Otonomy, Inc. (OTIC)

SunTrust Robinson Humphrey

CORRECTION: 2Q Financial Update, AuriPro PDUFA and Meniere's Phase III in 2H15

All clinical timelines remain on track

Buy

Price Target: $41.00
Prior: $41.00

Price (Aug. 12, 2015)	$24.71
52-Wk Range	$40.00-$15.84
Market Cap ($M)	$596
ADTV	237,265
Shares Out (M)	24.1
Short Interest Ratio/% Of Float	13.2%
Dividend/Yield	$0.00/0.0%
TR to Target	65.9%

Cash Per Share	$8.78
Total Debt	$0.0
Long-Term Debt/Total Cap	0%
Cash And Equivalents ($M)	$211.9
Enterprise Value ($M)	$383.6

	2014A	2015E		2016E	
		Curr.	Prior	Curr.	Prior
EPS					
1Q	($0.03)	($0.52)A	($0.52)	--	
2Q	($1.78)	($0.52)A	($0.58)	--	
3Q	($1.23)	($0.88)	($0.86)	--	
4Q	($0.46)	($0.99)	($0.98)	--	
FY	($5.46)	($2.92)	($2.96)	($4.22)	($4.05)
P/E	NM	NM		NM	
Consensus EPS					
FY	--	($2.96)	($2.95)	($3.45)	($3.36)
FYE Dec					

What's Incremental

Otonomy files 2Q15 10-Q filing. 2Q15 EPS reported as ($0.52), above consensus of ($0.67) and our estimate of ($0.58), due to lower R&D expense ($7.3M v.s. $10.0M). We spoke with management after the announcement. All major catalysts are intact with a PDUFA date set for Dec 25, 2015 for AuriPro in treating middle ear effusion in pediatric patients undergoing TTP surgery and a potential launch in 1Q16. Initiation of the first Phase III trial for OTO-104 for Ménière's disease is expected by YE15 and a second Phase III trial in 1Q16. We reiterate our Buy rating and $41 price target.

Otonomy Financial Updates and Upcoming Milestones

EPS	2Q15
Actual	($0.52)
STRH estimate	($0.58)
Consensus	($0.67)

OTONOMY FUNDING TO DATE			
Date	Price	Gross Proceeds (MM)	Type
Aug-14	$16.00	$115.0	IPO
Jan-15	$29.25	$85.8	Equity

BALANCE SHEET	30-Jun-15	31-Mar-15
Cash (MM)	$211.9	$223.6
LTD (MM)	$0.0	$0.0

UPCOMING MILESTONES	
Dec 25 2015	PDUFA date for AuriPro for middle ear effusion at time of TTP surgery
1Q16	Commercial launch of AuriPro for middle ear effusion at time of TTP surgery
2H15	Top-line data for AuriPro for AOMT
by YE15	Initiation of the first Phase III trial of OTO-104 for Ménière's disease
1Q16	Initiation of the second Phase III trial of OTO-104 for Ménière's disease
by YE15	IND application and initiation of a Phase I trial for OTO-311 for tinnitus

Source: SunTrust Robinson Humphrey

Correct models are now attached.

We are updating our 2015 EPS to ($2.92) v.s. previous ($2.96) and 2016 EPS to ($4.22) v.s. previous ($4.05). The changes are primarily due to a slightly lower than expected total shares outstanding, a slight increase in G&A and a decrease in R&D.

AuriPro could be Otonomy's first commercial product. With a PDUFA date of Dec 25, 2015, and commercial launch in 1Q16, AuriPro, targeting

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middle ear effusion in pediatric patients undergoing tympanostomy tube placement (TTP) surgery, could transform Otonomy from a clinical stage to commercial stage company. We remain confident in AuriPro's potential for approval and believe AuriPro has the promise of becoming a commercial success addressing unmet medical needs, as discussed in our previous note.

