Otonomy, Inc. (OTIC)

1Q15 Model Update; Phase IIb Data for Meniere's Disease in 2Q15

AuriPro PDUFA Has Been Set for Christmas Day

Buy

Price Target: $47.00
Prior: $47.00

Price (May 13, 2015)	$29.92
52-Wk Range	$40.00-$15.84
Market Cap ($M)	$721
ADTV	172,496
Shares Out (M)	24.1
Short Interest Ratio/% Of Float	6.3%
Dividend/Yield	$0.00/0.0%
TR to Target	57.1%

Cash Per Share	$9.28
Total Debt	$0.0
Long-Term Debt/Total Cap	0%
Cash And Equivalents ($M)	$223.6
Enterprise Value ($M)	$505.4

	2014E	2015E		2016E	
		Curr.	Prior	Curr.	Prior
EPS					
1Q	($0.03)A	($0.52)A	($0.49)	--	
2Q	($1.78)A	($0.58)	($0.60)	--	
3Q	($1.23)A	($0.86)	($0.90)	--	
4Q	($0.46)A	($0.98)	($1.05)	--	
FY	($5.46)A	($2.96)	($3.05)	($3.47)	($3.57)
P/E	NM	NM		NM	
Consensus EPS					
FY	($4.14)	($3.04)	($2.81)	($3.28)	($2.92)
FYE Dec					

What's Incremental

Updating Otonomy financials based on 1Q15 10-Q filing. We had the opportunity to speak with management after the filing. All anticipated milestones are intact with a set PDUFA date of Dec 25, 2015 for AuriPro in treating middle ear effusion in pediatric patients undergoing tympanostomy tube placement (TTP) surgery; a launch is expected in 1Q16. Initiation of a clinical trial for a second label expansion indication for AuriPro is expected in 2015. Phase IIb read-out of OTO-104 for Ménière's disease in 2Q15 remains to the major imminent catalyst. We reiterate our Buy rating and $47 price target.

Otonomy Financial Updates and Upcoming Milestones

EPS	1Q15
Actual	($0.52)
STRH estimate	($0.49)
Consensus	($0.56)

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-Mar-15	31-Dec-14
Cash (MM)	$223.6	$156.0
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
2015	Initiation of a clinical trial for AuriPro in a second expansion indication, potentially AOE
2Q15	Ph IIb topline readout of OTO-104 for Ménière's disease
2H15	Initiation of a second pivotal trial of OTO-104 for Ménière's disease
2015	IND application of OTO-311 for tinnitus

Source: SunTrust Robinson Humphrey

AuriPro PDUFA date is Dec 25, 2015. Recall that Otonomy submitted an NDA on Feb 26, 2015 for AuriPro in TTP surgery. The newly announced PDUFA date is in-line with our 10-month standard review projection. We remain confident in AuriPro's approvability and anticipate an FDA approval on or before the PDUFA date. Otonomy has been diligently preparing for the commercial launch and we believe AuriPro has strong potential of becoming a commercial success, as discussed in our previous note.

Otonomy expects to expand into a third indication for AuriPro. On May 7th Otonomy announced the completion of patient enrollment for a Phase II label expansion study of AuriPro in treating pediatric patients with acute otitis media with tympanostomy tubes (AOMT), which is less than one and a half months after the initiation of the trial on March 26th. As discussed in a

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previous note, we believe the clinical success rate is high for AuriPro in this sizable market. We estimate close to 75% of the market share for AuriPro in TTP surgeries and for the AOMT indication. The Company announced plans to initiate a clinical trial for AuriPro in a second expansion indications (the third indication so far for AuriPro) in 2015. We believe acute otitis externa (AOE), a common ear-canal inflammation caused predominantly by bacterial infections, could be a potential candidate. Although most of the over two million annual ambulatory visits caused by AOE are treated by pediatricians and primary care physicians, a small fraction, ~3%, of AOEs are more severe and are treated by ENTs. We believe the convenience and effectiveness of AuriPro could be appealing to ENTs who are already familiar with AuriPro, should AuriPro be approved for use during TTP surgeries before the AOE indication.

