Otonomy, Inc. (OTIC)

OTO-104 Phase IIb Misses; Now Two Phase III Trials In The Works

Reducing PT from $47 to $41

Buy

Price Target: $41.00
Prior: $47.00

Price (May 21, 2015)	$31.05
52-Wk Range	$40.00-$15.84
Market Cap ($M)	$748
ADTV	181,130
Shares Out (M)	24.1
Short Interest Ratio/% Of Float	6.3%
Dividend/Yield	$0.00/0.0%
TR to Target	32.0%

Cash Per Share	$9.28
Total Debt	$0.0
Long-Term Debt/Total Cap	0%
Cash And Equivalents ($M)	$223.6
Enterprise Value ($M)	$524.7

	2014E	2015E		2016E	
		Curr.	Prior	Curr.	Prior
EPS					
1Q	($0.03)A	($0.52)A	($0.52)	--	
2Q	($1.78)A	($0.58)	($0.58)	--	
3Q	($1.23)A	($0.86)	($0.86)	--	
4Q	($0.46)A	($0.98)	($0.98)	--	
FY	($5.46)A	($2.96)	($2.96)	($4.05)	($3.47)
P/E	NM	NM		NM	
Consensus EPS					
FY	($4.14)	($2.95)	($3.04)	($3.36)	($3.28)
FYE Dec					

What's Incremental

OTIC reported Phase IIb top-line data for OTO-104 in patients with Ménière's disease. The bad news is that the trial missed the primary endpoint of vertigo frequency reduction (p=0.067), and will now need two Phase III trials for approval. The good news is that multiple secondary endpoints achieved statistical significance, and OTO-104 demonstrated a therapeutic benefit in reducing vertigo frequency and severity. The first Phase III trial will initiate in 2H15 and a second Phase III will be initiated in parallel and we believe will initiate within three months of the first trial.

Disease: Ménière's disease
U.S. Prevalence: 600,000
FDA Approved Therapies: 0

Otonomy reported Phase IIb top-line data for OTO-104 in treating Ménière's disease after the close yesterday. The trial just missed its primary endpoint of reduction in vertigo frequency at month three following treatment with OTO-104 as compared to a one-month baseline period (p=0.067). Management has not yet provided an explanation or hypothesis as to the reason for the miss on the primary endpoint, albeit minimal as more time is needed to review the dataset in its totality. We believe one explanation may be insufficient statistical power as the Phase IIb with 154 patients demonstrated an improvement in statistical significance as compared to the previous Phase Ib trial with 44 patients (p=0.086). Multiple prospectively defined secondary endpoints, including reduction in definitive vertigo days, and reduction of vertigo severity score from baseline, both achieved statistical significance, as demonstrated in the exhibit and here:

OTO-104 Top-line Phase IIb Data

	Month 2			Month 3		
	OTO-104	Placebo	p value	OTO-104	Placebo	p value
Primary Endpoint						
Reduction in vertigo frequency	-0.14	-0.09	0.087	-0.17	-0.77	0.067
Secondary Endpoint						
Count of definitive vertigo days	2.16	3.11	0.035	1.64	2.54	0.03
Change in vertigo severity score from baseline	-0.39	-0.25	0.046	-0.46	-0.32	0.046
Change in average daily vertigo count from baseline	-0.48	-0.24	0.042	-0.53	-0.33	0.065

Note: Statistically significant endpoints are highlighted; Source: Company presentation, SunTrust Robinson Humphrey

A subgroup analysis demonstrated that more severe patients, those with a higher number of days with definitive vertigo at baseline, achieved a more profound reduction in vertigo frequency as compared to milder patients.

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SEE PAGE 7 FOR REQUIRED DISCLOSURE INFORMATION

OTO-104 appeared to have benign safety profile with no drug-related serious adverse events. Persistent perforation was observed in 2.6% of patients treated with OTO-104, similar to what was reported in the Phase Ib trial.

