Otonomy

Equity Research

Quick Take: Earnings Update

March 19, 2015

Price: $38.50 (03/18/2015)

Price Target: $55.00

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: OTIC
Market Cap (MM)	$928.9

AuriPro Commercialization Remains On Track; Dev. Programs Continue To Progress

The Cowen Insight

Reiterating our Outperform rating and $55 price target. Our rating is predicated on the eventual U.S. approval and launch of AuriPro in early 2016 and successful development of OTO-104. Importantly, our consultants believe the company's technology is novel, needed, and applicable to numerous additional ear-related disorders and should provide significant value from these levels.

AuriPro Approval And Launch Expected Early 2016; OTO-104 First Pivotal Trial To Read Out Next Quarter

Otonomy reported Q4 and year-end earnings and provided updates on its AuriPro, OTO-104, and OTO-311 development programs. For the lead product AuriPro (sustained-release ciprofloxacin) for the treatment of middle ear effusion at the time of TTP surgery, the company has submitted the NDA application in late February and we would expect it to be accepted by the FDA in the next month. Worth noting, based upon previous FDA feedback, it appears that the company will not be required to have an advisory committee meeting. Upon potential approval – which we believe will occur – Otonomy expects to launch the product in the first quarter of 2016 and commercial activities should continue to accelerate through the end of the year. Otonomy is also expected to initiate another clinical trial for AuriPro in one or more additional indications to expand the proposed label - that should begin by mid-year. These expansion indications could more than double the market opportunity for AuriPro and we currently do not include them in our model. The second late-stage clinical candidate in development, OTO-104 (sustained-release dexamethasone), has its first pivotal trial ongoing for the treatment of Ménière's disease, a condition that causes vertigo, tinnitus, and hearing loss. Ménière's has significant unmet need as it can eventually lead to permanent hearing loss and currently there are no approved treatments. OTO-104's ongoing pivotal trial will be one of two required for approval and should have topline data readout next quarter. Given the powering assumptions for the trial and the significant clinical effects observed in Phase Ib – which had an almost identical design to the ongoing trial – we are confident that the study should succeed. Upon trial success, we would expect the second pivotal trial to be initiated in the second half of 2015. Finally, Otonomy is also developing a third drug candidate, OTO-311 (sustained-release gacyclidine), for the treatment of tinnitus, which is ringing in the ear in the absence of an external source. Approximately 16MM patients in the U.S. suffer from tinnitus severe enough to require medical attention. However, like Ménière's, there are no currently approved treatments for this debilitating condition. Otonomy expects to file an IND and initiate an early clinical trial for OTO-311 by year-end. The bottom line is that for a small company Otonomy has a relatively impressive amount of development programs ongoing/planned and management continues to execute exceptionally well. Ultimately, we believe the company will be successful in developing these novel and innovative drugs for the treatment of various ear disorders – historically an area with a lack of treatment options – that serve real unmet needs and offer product profiles that our physician consultants find very attractive.

Otonomy Has Generated Compelling Clinical Data

For AuriPro, Otonomy has completed two identical Phase III trials (Study 302 and Study 303) in 532 total pediatric patients across ~60 sites in the U.S. and Canada and the results of these trials form the basis for the NDA submission. Importantly, AuriPro achieved its primary efficacy endpoint along with several secondary endpoints. AuriPro reduced the risk of treatment failure by an average of 49% ($p<0.001$) and also reduced the proportion of patients that were treatment failures due to otorrhea or use of antibiotics by an average of 62% ($p\leq0.004$) across both trials. AuriPro was well-tolerated, and there were no notable differences in safety between patients treated with AuriPro or sham. Of note, the AuriPro gel did not cause any increase in the incidence of tube clogging relative to sham in either the Phase II or Phase III studies. Overall, our consultants found the Phase III data to be impressive and highlighted that in terms of safety, efficacy, and convenience, AuriPro's product profile would provide a superior option relative to current antibiotic ear drops.

Regarding OTO-104, we view the development risk as very low given that IT steroid injections are already used quite frequently in practice and appear to be moderately effective. The goal of OTO-104, is simply to provide higher and sustained concentration of dexamethasone relative to existing injections, which we believe will not adversely affect future clinical trial results. In a Phase Ib clinical trial, OTO-104 demonstrated a significant mean reduction in vertigo frequency (primary endpoint) during month 3 relative to baseline. There was a clear dose response as a 56% and 73% (p-value=0.086) reductions in vertigo frequency in month 3 was observed with the 3mg and 12mg OTO-104 dosing cohorts. The 73% reduction in the 12mg group was equivalent to a reduction in days with vertigo from 8 at baseline to 2 in month 3. A day with vertigo is defined as an episode lasting at least 20 minutes and being completely debilitating. Interestingly, 50% of patients in this study had no vertigo in the third month. Furthermore, 81% of patients in the 1mg OTO-104 arm had at least a 50% improvement in vertigo frequency in month 3 versus baseline. Clearly, the 12mg OTO-104 group was not statistically significant, but we would note that it is due to the study arm only having 16 patients and the fact that it was even close (0.036 off) is impressive. In general, a single injection of OTO-104 was well tolerated and there were no serious adverse events observed during the trial. Moreover, there were no instances of persistent conductive hearing loss associated with OTO-104 injection. We believe the physician experience with dexamethasone for Ménière's – in conjunction with the existing early clinical data showing an impressive effect – substantially de-risks the program. OTO-104 is currently in a Phase IIb clinical trial, which has completed enrollment, and results are expected in Q2:2015. This trial will serve as one of two pivotal efficacy studies. The second pivotal study is expected to start in the second half of 2015 and we estimate final results should come by mid-year 2017 or potentially earlier. Therefore, OTO-104 could be launched in the U.S. by early 2018 and potentially sooner, assuming successful development. It is important to note that OTO-104 has been granted Fast Track Designation, so the there is potential to receive an expedited 6-month regulatory review. In the EU, a multiple-dose safety study was initiated in the U.K in October 2014 and is underway and we generally expect a potential European launch at least 1-2 years later as the priority post launching in the U.S. market will be to expand in additional indications.

