM)	4.5	2.1	2.6	9.8	21.2	7.9	23.2	23.3	23.5	23.6	23

Source: Company Reports and Piper Jaffray.

Current disclosure information for this company can be found at <http://www.piperjaffray.com/researchdisclosures>.

Proprietary to Piper Jaffray & Co. May 21, 2015

Joshua Schimmer: 212-284-9322

Joshua.E.Schimmer@pjc.com

OTIC Product Model	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
TTP Procedures/Yr, U.S. (000s)	1,000	1,000	1,000	1,005	1,010	1,015	1,020	1,025	1,030	1,036	1,041
% children	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%
# children TTP procedures/yr, U.S. (000s)	900	900	900	905	909	914	918	923	927	932	937
% of market without payor obstacles	55%	55%	55%	55%	55%	55%	55%	55%	55%	55%	55%
% penetration, low barrier population	0%	0%	0%	0%	10%	20%	30%	35%	40%	45%	50%
% penetration, high barrier population	0%	0%	0%	0%	2%	5%	15%	20%	25%	30%	35%
# adult TTP procedures/yr, U.S. (000s)	100	100	100	101	101	102	102	103	103	104	104
% penetration, adults	0%	0%	0%	0%	1%	5%	15%	35%	40%	50%	50%
AuriPro treatments/yr, U.S. (000s)	\$0	\$0	\$0	\$0	\$59	126	229	297	350	408	457
Cost/treatment	\$225	\$225	\$225	\$225	\$225	234	243	253	263	274	285
Total AuriPro revenue, U.S. (mm) For TTP	\$0	\$0	\$0	\$0	\$13	\$30	\$56	\$75	\$92	\$112	\$135
AuriPro revenue, Other (mm)	\$0	\$0	\$0	\$0	\$0	\$0	\$10	\$25	\$40	\$55	\$65
Total AuriPro revenue, U.S. (mm)	\$0	\$0	\$0	\$0	\$13	\$30	\$66	\$100	\$132	\$167	\$200
Meniere's patients, U.S. (000s)	650	650	650	663	676	697	717	746	776	807	839
% OTO-104 penetration	0%	0%	0%	0%	0%	0%	1%	3%	5%	6%	7%
OTO-104 ears treated, U.S. (000s)	0	0	0	0	0	0	4	19	39	48	59
Cost/yr	\$5,000	\$5,000	\$5,000	\$5,000	\$5,150	\$5,305	\$5,517	\$5,737	\$5,967	\$6,206	\$6,454
OTO-104 revenue/yr, U.S. (mm)	\$0	\$0	\$0	\$0	\$0	\$0	\$20	\$107	\$232	\$300	\$380