Management now plans to run two Phase III trials in parallel instead of one as the current Phase IIb trial did not meet the primary endpoint. One Phase III will be initiated in 2H15 as guided previously. However, the Phase III trial design was not disclosed, neither was a time-line for the complete analysis of the Phase IIb data. The Company will request an End-of-Phase II meeting with the FDA to discuss the Phase III trial design. We believe management might adopt the following changes for the Phase III trial design:

- Increase the total patient number to enhance statistical power
- Enroll more severe patients to better demonstrate efficacy
- The three-month trial duration should remain the same as at month three OTO-104 demonstrated the best benefit as compared to placebo

We believe OTO-104 clearly demonstrated therapeutic benefit in reducing vertigo frequency and vertigo severity in treating Ménière's disease which represents a significant unmet medical need as no FDA-approved drugs exist for this indication. Not meeting the primary endpoint will likely delay the commercial time-line slightly and increase inherent risk associated with the clinical program. We are reducing our 12-month price target from $47 to $41 mainly due to an increase in the discount period of three-months to 4Q17 for the commercial launch of OTO-104 and an increase in the discount rate applied in our model from 30% to 35%. Details of our model changes are as follows:

Revenue Buildup:
- Postpone the commercial launch of OTO-104 by three-months to 4Q17

Income Statement:
- Increase R&D expense by $10M in 2016 and $15M in 2017 for the additional Phase III trial and potential increased patient enrollment per trial
- Reduce 2016 EPS to ($4.05) from ($3.47)

Discounted Earnings Model, Reduce PT to $44.13 from $50.14:
- Increase discount rate to 35% from 30% due to potentially higher inherent risk of OTO-104 program
- Change first profitable year and EPS to $3.85 from $4.41 in 2018
- Decrease discount period to 2.6 from 3

DCF Model, Reduce PT to $41.47 from $46.99:
- Reduce probability of success of the OTO-104 program to 60% from 70%

Clinical NPV Model, Reduce PT to $37.39 from $42.57:
- Increase discount rate to 35% from 30%
- Reduce years to peak sales to 8.6 from 9

Despite that OTO-104 did not meet the primary endpoint in the Phase IIb, we continue to believe that Otonomy is a differentiated otology play and that OTO-104 can still potentially be clinically successful in a more highly powered trial. Lead program AuriPro is not impacted by data from the OTO-104 trial. We look forward to the PDUFA date of Dec 25, 2015 for AuriPro in treating middle ear effusion during tympanostomy tube placement (TTP) surgery. We await more details on OTO-104's Phase III trial design of and clinical development time-line.

Important Points To Keep In Mind:
1. Phase III for this condition are not as expensive as typical Phase III trials
2. The trial design is not the issue, but only powering
3. There is no ambiguity over the primary endpoint, which is the correct endpoint to measure and what the FDA wants to see

We now wait for Company to meet with the FDA and provide an update on design and timing.

