# J.P.Morgan

### **Otonomy**

#### 2Q Snapshot & Model Update

We are updating our model and maintaining our Neutral rating on OTIC following the 2Q report (there was no call). The quarterly update was largely uneventful as the company reviewed clinical and regulatory progress including filing AuriPro's NDA, evaluating AuriPro in two label expansion indications, and top-line Phase 2b data for OTO-104 in Ménière's disease released in May. Importantly, OTIC has scheduled an EOP2 meeting with the FDA to discuss Phase 3 plans for OTO-104. The company plans to initiate two parallel Phase 3 trials beginning this year (timing in-line with initial plans). Bottom line, while we remain confident in AuriPro ahead of its Dec 25th PDUFA, we are sitting on the sidelines as we await clarity on the path and timing for 104.

- Upcoming events. A near-term EOP2 meeting is scheduled with the FDA to discuss Phase 3 plans for OTO-104 in Ménière's disease. OTIC plans to initiate two parallel Phase 3 trials with one to begin by YE15 and the second in 1Q16. The PDUFA for AuriPro in middle ear effusion in peds patients undergoing TTP surgery is set for Dec 25th and a potential launch could come in 1Q16. We also expect the company to file an IND and initiate clinical development of OTO-311 in tinnitus in 4Q15.
- 2Q results. 2Q EPS was (\$0.52) vs. JPMe of (\$0.76). 2Q OpEx of \$12.6M was lower than JPMe of \$18.6M. That said, OTIC is not yet an earnings story.
- Estimate changes; establishing a YE16 PT of \$30 (vs. our previous YE15 PT of \$30). We have updated our model for 2Q results and rolled our price target forward to 2016.
- Balance sheet update. OTIC ended 2Q with ~\$212M in cash (and no debt).

#### Neutral

OTIC, OTIC US Price: \$24.71

Price Target: \$30.00

#### Biotechnology

Cory Kasimov AC

(1-212) 622-5266

cory.w.kasimov@jpmorgan.com

Bloomberg JPMA KASIMOV <GO>

#### **Brittany Terner**

(1-212) 622-8527

brittany.terner@jpmorgan.com

#### Whitney G Ijem

(1-212) 622-4668

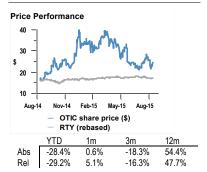
whitney.g.ijem@jpmorgan.com

#### Morgan T Haller

(1-212) 622-9486

morgan.t.haller@jpmorgan.com

J.P. Morgan Securities LLC



Otonomy, Inc. (OTIC;OTIC US)

FYE Dec	2012A	2013A	2014A	<b>2015E</b> ( <i>Prev</i> )	<b>2015E</b> (Curr)	<b>2016E</b> ( <i>Prev</i> )	<b>2016E</b> (Curr)
EPS Reported (\$)							
Q1 (Mar)	-	(1.04)	(3.65)	(0.52)A	(0.52)A	-	-
Q2 (Jun)	-		(3.40)	(0.76)A	(0.52)A	-	-
Q3 (Sep)	-	-	(1.23)	(0.81)	(0.86)	-	-
Q4 (Dec)	-	-	(0.46)	(0.85)	(0.90)	-	-
FY Č	(3.38)	(7.64)	(5.46)	(2.95)	(2.80)	(3.29)	(3.41)

Company Data	
Price (\$)	24.71
Date Of Price	12 Aug 15
52-week Range (\$)	41.99-15.19
Market Cap (\$ mn)	596.35
Fiscal Year End	Dec
Shares O/S (mn)	24
Price Target (\$)	30.00
Price Target End Date	31-Dec-16

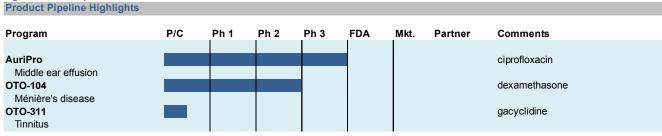
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## **Pipeline**

Figure 1: OTIC Pipeline



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

### **Upcoming Events**

**Figure 2: OTIC Upcoming Events** 

Anticipated Newsflow	Highlights		
Program	Event	Expected Timing	Significance
AuriPro	Potential US approval	PDUFA: Dec 25	High
	Potential US Launch	1Q16	High
OTO-104	Hold an EOP2 meeting with the FDA	2H15	Medium
	Initiate two parallel Phase 3 trials in Ménière's disease	YE15/1Q16	Low
OTO-311	File IND/Initiate Phase 1 study in tinnitus	4Q15	Medium

