Otonomy, Inc. (OTIC)

SunTrust Robinson Humphrey

4Q14 Model Update; All Eyes On Phase IIb Data Readout For OTO-104 In 2Q15

Otonomy continues to focus on pipeline as lead drug reaches the FDA

Buy

Price Target: $47.00
Prior: $47.00

Price (Mar. 18, 2015)	$38.50
52-Wk Range	$40.00-$15.84
Market Cap ($M)	$928
ADTV	187,829
Shares Out (M)	24.1
Short Interest Ratio/% Of Float	4.0%
Dividend/Yield	$0.00/0.0%
TR to Target	22.1%

Cash Per Share	$10.08
Total Debt	$5.6
Long-Term Debt/Total Cap	0%
Cash And Equivalents ($M)	$236.0
Enterprise Value ($M)	$668.6

	2014E	2015E Curr.	2015E Prior	2016E Curr.	2016E Prior
EPS					
1Q	($0.03)	($0.49)	($0.80)	--	
2Q	($1.78)	($0.60)	($0.79)	--	
3Q	($1.23)	($0.90)	($0.79)	--	
4Q	($0.46)	($1.05)	($0.79)	--	
FY	($5.46)	($3.05)	($3.17)	($3.57)	($2.76)
P/E	NM	NM		NM	
Consensus EPS					
FY	($4.14)	($2.81)	($2.91)	($2.92)	($3.21)
FYE Dec					

What's Incremental

Otonomy reported 4Q14 financial results yesterday after the close and we had the opportunity to chat extensively with management this morning. Current focus is on launch preparations for AuriPro. Phase IIb trial of OTO-104 for Ménière's disease completed enrollment in Dec-2014 and is on track to report top-line results in 2Q15. With the licensing of preclinical/clinical data for gacyclidine from Ipsen, an IND for OTO-311 is expected to be filed in 2015. We reiterate our Buy rating and $47 price target on shares of Otonomy.

EPS	4Q14	FY2014
Actual	($0.46)	($5.46)
STRH estimate	($0.64)	($3.63)
Consensus	($0.64)	($4.14)

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	31-Dec-13	31-Dec-14
Cash (MM)	$37.3	$139.8
LTD (MM)	$0.0	$0.0

UPCOMING MILESTONES	
1Q15	NDA filing of AuriPro for middle ear effusion at time of TTP surgery
1H16	FDA approval of AuriPro for middle ear effusion at time of TTP surgery
1H15	Ph I initiation of AuriPro for additional ear indications
2Q15	Ph IIb topline readout of OTO-104 for Ménière's disease
2H15	Second pivotal trial initiation of OTO-104 for Ménière's disease
2015	IND application of OTO-311 for tinnitus

Source: SunTrust Robinson Humphrey

Otonomy is diligently preparing for the commercial launch of AuriPro. With the submission of an NDA in February 2015, the company is now in launch preparation mode. In October 2014, Otonomy hired Anthony Yost as Chief Commercial Officer. Yost brings more than 30 years of pharma commercialization experience and has launched more than 20 new products. The company reiterated plans to launch AuriPro by hiring 40 reps to target 2,500 ENT physicians that perform 80% of tympanostomy tube placement (TTP) procedures in the U.S. Otonomy maintained guidance in pricing of $200 to $250 per treatment for AuriPro. As discussed in our previous note, we expect the next step will be the response from the FDA by late April as to whether or not the NDA submission will be filed for review and the issuance of a PDUFA date if the submission is filed.

OTO-104 for Ménière's disease is on track and all eyes are on the 2Q15 Phase IIb data readout. As previously announced, the company completed the enrollment of 154 patients in a Phase IIb trial for OTO-104 in Ménière's disease in December 2014. Management is guiding for a 2Q15 top-line data readout. Should the outcome be positive, the Company intends to start

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a second pivotal trial in 2H15 with a very similar or identical trial design which had been discussed with the FDA during an end of Phase Ib meeting. Management noted that the potential exists to adjust the powering and to reduce the number of patients in the second pivotal trial if the current Phase IIb trial suggests overpowering.

OTO-311 (gacyclidine) for tinnitus is expected to enter the clinic in 2015. As previously announced, Otonomy exclusively licensed preclinical and clinical data for gacyclidine (studied as a neuroprotectant administered systemically) from Ispen, which included data on the maximum tolerated dose (MTD) for the drug. Management continues to guide for the initiation of a Phase I trial in 2015. Competitor Auris Medical's AM-101, also an NMDA receptor antagonist similar to gacyclidine, is further along in development (currently in Phase III), which we believe paves the way for OTO-311's clinical development. One of the key questions to track is when to target tinnitus and at what stage, acute (within three or six months of onset) or chronic (six months and beyond). We believe OTO-311 significantly differentiates via its Sustained Exposure technology.