Otonomy Revenue Buildup Model

	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
AuriPro for Otitis Media Patients Undergoing TTP Surgery											
U.S.											
# of TTP procedures performed annually (000s)	1,000.0	1,010.0	1,020.1	1,030.3	1,040.6	1,051.0	1,061.5	1,072.1	1,082.9	1,093.7	1,104.6
% of patients ≤ 5 yrs of age	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*
# of patients ≤ 5 years of age with TTP surgeries annually (000s)	667.0	673.7	680.4	687.2	694.1	701.0	708.0	715.1	722.3	729.5	736.8
% of pediatric patients given antibiotic post surgery	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*
# of pediatric patients given antibiotic post surgery (000s)	633.7	640.0	646.4	652.9	659.4	666.0	672.6	679.4	686.2	693.0	699.9
% market penetration by AuriPro	*0.0%*	*10.0%*	*20.0%*	*30.0%*	*40.0%*	*45.0%*	*47.5%*	*50.0%*	*52.5%*	*55.0%*	*55.0%*
# of pediatric patients receiving AuriPro treatment (000s)	0.0	64.0	129.3	195.9	263.8	299.7	319.5	339.7	360.2	381.2	385.0
Cost per course (1 administration) of treatment (AWP)	$250	$188	$250	$255	$260	$265	$271	$276	$282	$287	$293
U.S. Total AuriPro Revenue from TTP Surgery (MM)	**$0.00**	**$12.00**	**$32.32**	**$49.94**	**$68.60**	**$79.51**	**$86.46**	**$93.76**	**$101.42**	**$109.46**	**$112.76**
EU											
# of TTP procedures performed annually (000s)	1,562.5	1,578.1	1,593.9	1,609.8	1,625.9	1,642.2	1,658.6	1,675.2	1,692.0	1,708.9	1,726.0
% of patients ≤ 5 yrs of age	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*	*66.7%*
# of patients ≤ 5 years of age with TTP surgeries annually (000s)	1042.2	1052.6	1063.1	1073.8	1084.5	1095.3	1106.3	1117.4	1128.5	1139.8	1151.2
% of pediatric patients given antibiotic post surgery	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*	*95.0%*
# of pediatric patients given antibiotic post surgery (000s)	990.1	1000.0	1010.0	1020.1	1030.3	1040.6	1051.0	1061.5	1072.1	1082.8	1093.7
% market penetration by AuriPro	*0.0%*	*5.0%*	*10.0%*	*20.0%*	*30.0%*	*40.0%*	*45.0%*	*47.5%*	*50.0%*	*52.5%*	*55.0%*
# of pediatric patients receiving AuriPro treatment (000s)	0.0	50.0	101.0	204.0	309.1	416.2	472.9	504.2	536.1	568.5	601.5
Cost per course (1 administration) of treatment (AWP)	$150	$38	$150	$153	$156	$159	$162	$166	$169	$172	$176
EU Total AuriPro Revenue from TTP Surgery (MM)	$0.00	$1.87	$15.15	$31.21	$48.24	$66.26	$76.79	$83.50	$90.55	$97.95	$105.72
Royalty of EU Sales of AuriPro Booked by Otonomy (20%) (MM)	**$0.0**	**$0.4**	**$3.0**	**$6.2**	**$9.6**	**$13.3**	**$15.4**	**$16.7**	**$18.1**	**$19.6**	**$21.1**
