Otonomy, Inc. (OTIC)

AuriPro NDA Filed; Expect FDA Response In Next 60 Days

Timely NDA Submission Puts AuriPro On Track For 1H16 U.S. Launch

This morning Otonomy announced submission of an NDA for the approval of AuriPro to treat middle ear effusion in pediatric patients undergoing tympanostomy tube placement (TTP) surgery. This is in-line with management's previous guidance placing the Company on track to launch AuriPro in the U.S. 1H16, if approved.

Both Phase III trials successful. Otonomy released data from two Phase III trials (study 302 and 303) in July 2014 in a total of 532 patients between the ages of six months and 12 years. AuriPro met the primary efficacy endpoint of reducing the incidence of treatment failures ($p<0.001$) and was well tolerated.

NDA submission submitted under Section 505(b)(2). Otonomy submitted an NDA under the 505(b)(2) pathway as the active pharmaceutical ingredient (API) of AuriPro, ciprofloxacin, is an approved product. At the pre-NDA meeting held with the FDA in September 2014, the FDA confirmed that the current dataset, including preclinical studies, a Phase Ib, and two Phase III studies, was sufficient for an NDA filing.

FDA has the next move: The Agency has 60 days from NDA submission to determine whether to file the NDA and if accepted for filing, give notice of the exact PDUFA date. We believe that AuriPro is on track for a 1H16 U.S. launch based on a ten-month standard review timeline. Additional catalysts are as follows:

Product	Indication	Timing	Event	Importance
AuriPro	Middle ear effusion at time of TTP surgery	1Q15	NDA filing	++
AuriPro	Middle ear effusion at time of TTP surgery	1H16	FDA approval	+++
AuriPro	Other ear indications expansion	1H15	Ph II initiation	++
OTO-104	Ménière's disease	2Q15	Ph IIb topline readout	+++
OTO-104	Ménière's disease	2H15	Ph III initiation	++
OTO-311	Tinnitus	2015	IND application	+

Source: SunTrust Robinson Humphrey

We reiterate our Buy rating and $47 PT. We maintain a 90% success rate for AuriPro and a U.S. launch in 2Q16 with peak WW revenue of ~$200M in 2025.

Buy

Price Target: $47.00
Prior: $47.00

Price (Feb. 25, 2015)	$33.92
52-Wk Range	$40.00-$15.84
Market Cap ($M)	$817
ADTV	183,132
Shares Out (M)	24.1
Short Interest Ratio/% Of Float	4.6%
Dividend/Yield	$0.00/0.0%
TR to Target	38.6%

Cash Per Share	$10.20
Total Debt	$5.7
Long-Term Debt/Total Cap	0%
Cash And Equivalents ($M)	$246.0
Enterprise Value ($M)	$480.0

	2014E	2015E		2016E	
		Curr.	Prior	Curr.	Prior
EPS					
1Q	($0.03)	($0.80)	($0.80)	--	
2Q	($1.78)	($0.79)	($0.79)	--	
3Q	($1.23)	($0.79)	($0.79)	--	
4Q	($0.64)	($0.79)	($0.79)	--	
FY	($3.63)	($3.17)	($3.17)	($2.76)	($2.76)
P/E	NM	NM		NM	
Consensus EPS					
FY	($4.24)	($2.91)	($2.91)	($3.21)	($3.21)
FYE Dec					