Source: Company reports and J.P. Morgan estimates

Figure 3: OTIC Income Statement

Figure 3: OTIC income Statement												
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Cory Kasimov										J.P.N	1018	all
cory.w.kasimov@ipmorgan.com 212.622.5266											U	
212.022.5200												
	2012A	2013A	2014A	1Q15A	2Q15A	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E
	ZUIZA	2013A	20144	10137	LQIJA	JQIJL	40131	20132	20101	20172	20101	20132
AuriPro Revenues				_	_	_	_		6.9	31.7	63.8	106.6
OTO-104 Revenues				_	-	-	.		_	-	10.7	68.2
Total Product Revnue			-	-	-	-	-		6.9	31.7	74.6	174.8
License & Milestone	-	-	-	-	-	-	-		-	-		-
Contract, Grant & Collaboration	-	-	-		-	-	-	-	-	-	-	-
Total Revenues	-	-	-	-	-	-	-	-	6.9	31.7	74.6	174.8
COGS	L I	-		-	-	-	-		1.0	4.1	8.2	15.7
R&D	8.5	16.3	31.8	8.6	7.3	13.2	13.5	42.6	63.0	68.3	68.7	71.5
SG&A	2.4	3.5	7.8	3.5	5.4	7.8	8.5	25.1	37.7	51.5	56.8	58.3
Total Operating Expenses	10.9	19.9	39.6	12.1	12.6	21.0	22.0	67.7	101.8	123.9	133.6	145.5
							,	/a= =:				
Operating Income	(10.9)	(19.9)	(39.6)	(12.1)	(12.6)	(21.0)	(22.0)	(67.7)	(94.9)	(92.2)	(59.1)	29.3
Other income (expense)	(0.4)	(2.5)	(3.2)	0.1	0.1	0.1	0.1	0.4	0.4	0.3	0.4	0.5
Change in fair value of convertible pref. stock	3.8	2.8	.	-	-	-			-	-	-	-
Income Tax (benefit)  GAAP Net Income	(7.6)	(19.6)	(42.9)	(12.0)	(12.5)	(20.9)	(21.8)	(67.3)	(94.4)	(91.8)	(58.7)	29.8
Accretion to redemption value of convertible pref. stock	(0.8)	(0.5)	(0.0)	(12.0)	(12.5)	(20.9)	(21.8)	(67.3)	(94.4)	(91.8)	(58.7)	29.8
GAAP Net Income attributable to common stockholders	(8.4)	(20.1)	(42.9)	(12.0)	(12.5)	(20.9)	(21.8)	(67.3)	(94.4)	(91.8)	(58.7)	29.8
Non-GAAP Net Income	(8.4)	(20.1)	(41.2)	(10.7)	(10.8)	(19.1)	(20.0)	(60.6)	(90.7)	(87.5)	(53.5)	35.5
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GAAP Basic EPS	(3.38)	(7.64)	(5.46)	(0.52)	(0.52)	(0.86)	(0.90)	(2.80)	(3.41)	(2.96)	(1.73)	0.81
GAAP Diluted EPS	(3.38)	(7.64)	(5.46)	(0.52)	(0.52)	(0.86)	(0.90)	(2.80)	(3.41)	(2.96)	(1.73)	0.74
								,				
Basic Shares Outstanding	2.5	2.6	7.9	23.2	24.1	24.3	24.4	24.0	27.7	31.1	33.9	36.8
Diluted Shares Outstanding	2.5	2.6	7.9	23.2	24.1	24.3	24.4	24.0	27.7	31.1	33.9	40.0
Administration												
Margin Analysis: Gross marqin	NM	NM	NM	NM	NM	NM	NM	NM	85%	87%	89%	91%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	16.75%
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM NM	NM	NM	17.05%
Tax Rate	0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cost Analysis:	0,0	0.070	0.070	0.070	0.070	0.070	0.070	0.070	0.075	0.070	0.070	0.070
COGS as % of tot. prod. sales	NM	NM	NM	0.00%	0.00%	0.00%	0.00%	0.00%	15.00%	13.00%	11.00%	9.00%
R&D as % of tot. revenue	NM	NM	NM	NM	NM	NM	NM	NM	914.28%	215.25%	92.08%	40.91%
SG&A as % of tot. revenue	NM	NM	NM	NM	NM	NM	NM	NM	547.05%	162.18%	76.13%	33.34%
Year-over-year growth:												
Total revenue		NM	NM	NM	NM	NM	NM	NM	NM	360.50%	134.89%	134.51%
R&D Expense		91.67%	94.68%	-4.27%	-11.80%	79.92%	87.24%	33.94%	47.94%	8.41%	0.49%	4.17%
SG&A Expense		45.93%	122.99%	123.71%	242.20%	280.69%	218.64%	220.53%	50.12%	36.52%	10.26%	2.71%
Total operating expenses		81.59%	99.69%	14.70%	28.62%	123.48%	122.80%	70.83%	50.28%	21.78%	7.82%	8.93%
	1	NM	99.69%	NM	NM	NM	NM	70.83%	40.10%	-2.83%	-35.93%	-149.58%
Operating income												
Net income		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net income EPS		NM	-28.50%	NM	NM	NM	NM	-48.69%	21.46%	-13.21%	-41.44%	-143.01%
Net income												