WW Total AuriPro Revenue During TTP Surgery (MM)	$0.0	$13.9	$47.5	$81.2	$116.8	$145.8	$163.2	$177.3	$192.0	$207.4	$218.5
WW Total AuriPro Revenue Booked by Otonomy (MM)	**$0.0**	**$12.4**	**$35.3**	**$56.2**	**$78.2**	**$92.8**	**$101.8**	**$110.5**	**$119.5**	**$129.0**	**$133.9**

OTO-104 for Ménière's Disease											
U.S.											
Prevalence of Ménière's disease (000s)	600.0	640.7	681.1	721.1	760.9	800.3	839.4	878.2	916.6	954.8	992.7
% of patients receiving corticosteroid	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*
# of patients receiving corticosteroid (000s)	120.0	128.1	136.2	144.2	152.2	160.1	167.9	175.6	183.3	191.0	198.5
% market penetration by OTO-104	*0.0%*	*0.0%*	*10.0%*	*25.0%*	*35.0%*	*40.0%*	*42.5%*	*45.0%*	*45.0%*	*45.0%*	*45.0%*
# of patients receiving OTO-104 treatment (000s)	0.0	0.0	13.6	36.1	53.3	64.0	71.3	79.0	82.5	85.9	89.3
Cost per patient per year (AWP)	$6,000	$6,000	$1,500	$6,000	$6,120	$6,242	$6,367	$6,495	$6,624	$6,757	$6,892
U.S. Total OTO-104 Revenue for Ménière's Disease	**$0.0**	**$0.0**	**$20.43**	**$216.34**	**$325.95**	**$399.65**	**$454.28**	**$513.29**	**$546.50**	**$580.64**	**$615.73**
EU											
Prevalence of Ménière's disease (000s)	937.5	946.9	956.3	965.9	975.6	985.3	995.2	1,005.1	1,015.2	1,025.3	1,035.6
% of patients receiving corticosteroid	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*	*20.0%*
# of patients receiving corticosteroid (000s)	187.5	189.4	191.3	193.2	195.1	197.1	199.0	201.0	203.0	205.1	207.1
% market penetration by OTO-104	*0.0%*	*0.0%*	*5.0%*	*15.0%*	*25.0%*	*30.0%*	*35.0%*	*40.0%*	*42.5%*	*45.0%*	*45.0%*
# of patients receiving OTO-104 treatment (000s)	0.0	0.0	9.6	29.0	48.8	59.1	69.7	80.4	86.3	92.3	93.2
Cost per patient per year (AWP)	$3,600	$3,600	$900	$3,600	$3,672	$3,745	$3,820	$3,897	$3,975	$4,054	$4,135
EU Total OTO-104 Revenue For Ménière's disease	$0.0	$0.0	$8.61	$104.32	$179.11	$221.43	$266.13	$313.34	$342.98	$374.12	$385.42
Royalty of EU Sales of OTO-104 Booked by Otonomy (20%) (MM)	**$0.0**	**$0.0**	**$1.7**	**$20.9**	**$35.8**	**$44.3**	**$53.2**	**$62.7**	**$68.6**	**$74.8**	**$77.1**
WW Total OTO-104 Revenue For Ménière's disease	$0.0	$0.0	$29.0	$320.7	$505.1	$621.1	$720.4	$826.6	$889.5	$954.8	$1,001.2
WW Total OTO-104 Booked by Otonomy (MM)	**$0.0**	**$0.0**	**$22.2**	**$237.2**	**$361.8**	**$443.9**	**$507.5**	**$576.0**	**$615.1**	**$655.5**	**$692.8**