Source: Company reports, PJC estimates

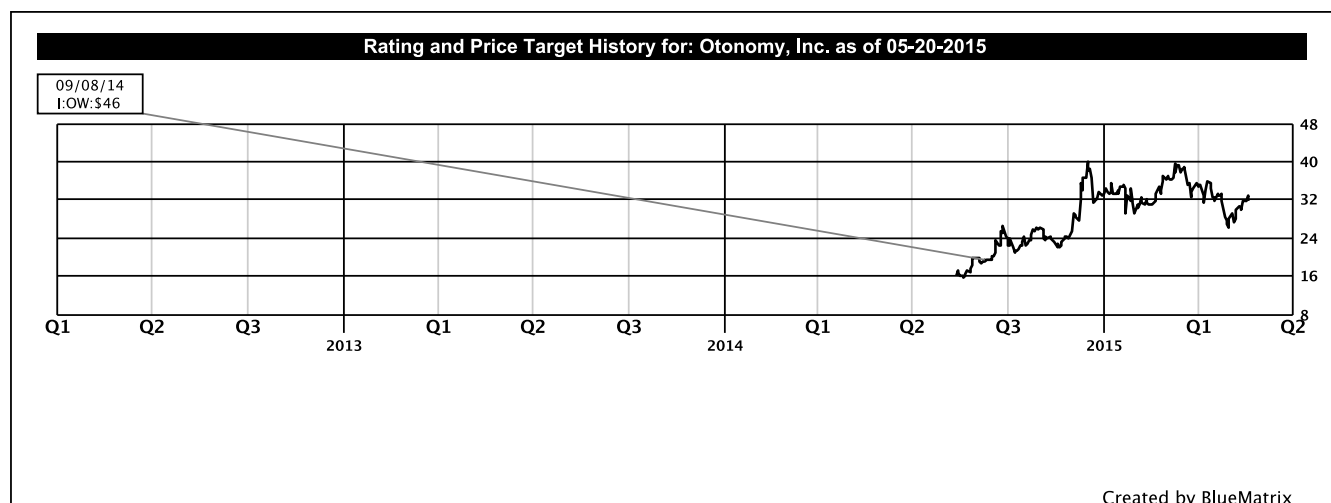
OTIC Annual P&L	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Total U.S. Product Sales (000s)	\$0	\$0	\$0	\$0	\$13	\$30	\$85	\$207	\$364	\$467	\$580
ex-US royalty	\$0	\$0	\$0	\$0	\$0	\$5	\$15	\$25	\$30	\$35	\$50
Total Revenues	\$0	\$0	\$0	\$0	\$13	\$35	\$100	\$232	\$394	\$502	\$630
Cost of Goods Sold	\$0	\$0	\$0	\$0	\$1	\$3	\$9	\$21	\$36	\$47	\$58
% Product sales	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%
R&D	\$8.5	\$16.3	\$32	\$49	\$50	\$50	\$55	\$55	\$75	\$75	\$80
% Revenue	N/A	N/A	N/A	N/A	N/A	N/A	54.7%	23.7%	19.1%	14.9%	12.7%
SG&A	\$2.4	\$3.5	\$8	\$22	\$70	\$85	\$100	\$120	\$150	\$165	\$180
% Revenue	N/A	N/A	N/A	N/A	N/A	N/A	99.5%	51.7%	38.1%	32.9%	28.6%
Total Operating Expenses	\$10.9	\$19.9	\$40	\$70	\$121	\$138	\$164	\$196	\$261	\$287	\$318
Operating Income (loss)	(10.9)	(19.9)	(\$40)	(\$70)	(\$108)	(\$103)	(\$63)	\$36	\$132	\$216	\$312
Interest and Other Income, Net	\$3.4	\$0.3	(\$3)	\$1	\$1	\$1	\$1	\$1	\$1	\$1	\$1
Accretion, convertible preferred	(0.8)	(0.5)	(\$0)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Pretax Income (Loss)	(\$8)	(\$20)	(\$43)	(\$69)	(\$107)	(\$102)	(\$62)	\$37	\$133	\$217	\$313
Income Taxes (Benefit)	0.0	0.0	\$0	\$0	\$0	\$0	\$0	\$11	\$40	\$65	\$94
Tax rate	0%	0%	0%	0%	0%	0%	0%	30%	30%	30%	30%
Net Income, adjusted (GAAP)	(8.37)	(20.1)	(\$43)	(\$70)	(\$107)	(\$102)	(\$62)	\$26	\$93	\$152	\$219
Stock option expenses	0	0	2	2	2	3	4	5	8	10	13
% Revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	2%	2%	2%	2%
Net Income, non-GAAP	(\$8.6)	(\$20.3)	(\$41)	(\$68)	(\$105)	(\$99)	(\$59)	\$31	\$101	\$162	\$232
Diluted EPS (Non-GAAP)	(\$3.46)	(\$4.51)	(\$5.24)	(\$2.89)	(\$3.69)	(\$3.40)	(\$1.83)	\$0.93	\$2.95	\$4.55	\$6.28
Diluted EPS, GAAP	(\$3.38)	(\$4.47)	(\$5.46)	(\$2.98)	(\$3.76)	(\$3.50)	(\$1.94)	\$0.79	\$2.72	\$4.27	\$5.94
Diluted Shares Outstanding (MM)	2.5	4.5	7.9	23.4	28.5	29.3	31.9	33.0	34.2	35.5	36.9

Source: Company Reports and Piper Jaffray.