Otonomy expects to hold an End-of-Phase II meeting with the FDA in 2H15 and initiate the first Phase III trial for OTO-104 for Ménière's disease by YE15. The purpose of the End-of-Phase II meeting with the FDA is to discuss Phase IIb results and plans for the Phase III program. Recall that OTO-104 missed the primary endpoint of vertigo frequency reduction (p=0.067) although OTO-104 demonstrated a therapeutic benefit in reducing vertigo frequency and severity according to the top-line data released in May (see our previous note here). Management emphasized during our conversation yesterday that the primary endpoint was a slight miss statistically. Any of the below modifications in a *post hoc* analysis could lead to a *p* value less than 0.05, including:

- Exclude less severe patients with low baseline vertigo frequency of <4 (32% of total patient population in the Phase IIb trial)
- Exclude the most severe patients with high baseline vertigo frequency (potentially larger than 16 to 22)
- Apply alternative statistical analysis methods, e.g., Poisson analysis (note: Otonomy has not released details regarding the analysis, but commented that the method is accepted by the FDA)

We believe that these could be the potential changes in the Phase III trial and topics to discuss during the meeting with the FDA. We believe the primary endpoint could still be reduction of vertigo frequency which had been requested by the FDA previously. And endpoints could be measured at the end of three-months, similar to previous trials, as this time point has demonstrated the greatest efficacy over placebo.

Otonomy has a strong cash position. The company reported $211.9M in cash, cash equivalents, and short-term investments at the end of 2Q15. We believe the strong cash position will provide the Company with a cash runway through YE2016 at a projected burn-rate of approximately $70M to $75M in 2015 and $90M to $100M in 2016.

We remain bullish on shares of Otonomy, and reiterate our $41 price target. We look forward to the PDUFA date for AuriPro for middle ear effusion at time of TTP surgery in December, updates from the FDA meeting, and the initiation of the second Phase III trial of OTO-104 for Ménière's disease by YE15.

Otonomy Quarterly P&L Model

(in millions)	2012A	2013A	2014A	Q1:15A	Q2:15A	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	31.8	8.6	7.3	15.0	17.1	48.0
General and Administrative	2.4	3.5	7.8	3.5	5.4	6.4	7.3	22.6
Sales Force	-	-	-	-	-	-	-	-
Total Operating Expenses	**10.9**	**19.9**	**39.6**	**12.1**	**12.6**	**21.4**	**24.4**	**70.5**
Income (Loss) from Operations	**(11.0)**	**(19.9)**	**(39.6)**	**(12.1)**	**(12.6)**	**(21.4)**	**(24.4)**	**(70.5)**
Other income (loss)								
Interest expense	-	-	(0.1)	-	0.1	-	-	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**	**0.1**	**-**	**-**	**0.2**
Net Income (Loss)	**(7.6)**	**(19.6)**	**(42.9)**	**(12.0)**	**(12.5)**	**(21.4)**	**(24.4)**	**(70.4)**
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)**	**(12.0)**	**(12.5)**	**(21.4)**	**(24.4)**	**(70.4)**
Tax rate	-	-	-	-	-	-	-	-
Income Tax	-	-	-	-	-	-	-	-
Net Income (Loss) per Share - Basic	**(3.38)**	**(7.64)**	**(5.46)**	**(0.52)**	**(0.52)**	**(0.88)**	**(0.99)**	**(2.92)**
Net Income (Loss) per Share - Diluted	**(3.38)**	**(7.64)**	**(5.46)**	**(0.52)**	**(0.52)**	**(0.88)**	**(0.99)**	**(2.92)**
Weighted average common shares outstanding - basic	2.5	2.6	7.9	23.2	24.1	24.4	24.6	24.1
Weighted average common shares outstanding - diluted	2.5	2.6	7.9	23.2	24.1	24.4	24.6	24.1

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	48.0	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	22.6	32.9	37.6	35.2	35.2	36.7	41.7	46.9	50.2	53.6	56.5
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**	**70.5**	**114.7**	**145.5**	**170.6**	**190.2**	**207.9**	**233.1**	**259.9**	**276.8**	**294.3**	**309.5**
Income (Loss) from Operations	**(11.0)**	**(19.9)**	**(39.6)**	**(70.5)**	**(102.7)**	**(89.7)**	**114.0**	**236.6**	**312.7**	**358.0**	**405.9**	**435.8**	**466.7**	**492.4**
Other income (loss)														
Interest expense	-	-	(0.1)	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)**	**0.2**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Income (Loss)	**(7.6)**	**(19.6)**	**(42.9)**	**(70.4)**	**(102.7)**	**(89.7)**	**114.0**	**236.6**	**312.7**	**358.0**	**405.9**	**435.8**	**466.7**	**492.4**
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)**	**(70.4)**	**(102.7)**	**(89.7)**	**114.0**	**236.6**	**312.7**	**358.0**	**405.9**	**435.8**	**466.7**	**492.4**
Tax rate	*-*	*-*	*-*	*-*	*-*	*-*	*3%*	*8%*	*12%*	*18%*	*27%*	*35%*	*35%*	*35%*
Income Tax	-	-	-	-	-	-	3.4	18.9	37.5	64.4	109.6	152.5	163.3	172.3
Net Income (Loss) per Share - Basic	**(3.38)**	**(7.64)**	**(5.46)**	**(2.92)**	**(4.22)**	**(3.28)**	**4.05**	**8.16**	**10.47**	**11.64**	**12.81**	**13.35**	**13.89**	**14.22**
Net Income (Loss) per Share - Diluted	**(3.38)**	**(7.64)**	**(5.46)**	**(2.92)**	**(4.22)**	**(3.28)**	**3.79**	**7.66**	**9.85**	**10.96**	**12.09**	**12.62**	**13.14**	**13.48**
Weighted average common shares outstanding - basic	2.5	2.6	7.9	24.1	24.3	27.3	28.1	29.0	29.9	30.8	31.7	32.6	33.6	34.6
Weighted average common shares outstanding - diluted	2.5	2.6	7.9	24.1	24.3	27.3	30.0	30.9	31.8	32.7	33.6	34.5	35.5	36.5