Indication expansion opportunities exist for all three assets. Otonomy continues to guide for the initiation of a clinical trial in one or more additional indications for AuriPro in 2015, such as recurrent otic infections in patients with tympanostomy tubes, acute otitis externa, and prophylaxis following middle-ear surgery. Management noted that these expanded indications could potentially double the market size of AuriPro. The Company is evaluating indication expansion opportunities for other assets as well, including sudden hearing loss, and tinnitus for OTO-104; chronic hearing loss, and age-related hearing loss for OTO-311.

Otonomy has a strong balance sheet. With net proceeds of $80M from a follow-on offering in January 2015, the company has approximately $236M *pro forma* of cash and cash equivalents on its balance sheet. Management noted that current cash on hand can fund the Company for at least 24 months, but management could not comment on whether it might need another round of financing before the company reaches breakeven.

We continue to be bullish on shares of Otonomy and reiterate our $47 price target. We believe with a strong management team, a differentiated and de-risked technology, a clear vision and focus on ear indications, and a large untapped market, Otonomy has the potential to be a formidable otology-focused company. We would continue to be strong buyers of Otonomy shares and maintain our $47 price target.

Otonomy Quarterly P&L Model

(in millions)	2012A	2013A	Q1+Q2:14A	Q3:14A	Q4:14A	2014A	Q1:15E	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	8.0	10.0	15.0	17.8	50.8
General and Administrative	2.4	3.5	3.1	2.0	2.7	7.8	3.4	4.3	6.4	7.6	21.8
Sales Force	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	**10.9**	**19.9**	**20.4**	**9.4**	**9.9**	**39.6**	**11.4**	**14.3**	**21.4**	**25.4**	**72.5**
Income (Loss) from Operations	**(11.0)**	**(19.9)**	**(20.4)**	**(9.4)**	**(9.9)**	**(39.6)**	**(11.4)**	**(14.3)**	**(21.4)**	**(25.4)**	**(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)**	**-**	**-**	**-**	**-**	**-**
Net Income (Loss)	**(7.6)**	**(19.6)**	**(21.1)**	**(12.0)**	**(9.8)**	**(42.9)**	**(11.4)**	**(14.3)**	**(21.4)**	**(25.4)**	**(72.5)**
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)**	**(11.4)**	**(14.3)**	**(21.4)**	**(25.4)**	**(72.5)**
Tax rate	-	-	-	-	-	-	-	-	-	-	-
Income Tax	-	-	-	-	-	-	-	-	-	-	-
Net Income (Loss) per Share - Basic	**(3.38)**	**(7.64)**	**-**	**(1.23)**	**(0.46)**	**(5.46)**	**(0.49)**	**(0.60)**	**(0.90)**	**(1.05)**	**(3.05)**
Net Income (Loss) per Share - Diluted	**(3.38)**	**(7.64)**	**-**	**(1.23)**	**(0.46)**	**(5.46)**	**(0.49)**	**(0.60)**	**(0.90)**	**(1.05)**	**(3.05)**
Weighted average common shares outstanding - basic	2.5	2.6	-	9.8	21.2	7.9	23.4	23.6	23.9	24.1	23.7
Weighted average common shares outstanding - diluted	2.5	2.6	-	9.8	21.2	7.9	23.4	23.6	23.9	24.1	23.7

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					-	40.9	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)					-	3.4	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	79.7	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)	(2.4)	(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)**	**(2.4)**	**(8.8)**	**(13.2)**	**(16.1)**	**(18.3)**	**(20.6)**	**(22.0)**	**(23.5)**	**(24.8)**
Total Revenues	**(0.0)**	**-**	**-**	**-**	**12.0**	**77.3**	**284.6**	**426.8**	**520.6**	**591.0**	**665.8**	**712.6**	**761.0**	**801.9**
Operating Expenses														
COGS	-	-	-	-	1.8	11.0	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	60.0	65.0	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	25.7	27.9	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**	**97.5**	**123.8**	**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)**	**(85.5)**	**(46.6)**	**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)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Income (Loss)	**(7.6)**	**(19.6)**	**(42.9)**	**(72.5)**	**(85.5)**	**(46.6)**	**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)**	**(72.5)**	**(85.5)**	**(46.6)**	**117.1**	**239.7**	**315.9**	**361.6**	**410.0**	**440.2**	**471.4**	**497.4**
Tax rate	*-*	*-*	*-*	*-*	*-*	*0.0*	*0.1*	*0.1*	*0.2*	*0.3*	*0.4*	*0.4*	*0.4*	*0.4*
Income Tax	-	-	-	-	-	(1.4)	9.4	28.8	56.9	97.6	143.5	154.1	165.0	174.1
Net Income (Loss) per Share - Basic	**(3.38)**	**(7.64)**	**(5.46)**	**(3.05)**	**(3.57)**	**(1.73)**	**4.21**	**8.37**	**10.72**	**11.91**	**13.11**	**13.66**	**14.21**	**14.55**
Net Income (Loss) per Share - Diluted	**(3.38)**	**(7.64)**	**(5.46)**	**(3.05)**	**(3.29)**	**(1.61)**	**3.94**	**7.85**	**10.07**	**11.21**	**12.36**	**12.90**	**13.44**	**13.79**
Weighted average common shares outstanding - basic	2.5	2.6	7.9	23.7	24.0	27.0	27.8	28.6	29.5	30.4	31.3	32.2	33.2	34.2
Weighted average common shares outstanding - diluted	2.5	2.6	7.9	23.7	26.0	28.9	29.7	30.5	31.4	32.3	33.2	34.1	35.1	36.1