WW Total Product Revenues Booked by Otonomy	**$0.0**	**$12.4**	**$57.5**	**$293.4**	**$440.0**	**$536.7**	**$609.3**	**$686.4**	**$734.6**	**$784.5**	**$826.7**

Source: SunTrust Robinson Humphrey and Company filings

Otonomy Quarterly P&L Model

(in millions)	2012A	2013A	Q1+Q2:14A	Q3:14A	Q4:14A	2014A	Q1:15A	Q2:15E	Q3:15E	Q4:15E	2015E
Product Revenues	-	-	-	-	-	-	-	-	-	-	-
U.S. Total AuriPro Revenue from TTP Surgery (MM)	-	-	-	-	-	-	-	-	-	-	-
Royalty of EU Sales of AuriPro Booked by Otonomy (20%) (MM)	-	-	-	-	-	-	-	-	-	-	-
U.S. Total OTO-104 Revenue for Ménière's Disease	-	-	-	-	-	-	-	-	-	-	-
Royalty of EU Sales of OTO-104 Booked by Otonomy (20%) (MM)	-	-	-	-	-	-	-	-	-	-	-
WW Total Product Revenues Booked by Otonomy	-	-	-	-	-	-	-	-	-	-	-
Collaboration revenue (cost)	-	-	-	-	-	-	-	-	-	-	-
Licensing payment to University of California	-	-	-	-	-	-	-	-	-	-	-
Licensing payment to DURECT Corporation	(0.0)	-	-	-	-	-	-	-	-	-	-
Licensing payment to INSERM	-	-	-	-	-	-	-	-	-	-	-
Total Collaboration Revenue (Cost)	**(0.0)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Total Revenues	**(0.0)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Operating Expenses											
COGS	-	-	-	-	-	-	-	-	-	-	-
Research and Development	8.5	16.3	17.3	7.4	7.2	31.8	8.6	10.0	15.0	17.1	50.8
General and Administrative	2.4	3.5	3.1	2.0	2.7	7.8	3.5	4.3	6.4	7.3	21.8
Sales Force	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	**10.9**	**19.9**	**20.4**	**9.4**	**9.9**	**39.6**	**12.1**	**14.3**	**21.4**	**24.5**	**72.5**
Income (Loss) from Operations	**(11.0)**	**(19.9)**	**(20.4)**	**(9.4)**	**(9.9)**	**(39.6)**	**(12.1)**	**(14.3)**	**(21.4)**	**(24.5)**	**(72.5)**
Other income (loss)											
Interest expense	-	-	-	(0.0)	(0.0)	(0.1)	-	-	-	-	-
Change in fair value of convertible preferred stock warrant liability	-	-	(0.7)	(2.6)	0.1	(3.2)	-	-	-	-	-
Other income (loss), net	**-**	**-**	-	0.0	0.0	0.0	-	-	-	-	-
Total other income (loss)	**3.4**	**0.3**	**(0.7)**	**(2.6)**	**0.1**	**(3.2)**	**0.1**	**-**	**-**	**-**	**0.1**
Net Income (Loss)	**(7.6)**	**(19.6)**	**(21.1)**	**(12.0)**	**(9.8)**	**(42.9)**	**(12.0)**	**(14.3)**	**(21.4)**	**(24.5)**	**(72.2)**
Accretion to redemption value of convertible preferred stock	(0.8)	(0.5)	0.0	(0.0)	-	0.0	-	-	-	-	-
Net income attributable to common stockholders	**(8.4)**	**(20.1)**	**(21.1)**	**(12.0)**	**(9.8)**	**(42.9)**	**(12.0)**	**(14.3)**	**(21.4)**	**(24.5)**	**(72.2)**
Tax rate	-	-	-	-	-	-	-	-	-	-	-
Income Tax	-	-	-	-	-	-	-	-	-	-	-
Net Income (Loss) per Share - Basic	**(3.38)**	**(7.64)**	**-**	**(1.23)**	**(0.46)**	**(5.46)**	**(0.52)**	**(0.58)**	**(0.86)**	**(0.98)**	**(2.96)**
Net Income (Loss) per Share - Diluted	**(3.38)**	**(7.64)**	**-**	**(1.23)**	**(0.46)**	**(5.46)**	**(0.52)**	**(0.58)**	**(0.86)**	**(0.98)**	**(2.96)**
Weighted average common shares outstanding - basic	2.5	2.6	-	9.8	21.2	7.9	23.2	24.6	24.8	25.1	24.4
Weighted average common shares outstanding - diluted	2.5	2.6	-	9.8	21.2	7.9	23.2	24.6	24.8	25.1	24.4