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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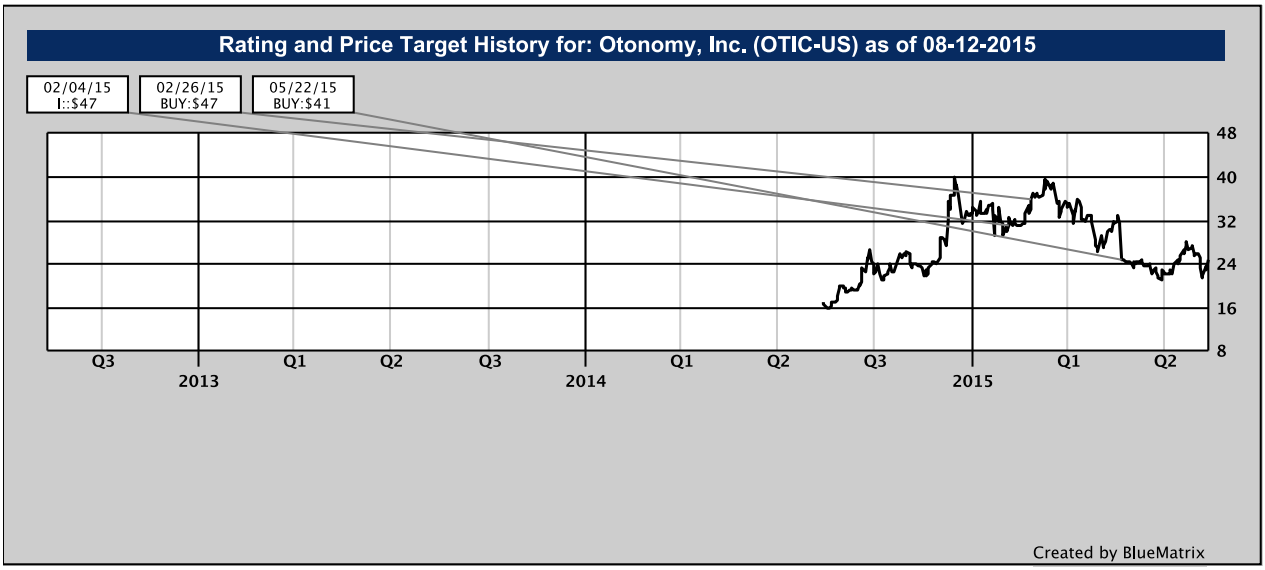

STRH Ratings System for Equity Securities

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

- **Buy** – total return ≥ 15% (10% for low-Beta securities)***
- **Reduce** – total return ≤ negative 10% (5% for low Beta securities)
- **Neutral** – total return is within the bounds above
- **NR** – NOT RATED, STRH does not provide equity research coverage
- **CS** – Coverage Suspended

*Total return (price appreciation + dividends)
**Price targets are within a 12-month period, unless otherwise noted
***Low Beta defined as securities with an average Beta of 0.8 or less, using Bloomberg's 5-year average Beta

Legend for Rating and Price Target History Charts:
D = drop coverage
I = initiate coverage
T = transfer coverage

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Coverage Universe			Investment Banking Clients Past 12 Months		
Rating	**Count**	**Percent**	**Rating**	**Count**	**Percent**
Buy	323	56.17%	Buy	124	38.39%
Neutral	246	42.78%	Neutral	55	22.36%
Sell/Reduce	6	1.04%	Sell/Reduce	1	16.67%

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