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

### 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 2016 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%).

#### **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	2Q15A	3Q15E	4Q15E
Revenues	0	0	7	-	Revenues	0A	0A	0	0
Cost of products sold	0	0	(1)	-	Cost of products sold	0A	0A	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(8)	(25)	(38)	-	SG&A	(4)A	(5)A	(8)	(8)
R&D	(32)	(43)	(63)	-	R&D	(9)A	(7)A	(13)	(13)
Operating income	(40)	(68)	(95)	-	Operating income	(12)A	(13)A	(21)	(22)
Adjusted EBITDA	(40)	(68)	(95)	-	Adjusted EBITDA	(12)A	(13)A	(21)	(22)
Net interest (income) / expense				-	Net interest (income) / expense	` -	· ´-		
Other income / (expense)	(3)	0	0	-	Other income / (expense)	0A	0A	0	0
Income taxes	Ó	0	0	-	Income taxes	0A	0A	0	0
Net income - GAAP	(43)	(67)	(94)	-	Net income - GAAP	(12)A	(13)A	(21)	(22)
Net income - recurring	(43)	(67)	(94)	-	Net income - recurring	(12)A	(13)A	(21)	(22)
Diluted shares outstanding	8	24	28	-	Diluted shares outstanding	23A	24A	24	24
EPS - excluding non-recurring	(5.46)	(2.80)	(3.41)	-	EPS - excluding non-recurring	(0.52)A	(0.52)A	(0.86)	(0.90)
EPS - recurring	(5.46)	(2.80)	(3.41)	-	EPS - recurring	(0.52)A	(0.52)A	(0.86)	(0.90)
Balance Sheet and Cash Flow Data	FY14A	FY15E	FY16E	FY17E	Ratio Analysis	FY14A	FY15E	FY16E	FY17E
Cash and cash equivalents	156	162	175	-	Sales growth	-	-	-	
Accounts receivable	-	-	-	-	EBIT growth	99.7%	70.8%	40.1%	-
Inventories	-	-	-	-	EPS growth - recurring	(28.5%)	(48.7%)	21.5%	-
Other current assets	2	2	2	-					
Current assets	158	164	177	-	Gross margin	-	-	-	-
PP&E	1	1	2	-	EBIT margin	-	-	(1376.3%)	-
Total assets	159	166	179	-	EBITDA margin	-	-	(1376.3%)	-
					Tax rate	0.0%	0.0%	0.0%	-
Total debt	0	0	0	-	Net margin	-	-	(1369.8%)	-
Total liabilities	6	6	6	-	-				
Shareholders' equity	154	160	173	-	Net Debt / EBITDA	393.6%	239.7%	184.5%	-
• •					Net Debt / Capital (book)	6447.6%	7035.5%	8019.6%	-
Net income (including charges)	(43)	(67)	(94)	-					
D&A	0	0	0	-	Return on assets (ROA)	(43.1%)	(41.4%)	(54.8%)	-
Change in working capital	2	0	0	-	Return on equity (ROE)	(45.2%)	(42.9%)	(56.7%)	-
Other	5	10	8	-	,	, ,	, ,	, ,	
Cash flow from operations	(35)	(57)	(86)	-	Enterprise value / sales	-	-	54.6	-
·	, ,	` ,	` ,		Enterprise value / EBITDA	NM	NM	NM	-
Capex	(1)	(1)	(1)	-	Free cash flow yield	(18.6%)	(9.7%)	(12.7%)	-
Free cash flow	(36)	(58)	(87)	-	•	, ,	, ,	, ,	
Cash flow from investing activities	(17)	(1)	`(1)	-					
Cash flow from financing activities	155	80	100	-					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

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

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

Cory Kasimov (1-212) 622-5266 cory.w.kasimov@jpmorgan.com

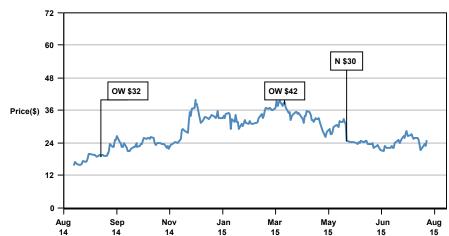
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#### Otonomy (OTIC, OTIC US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
08-Sep-14	OW	18.79	32.00
18-Mar-15	OW	38.50	42.00
21-May-15	N	24.86	30.00

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

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Cory Kasimov (1-212) 622-5266 cory.w.kasimov@jpmorgan.com

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Cory Kasimov (1-212) 622-5266 cory.w.kasimov@jpmorgan.com J.P.Morgan

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