Source: SunTrust Robinson Humphrey and Company filings

Otonomy Annual P&L Model

(in millions)	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Product Revenues	-	-	-	-										
U.S. Total AuriPro Revenue from TTP Surgery (MM)	-	-	-	-	12.0	32.3	49.9	68.6	79.5	86.5	93.8	101.4	109.5	112.8
Royalty of EU Sales of AuriPro Booked by Otonomy (20%) (MM)	-	-	-	-	0.4	3.0	6.2	9.6	13.3	15.4	16.7	18.1	19.6	21.1
U.S. Total OTO-104 Revenue for Ménière's Disease	-	-	-	-	-	20.4	216.3	326.0	399.6	454.3	513.3	546.5	580.6	615.7
Royalty of EU Sales of OTO-104 Booked by Otonomy (20%) (MM)	-	-	-	-	-	1.7	20.9	35.8	44.3	53.2	62.7	68.6	74.8	77.1
WW Total Product Revenues Booked by Otonomy	-	-	-	-	12.4	57.5	293.4	440.0	536.7	609.3	686.4	734.6	784.5	826.7
Collaboration revenue (cost)	-	-	-	-										
Licensing payment to University of California	-	-	-	-	(0.4)	(1.7)	(8.8)	(13.2)	(16.1)	(18.3)	(20.6)	(22.0)	(23.5)	(24.8)
Licensing payment to DURECT Corporation	(0.0)	-	-	-										
Licensing payment to INSERM	-	-	-	-										
Total Collaboration Revenue (Cost)	**(0.0)**	**-**	**-**	**-**	**(0.4)**	**(1.7)**	**(8.8)**	**(13.2)**	**(16.1)**	**(18.3)**	**(20.6)**	**(22.0)**	**(23.5)**	**(24.8)**
Total Revenues	**(0.0)**	**-**	**-**	**-**	**12.0**	**55.8**	**284.6**	**426.8**	**520.6**	**591.0**	**665.8**	**712.6**	**761.0**	**801.9**
Operating Expenses														
COGS	-	-	-	-	1.8	7.9	39.9	59.2	71.9	81.1	91.1	97.2	103.5	109.3
Research and Development	8.5	16.3	31.8	50.8	70.0	80.0	75.0	75.0	78.1	88.7	99.9	106.9	114.1	120.3
General and Administrative	2.4	3.5	7.8	21.8	30.0	34.3	32.1	32.1	33.5	38.0	42.8	45.8	48.9	51.6
Sales Force	-	-	-	-	10.0	20.0	20.4	20.8	21.2	21.6	22.1	22.5	23.0	23.4
Total Operating Expenses	**10.9**	**19.9**	**39.6**	**72.5**	**111.8**	**142.2**	**167.5**	**187.1**	**204.7**	**229.4**	**255.8**	**272.4**	**289.6**	**304.5**
Income (Loss) from Operations	**(11.0)**	**(19.9)**	**(39.6)**	**(72.5)**	**(99.8)**	**(86.4)**	**117.1**	**239.7**	**315.9**	**361.6**	**410.0**	**440.2**	**471.4**	**497.4**
Other income (loss)														
Interest expense	-	-	(0.1)	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of convertible preferred stock warrant liability	-	-	(3.2)	-	-	-	-	-	-	-	-	-	-	-
Other income (loss), net	-	-	0.0	-	-	-	-	-	-	-	-	-	-	-
Total other income (loss)	**3.4**	**0.3**	**(3.2)**	**0.1**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Income (Loss)	**(7.6)**	**(19.6)**	**(42.9)**	**(72.2)**	**(99.8)**	**(86.4)**	**117.1**	**239.7**	**315.9**	**361.6**	**410.0**	**440.2**	**471.4**	**497.4**
Accretion to redemption value of convertible preferred stock	(0.8)	(0.5)	0.0	-	-	-	-	-	-	-	-	-	-	-
Net income attributable to common stockholders	**(8.4)**	**(20.1)**	**(42.9)**	**(72.2)**	**(99.8)**	**(86.4)**	**117.1**	**239.7**	**315.9**	**361.6**	**410.0**	**440.2**	**471.4**	**497.4**
Tax rate	-	-	-	-	-	-	*3%*	*8%*	*12%*	*18%*	*27%*	*35%*	*35%*	*35%*
Income Tax	-	-	-	-	-	-	3.5	19.2	37.9	65.1	110.7	154.1	165.0	174.1
Net Income (Loss) per Share - Basic	**(3.38)**	**(7.64)**	**(5.46)**	**(2.96)**	**(4.05)**	**(3.12)**	**4.11**	**8.17**	**10.45**	**11.61**	**12.78**	**13.32**	**13.85**	**14.19**
Net Income (Loss) per Share - Diluted	**(3.38)**	**(7.64)**	**(5.46)**	**(2.96)**	**(4.05)**	**(3.12)**	**3.85**	**7.67**	**9.83**	**10.94**	**12.07**	**12.60**	**13.12**	**13.46**
Weighted average common shares outstanding - basic	2.5	2.6	7.9	24.4	24.7	27.7	28.5	29.4	30.2	31.1	32.1	33.0	34.0	35.1
Weighted average common shares outstanding - diluted	2.5	2.6	7.9	24.4	24.7	27.7	30.4	31.3	32.1	33.0	34.0	34.9	35.9	37.0

Source: SunTrust Robinson Humphrey and Company filings

Otonomy Discounted Earnings Model

Diluted	$3.85
PE	25
Discount Years	2.6
Discount Rate	35.0%
Valuation	$44.13

Forward P/E Ratio	Discount Rate 55.0%	50.0%	45.0%	40.0%	35.0%	30.0%	25.0%	20.0%
15x	$ 18.49	$ 20.13	$ 21.99	$ 24.09	$ 26.48	$ 29.21	$ 32.35	$ 35.97
20x	24.65	26.85	29.32	32.12	35.31	38.95	43.13	47.96
25x	30.82	33.56	36.65	40.15	44.13	48.68	53.91	59.95
30x	36.98	40.27	43.98	48.18	52.96	58.42	64.69	71.94
35x	43.14	46.98	51.31	56.21	61.79	68.16	75.47	83.93
40x	49.31	53.69	58.64	64.24	70.61	77.89	86.26	95.91
45x	55.47	60.40	65.97	72.27	79.44	87.63	97.04	107.90
50x	61.63	67.12	73.30	80.30	88.27	97.37	107.82	119.89
55x	67.80	73.83	80.63	88.33	97.09	107.10	118.60	131.88