The Valuation Is Attractive Here

Our base case valuation model assumes a U.S. approval and subsequent launch of AuriPro by the second quarter of 2016 and we believe U.S. peak sales could reach approximately ~$500MM for middle ear indications, assuming a penetration of roughly 30% of U.S. antibiotic ear drop prescriptions by 2025. We also assume modest EU sales beginning in 2018 for AuriPro with a peak sales value of $300MM +. For OTO-104, we assume U.S. approval and launch in 2018. Assuming a peak 15%

penetration of Ménière's patients results in a $750MM+ U.S. peak sales potential. We also expect approval in the EU in 2020 with peak sales eventually reaching $400MM +. Worth noting, our estimates for both products could ultimately be conservative as our consultants suggest each has very logical and viable follow-on indications that the company is exploring. We do not model any of these additional indication expansion opportunities. European approval could also potentially come sooner than we model. Approvals/partnerships in the rest of the world could also provide further upside. We would also note that our valuation does not attribute any potential sales of OTO-311, which like OTO-104, is competing in a market with no currently approved treatments and could potentially have significant pricing flexibility and provide further upside beyond our base case valuation. Using the sales estimates provided above, we arrive at a DCF valuation of $55 per share, which is the basis of our price target. Label expansion of AuriPro and OTO-104 is likely and should provide further upside. An approval and launch of OTO-311, the company's earlier stage candidate for tinnitus to enter the clinic this year, could provide even further upside. We would be buying here.

Valuation Methodology And Risks

Valuation Methodology

Pharmaceuticals/Specialty

For our valuation methodology, we arrive at fair value utilizing a discounted cash flow (DCF) approach to derive our 12-month price target.

Investment Risks

Pharmaceuticals/Specialty

Risks include: (1) growing competitive dynamics in the specialty pharmaceuticals space; (2) the ability of management to execute on external growth by successfully acquiring new strategic, accretive products; (3) the ability to grow organically and keep the product pipeline robust; (4) potential regulatory delays, rejections, or failures of pipeline products; (5) economic sensitivity of any self-pay products or weakening consumer demand; (6) domestic or international pricing pressures for marketed products; and (7) failure to execute on new product launches.

Risks To The Price Target

Otonomy is a development-stage company and with that carries risk. We believe the clinical risk is mitigated as Otonomy's products employ active ingredients that have been approved in other indications. However, failure for AuriPro to receive FDA approval in 2016 and for OTO-104 to achieve success in Phase IIb could result in significant downside to our valuation.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
OTIC	Otonomy

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

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Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

Underperform (3): Stock expected to underperform the S&P 500

Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

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Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

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Distribution of Ratings/Investment Banking Services (IB) as of 12/31/14

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	461	60.50%	109	23.64%
Hold (b)	288	37.80%	14	4.86%
Sell (c)	13	1.71%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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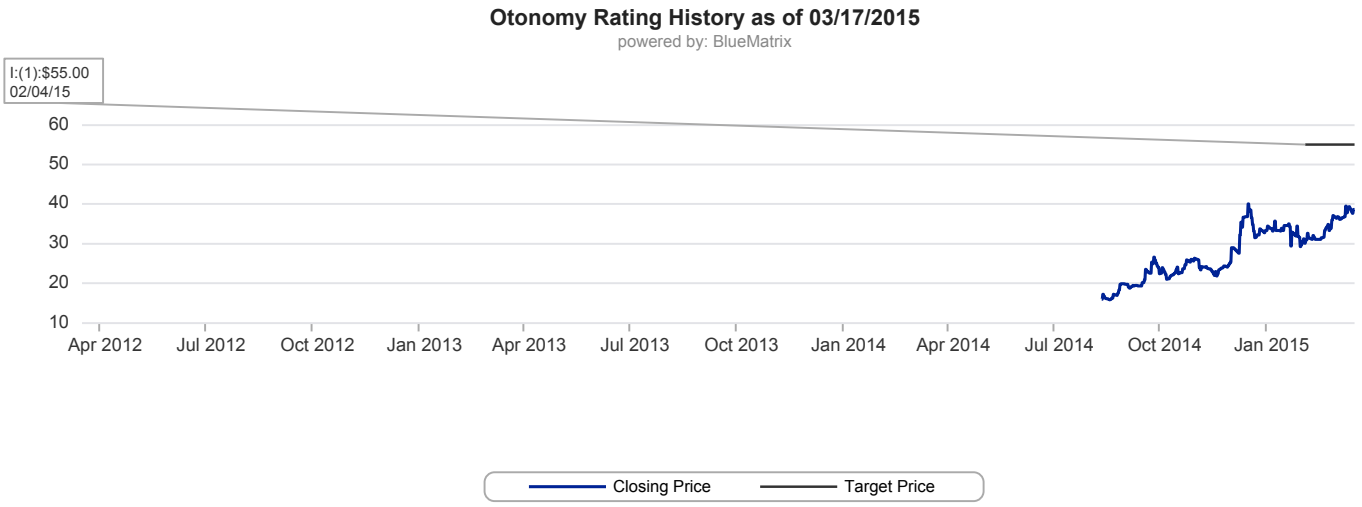

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

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