Cash Flow Statement	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Net Income (Loss)	-8.4	-20.1	-42.8	-69.7	-107.0	-102.4	-62.1	26.2	93.2	151.6	219.3
Accretion to RV of convert	0.8	0.5	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Depreciation and amortization	0.2	0.3	0.2	0.5	1.0	1.2	1.3	1.4	2.0	2.5	3.0
Stock-based compensation	0.2	0.2	1.7	2.0	2.0	3.0	3.5	4.6	7.9	10.0	12.6
Non cash interest exp	0.4	2.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Change in FV of convert	(3.8)	(2.8)	3.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Deferred rent	0.3	(0.0)	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Changes in operating assets and liability	(0.6)	(0.0)	2.6	(1.0)	(1.7)	(5.4)	(17.5)	(36.0)	(41.0)	(27.8)	(32.8)
Cash From Operations	(10.8)	(19.5)	(35.1)	(68.2)	(105.7)	(103.7)	(74.8)	(3.8)	62.1	136.3	202.1
Capex	(0.2)	(0.5)	(0.8)	(2.0)	(2.5)	(3.0)	(3.5)	(3.5)	(5.9)	(7.5)	(9.5)
FCF	(11.0)	(20.0)	(35.9)	(70.2)	(108.2)	(106.7)	(78.3)	(7.3)	56.2	128.8	192.7
Proceeds from convertible notes	8.0	7.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance of conv pref stocks	0.0	45.6	49.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance of common stocks	0.0	0.0	104.1	80.0	200.0	0.0	100.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Cash From Financing	8.0	52.6	154.7	80.0	200.0	0.0	100.0	0.0	0.0	0.0	0.0
Net increase in cash and cash equivalents	(3.0)	32.6	118.8	9.8	91.8	(106.7)	21.7	(7.3)	56.2	128.8	192.7
Cash/equivalents at beginning	7.7	4.7	37.3	156.1	165.9	257.7	151.1	172.8	165.5	221.7	350.4
Cash/equivalents at end	4.7	37.3	156.1	165.9	257.7	151.1	172.8	165.5	221.7	350.4	543.1

Proprietary to Piper Jaffray & Co. May 21, 2015

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Notes: The boxes on the Rating and Price Target History chart above indicate the date of the Research Note, the rating, and the price target. Each box represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first Note written during the past three years.

Legend:

I: Initiating Coverage
 R: Resuming Coverage
 T: Transferring Coverage
 D: Discontinuing Coverage
 S: Suspending Coverage
 OW: Overweight
 N: Neutral
 UW: Underweight
 NA: Not Available
 UR: Under Review

Distribution of Ratings/IB Services Piper Jaffray				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OW]	377	61.70	98	25.99
HOLD [N]	219	35.84	14	6.39
SELL [UW]	15	2.45	0	0.00

Note: Distribution of Ratings/IB Services shows the number of companies currently in each rating category from which Piper Jaffray and its affiliates received compensation for investment banking services within the past 12 months. FINRA rules require disclosure of which ratings most closely correspond with "buy," "hold," and "sell" recommendations. Piper Jaffray ratings are not the equivalent of buy, hold or sell, but instead represent recommended relative weightings. Nevertheless, Overweight corresponds most closely with buy, Neutral with hold and Underweight with sell. See Stock Rating definitions below.

Analyst Certification — Joshua E. Schimmer, MD, Sr Research Analyst

— Jerry Yang, Ph.D., Research Analyst

— Steven P. Breazzano, Ph.D., Research Analyst

The views expressed in this report accurately reflect my personal views about the subject company and the subject security. In addition, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this report.

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- **Neutral (N):** Anticipated to perform in line relative to the median of the group of stocks covered by the analyst.
- **Underweight (UW):** Anticipated to underperform relative to the median of the group of stocks covered by the analyst.

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