Otonomy has a strong cash position. With net proceeds of $80.0M from a financing in Jan 2015, the company had $223.6M cash, cash equivalents, and short-term investment on its balance sheet at the end of 1Q15. We believe the strong cash position could be adequate to fund the Company through YE2016 at a projected burn-rate of approximately $70M to $75M in 2015 and $90M to $100M in 2016. Minor model updates incorporating slight increase of shares outstanding according to the quarterly filing.

We remain confident on the success of the Company, continue to be bullish on shares of Otonomy, and reiterate our $47 price target. With almost all previously announced milestones successfully executed, we believe Otonomy is marching steadily toward becoming an otology-focused powerhouse. We would continue to be strong buyers of Otonomy shares ahead of a major inflection point in 2Q15 - the top-line data read for OTO-104 in Ménière's disease. We maintain our $47 price target.

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	-	-	-	-	-	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)**	**0.1**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Income (Loss)	**(7.6)**	**(19.6)**	**(42.9)**	**(72.2)**	**(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)**	**(72.2)**	**(85.5)**	**(46.6)**	**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%*	*35%*
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)**	**(2.96)**	**(3.47)**	**(1.68)**	**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)**	**(3.21)**	**(1.57)**	**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	26.7	29.6	30.4	31.3	32.1	33.0	34.0	34.9	35.9	37.0

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 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 otology indications. An NDA for lead asset AuriPro was submitted in 1Q15 with an FDA decision on or by December 25, 2015; top-line results for OTO-104 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 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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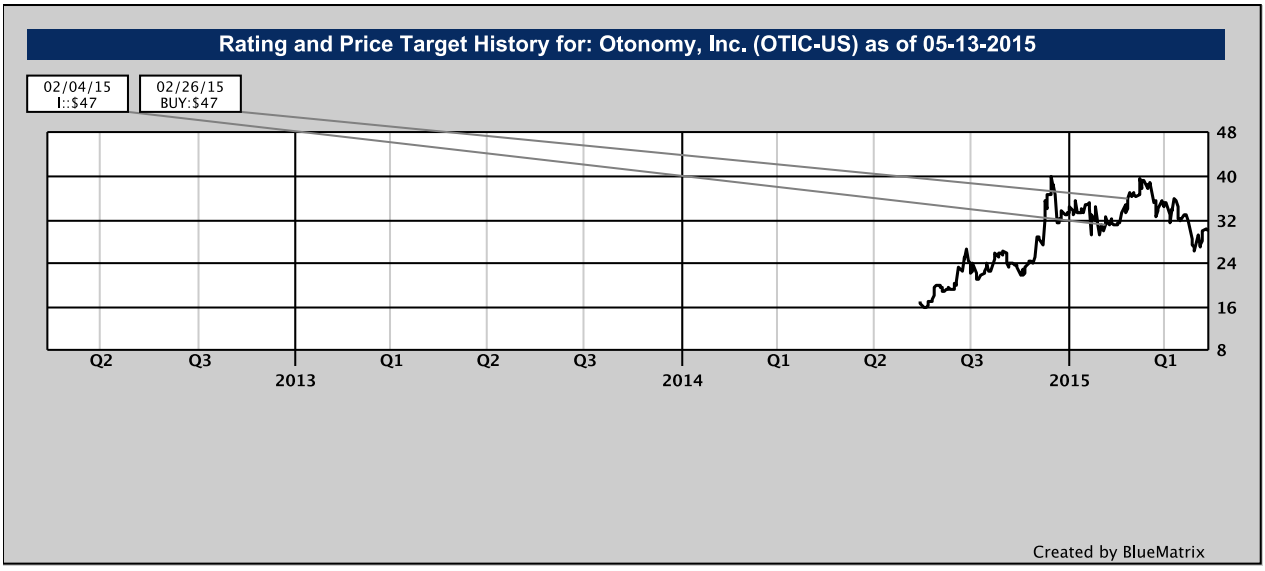

STRH Ratings System for Equity Securities

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

SunTrust Robinson Humphrey ratings distribution (as of 05/14/2015):

Coverage Universe			Investment Banking Clients Past 12 Months		
Rating	**Count**	**Percent**	**Rating**	**Count**	**Percent**
Buy	292	52.61%	Buy	105	35.96%
Neutral	252	45.41%	Neutral	50	19.84%
Sell/Reduce	11	1.98%	Sell/Reduce	1	9.09%

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