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. The second product candidate, OTO-104, is a sustained-exposure steroid that is in a Phase IIb clinical development for patients with Ménière's disease. Otonomy expects to report results from this trial in 2Q15. 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 otic indications. An NDA submission for lead asset AuriPro is expected in 1Q15 with an FDA decision as early as YE15; top-line results for OTO-103 Phase IIb addressing the larger market of Ménière's disease is expected in 2Q15.

Valuation and Risks

Our price target of $47 is determined by taking an average of three different model methodologies. We reach a 12-month price target of $51.0 with a discounted earnings model, a price target of $45.7 with a discounted cash flow model, and a price target of $43.1 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 may not translate into the current Phase IIb trial.

Technology risk of sustained exposure formulation technology: In theory, the sustained exposure formulation technology should be applicable to other otic 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 otic 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.

Companies Mentioned in This Note

Auris Medical (EARS, $5.79, NR)
Ipsen SA (IPN.NX, €45.23, NR)

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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OTIC-US

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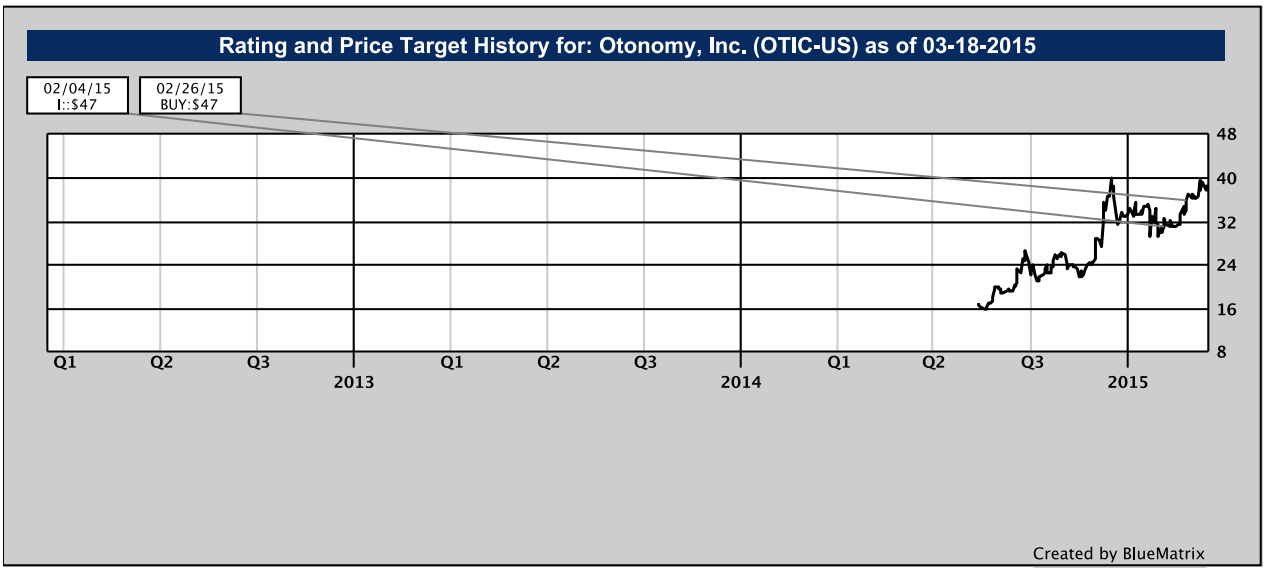

STRH Ratings System for Equity Securities

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	280	52.73%	Buy	100	35.71%
Neutral	244	45.95%	Neutral	43	17.62%
Sell/Reduce	7	1.32%	Sell/Reduce	2	28.57%

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