Source: SunTrust Robinson Humphrey and Company filings

Otonomy DCF Model

Final year FCF	323
Perpetual Growth Rate	0
Terminal Value	**2,694**
Discount Factor	0.30
Present Value of Terminal Value	**810**
Present Value of Cash Flows	**713**
Enterprise Value	**1,523**
Add: Net cash	165
Market Value	**1,688**
Fully Diluted Shares Outstanding	24.4
Value per Fully Diluted Share	**$69.11**
Average probablity of success	*60%*
Risk Adjusted Value per Fully Diluted Share	**$41.47**

Source: SunTrust Robinson Humphrey and Company filings

Otonomy Clinical NPV Model

Drug name	Indication	Status	Launch	Success	Peak Sales (US$m)	Economics	Profitability	NPV (US$)
AuriPro	Otitis media patients undergoing TTP surgery	NDA	2016	90%	134	100%	90%	8.40
OTO-104	Ménière's disease	Finished Ph IIb	2017	60%	693	100%	90%	28.99
							Total	**37.39**

Source: SunTrust Robinson Humphrey and Company filings

Company Description

Otonomy is a clinical-stage biopharmaceutical company focused on the development and commercialization of therapeutics for otic diseases. Otonomy has developed a proprietary technology to deliver drugs which are retained in the ear for an extended period of time. Based on this technology, Otonomy has three product candidates in clinical and preclinical development. Its lead product candidate, AuriPro, is a sustained-exposure formulation of the antibiotic ciprofloxacin which has recently completed two Phase III clinical trials for middle ear effusion during tympanostomy tube placement (TTP) surgery and submitted an NDA filing in February 2015 with a PDUFA date of December 25th 2015. The second product candidate, OTO-104, is a sustained-exposure steroid that has completed a Phase IIb clinical trial for patients with Ménière's disease. Otonomy expects to initiate one of two Phase III trials for OTO-104 in 2H15. Its third product candidate, OTO-311, is in preclinical development for the treatment for tinnitus.

Investment Thesis

We view Otonomy as an attractive clinical stage biotechnology play. Otonomy is building an otology powerhouse in a large and under-addressed space with limited competition. The company differentiates via a proprietary Sustained Exposure technology, which solves the issues of delivering drugs successfully to the mid/inner ear. We view the technology as largely de-risked with successful Phase III trial results from AuriPro, and Phase Ib trial results from OTO-104 in delivering different drugs in distinct otology indications. An NDA for lead asset AuriPro was submitted in 1Q15 with an FDA decision on or by December 25, 2015; The first of two Phase III trials for OTO-104 in Ménière's disease is expected to begin in 2H15.

Valuation and Risks

Our price target of $41 is determined by taking an average of three different model methodologies. We reach a 12-month price target of $44.1 with a discounted earnings model, a price target of $41.5 with a discounted cash flow model, and a price target of $37.4 with a clinical NPV model.

Regulatory risk of AuriPro: while AuriPro's Phase III clinical trials met their clinical endpoints and we believe the drug is approvable, there is no guarantee that the FDA will approve the product. One data point that is more concerning is the trials' secondary endpoint that evaluated the cumulative proportion of patients considered treatment failures due to an observation of otorrhea. A significant difference of failure rate is seen between the two sham groups (16% vs 28%). Although the reduction in the rate of otorrhea by AuriPro was statistically significant in both trials ($p=0.038$ and $p<0.001$), the FDA may have questions regarding the data.

Commercial risk of AuriPro: Otonomy has not previously launched or marketed products. In order to successfully commercialize AuriPro, Otonomy needs to secure payer coverage and AuriPro needs to be included in the formulary list of hospital outpatient facilities and ambulatory surgery centers. The decision will be based on not only the clinical data, but also pricing of AuriPro, which is still unknown. Should AuriPro fail to be covered by formularies, we expect it will significantly dim AuriPro's commercial prospects.