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SEE PAGE 3 FOR REQUIRED DISCLOSURE INFORMATION

Otonomy, Inc. Quarterly P&L Model

(in millions)	2012A	2013A	Q1+Q2:14A	Q3:14A	Q4:14E	2014E	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	24.6	7.4	10.7	42.6	18.0	18.0	18.0	18.0	72.0
General and Administrative	2.4	3.5	5.2	2.0	2.4	9.6	3.0	3.1	3.3	3.4	12.8
Sales Force	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	**10.9**	**19.9**	**29.8**	**9.4**	**13.1**	**52.2**	**21.0**	**21.1**	**21.3**	**21.4**	**84.8**
Income (Loss) from Operations	**(11.0)**	**(19.9)**	**(29.8)**	**(0.0)**	**(13.1)**	**(42.8)**	**(21.0)**	**(21.1)**	**(21.3)**	**(21.4)**	**(84.8)**
Other income (loss)											
Interest expense	-	-	(0.0)	(0.0)	(0.0)	(0.1)	-	-	-	-	-
Change in fair value of convertible preferred stock warrant liability	-	-	(3.3)	(2.6)	(2.0)	(7.9)	-	-	-	-	-
Other income (loss), net	-	-	0.0	0.0	0.0	0.1	-	-	-	-	-
Total other income (loss)	**3.4**	**0.3**	**(3.3)**	**(2.6)**	**(2.0)**	**(7.9)**	**-**	**-**	**-**	**-**	**-**
Net Income (Loss)	**(7.6)**	**(19.6)**	**(33.1)**	**(12.0)**	**(15.0)**	**(60.1)**	**(21.0)**	**(21.1)**	**(21.3)**	**(21.4)**	**(84.8)**
Accretion to redemption value of convertible preferred stock	(0.8)	(0.5)	(0.0)	(0.0)	(0.0)	(0.1)	-	-	-	-	-
Net income attributable to common stockholders	**(8.4)**	**(20.1)**	**(33.1)**	**(12.0)**	**(15.0)**	**(60.2)**	**(21.0)**	**(21.1)**	**(21.3)**	**(21.4)**	**(84.8)**
Tax rate	-	-	-	-	-	-	-	-	-	-	-
Income Tax	-	-	-	-	-	-	-	-	-	-	-
Net Income (Loss) per Share - Basic	**(3.38)**	**(7.64)**	**-**	**(1.23)**	**(0.71)**	**(3.88)**	**(0.87)**	**(0.87)**	**(0.87)**	**(0.86)**	**(3.46)**
Net Income (Loss) per Share - Diluted	**(3.38)**	**(7.64)**	**-**	**(1.23)**	**(0.64)**	**(3.63)**	**(0.80)**	**(0.79)**	**(0.79)**	**(0.79)**	**(3.17)**
Weighted average common shares outstanding - basic	2.5	2.6	-	9.8	21.2	15.5	24.1	24.4	24.6	24.9	24.5
Weighted average common shares outstanding - diluted	2.5	2.6	-	9.8	23.4	16.6	26.3	26.6	26.9	27.1	26.7

Source: SunTrust Robinson Humphrey and company reports

Otonomy, Inc. Annual P&L Model

(in millions)	2012A	2013A	2014E	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	42.6	72.0	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	9.6	12.8	14.0	14.5	15.0	16.0	17.0	18.0	18.5	19.0	20.0	20.5
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**	**52.2**	**84.8**	**85.8**	**110.5**	**150.3**	**171.0**	**188.2**	**209.4**	**231.5**	**245.6**	**260.6**	**273.5**
Income (Loss) from Operations	**(11.0)**	**(19.9)**	**(42.8)**	**(84.8)**	**(73.8)**	**(33.2)**	**134.2**	**255.8**	**332.4**	**381.6**	**434.3**	**467.0**	**500.3**	**528.4**
Other income (loss)														
Interest expense	-	-	(0.1)	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of convertible preferred stock warrant liability	-	-	(7.9)	-	-	-	-	-	-	-	-	-	-	-
Other income (loss), net	-	-	0.1	-	-	-	-	-	-	-	-	-	-	-
Total other income (loss)	**3.4**	**0.3**	**(7.9)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net Income (Loss)	**(7.6)**	**(19.6)**	**(60.1)**	**(84.8)**	**(73.8)**	**(33.2)**	**134.2**	**255.8**	**332.4**	**381.6**	**434.3**	**467.0**	**500.3**	**528.4**
Accretion to redemption value of convertible preferred stock	(0.8)	(0.5)	(0.1)	-	-	-	-	-	-	-	-	-	-	-
Net income attributable to common stockholders	**(8.4)**	**(20.1)**	**(60.2)**	**(84.8)**	**(73.8)**	**(33.2)**	**134.2**	**255.8**	**332.4**	**381.6**	**434.3**	**467.0**	**500.3**	**528.4**
Tax rate	-	-	-	-	-	*0.0*	*0.1*	*0.1*	*0.2*	*0.3*	*0.4*	*0.4*	*0.4*	*0.4*
Income Tax	-	-	-	-	-	(1.0)	10.7	30.7	59.8	103.0	152.0	163.4	175.1	184.9
Net Income (Loss) per Share - Basic	**(3.38)**	**(7.64)**	**(3.88)**	**(3.46)**	**(2.98)**	**(1.20)**	**4.70**	**8.69**	**10.97**	**12.22**	**13.51**	**14.10**	**14.67**	**15.04**
Net Income (Loss) per Share - Diluted	**(3.38)**	**(7.64)**	**(3.63)**	**(3.17)**	**(2.76)**	**(1.12)**	**4.41**	**8.17**	**10.32**	**11.52**	**12.75**	**13.34**	**13.89**	**14.27**
Weighted average common shares outstanding - basic	2.5	2.6	15.5	24.5	24.7	27.7	28.6	29.4	30.3	31.2	32.2	33.1	34.1	35.1
Weighted average common shares outstanding - diluted	2.5	2.6	16.6	26.7	26.7	29.6	30.5	31.3	32.2	33.1	34.1	35.0	36.0	37.0

