Otonomy

Equity Research

Quick Take: Earnings Update

May 13, 2015

Price: $30.25 (05/12/2015)
Price Target: $55.00

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: OTIC
Market Cap (MM)	$730.1

Ménière's Data Is Upcoming And Commercial AuriPro Preparations Also Underway

The Cowen Insight

Otonomy reported Q1 and provided an update. Importantly, we continue to believe AuriPro will receive U.S. approval & be launched in early 2016. Additionally, the first pivotal OTO-104 trial for Ménière's should readout soon and we believe will be significantly value creating. Our consultants believe the company's technology is novel, needed, and should provide significant value from these levels.

AuriPro NDA Accepted And Approval Expected With Launch In Early 2016; OTO-104 First Pivotal Ménière's Trial To Readout By End Of Q2

Otonomy reported Q1 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 received acceptance for the NDA application with a December 25, 2015 PDUFA date and we continue to believe it will receive a clean review. 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. On the commercial front, we would note that Otonomy has made some recent solid additions and that they appear to be taking a very deliberate, methodical approach to preparing for the product introduction. Otonomy also completed a one month Phase II trial for AuriPro in the first follow-on indication, acute otitis media in pediatric patients with tympanostomy tubes (AOMT), which demonstrated the feasibility of administering AuriPro. This is critical because it is the first demonstration of administering AuriPro in the physician's office while children are not under general anesthesia and this has significant implications for additional future follow-on indications. And we should expect to receive an update of another expansion opportunity in addition to AOMT by year-end with a clinical trial to follow. 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 and is expected to readout by the end of this quarter. Ménière's is a condition that causes vertigo, tinnitus, and hearing loss and has significant unmet need as it can eventually lead to permanent hearing loss, a difficult/poor quality of life, and currently there are no approved treatments. OTO-104's ongoing first pivotal trial will be one of two required for approval and if successful, the second pivotal trial will be initiated by year-end. 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 pivotal trial and that we discuss further below – we are confident that the study should succeed. We believe this could be a $1B+ worldwide market opportunity with pricing

and retreatment dynamics similar to anti-VEGF treatments for wet AMD, which we find very attractive.

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 and we expect this could be an additional meaningful future revenue stream for the company if successfully developed. 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. Given the significant value to still be created from these development programs and the near-term value inflections points, we would be buying here.

The Initial OTO-104 Ménière's Data Give Us – And Our Consultants – Confidence In The Eventual Results Of The Ongoing Pivotal Trial

We view the OTO-104 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 (pivotal primary endpoint) during month 3 relative to baseline. There was a clear dose response as a 56% and 73% (p-value=0.086; n=16) 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 by the end of this quarter. 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 there is potential to receive an expedited 6-month regulatory review. In the EU, a multiple-dose U.K safety study has completed enrollment in April 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.

Our Clinician Consultants Believe AuriPro Phase III Clinical Data Support Approval

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.

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 eventual 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.

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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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

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

Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013

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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Buy (a)	450	58.67%	103	22.89%
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Sell (c)	15	1.96%	0	0.00%

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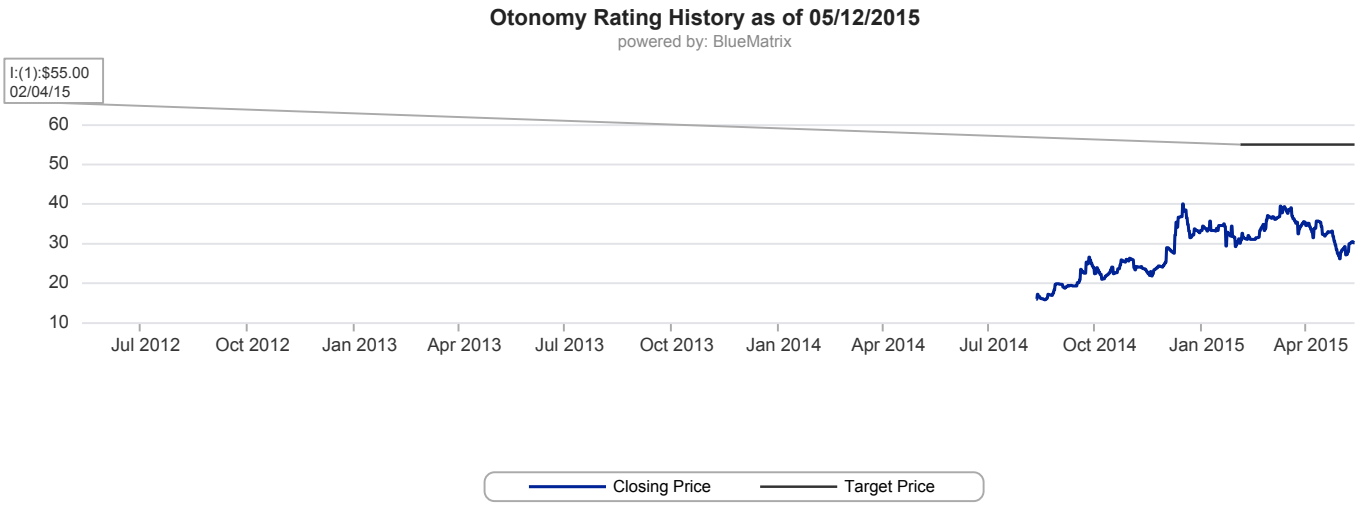

Legend for Price Chart:

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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