Otonomy also needs to build sales/marketing infrastructure, including sales force, medical science liaisons (MSL), etc., to commercialize AuriPro. According to Otonomy, the company expects to launch AuriPro with 30 to 40 reps (with a maximum of 80 reps including those for OTO-104).

Clinical risk of OTO-104 and OTO-311: OTO-104's Phase Ib demonstrated some therapeutic signals in reducing vertigo frequency. However, the study was not designed and powered to do so, and the results from the Phase IIb trial did not achieve statistical significance on the primary endpoint, so there is a definite risk that the planned Phase III trials could also fail.

Technology risk of sustained exposure formulation technology: In theory, the sustained exposure formulation technology should be applicable to other otology indications. Preclinical studies have demonstrated the possibility of co-formulating Poloxamer 407 (P407) with different therapeutic agents. However, different drugs will change the properties of co-polymers, including transition temperature, bioadhesive force, etc., which could make the co-formulation of drugs with P407 more difficult or even impossible.

Competition risk: A handful of other companies are developing therapeutics in the otology field, and some examples are listed below. We believe Otonomy's clinical assets with sustained exposure formulation technology offer an appealing treatment option to physicians and patients. However competitors may have a first-to-launch advantage if they launch products earlier or have better pricing/reimbursement coverage.

Analyst Certification

I, Edward Nash , hereby certify that the views expressed in this research report accurately reflect my personal views about the subject company(ies) and its (their) securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendation(s) in this report.

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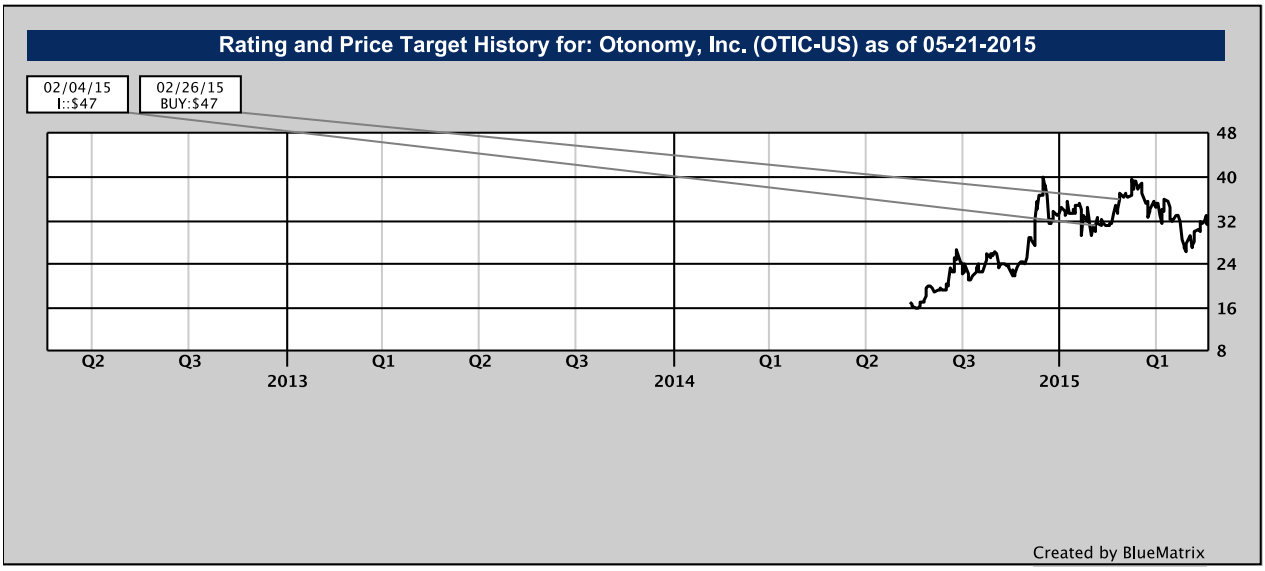

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3 designations based on total returns* within a 12-month period**

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- **Reduce** – total return ≤ negative 10% (5% for low Beta securities)
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*Total return (price appreciation + dividends)
**Price targets are within a 12-month period, unless otherwise noted
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Legend for Rating and Price Target History Charts:
D = drop coverage
I = initiate coverage
T = transfer coverage

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