Source: SunTrust Robinson Humphrey and company reports

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. Details of these models are contained within this report.

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.

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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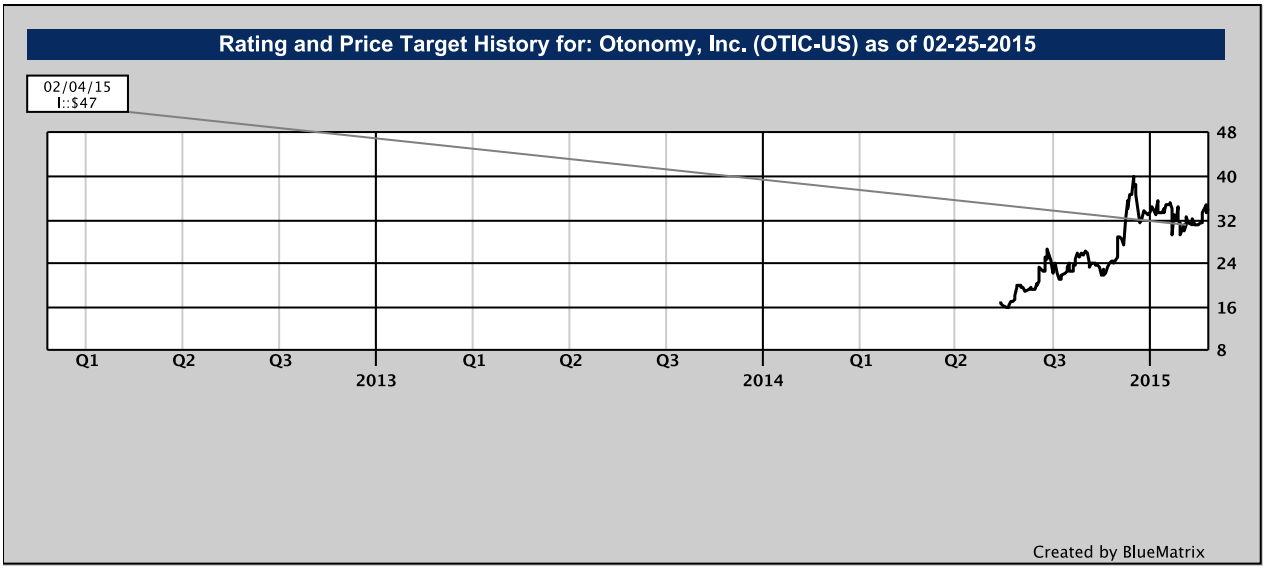

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- **Reduce** – total return ≤ negative 10% (5% for low Beta securities)
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*Total return (price appreciation + dividends)
**Price targets are within a 12-month period, unless otherwise noted
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Legend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

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