

Otonomy

Ears Are the New Eyes...Initiating at Overweight

We are initiating coverage of OTIC with an Overweight rating based on the potential of its two lead pipeline candidates: AuriPro (sustained exposure antibiotic) and OTO-104 (sustained exposure steroid). AuriPro has successfully completed Phase 3 trials in TTP surgery (ear tube placement); an NDA is expected in 1H15 and we expect a 2016 launch with peak sales of \$250M. OTO-104 is in a Phase 2b trial in Ménière's disease; data is expected in 1H15 and we assume launch in 2018 with peak sales of ~\$500M. A third candidate, OTO-311 for tinnitus, is preclinical – thus we do not break it out in our valuation – but its estimated \$1B+ sales potential represents a significant free call option, in our view. Bottom line, we think OTIC's de-risked AuriPro and OTO-104 represent a compelling opportunity on their own with the NDA filing and key data readout in 1H15 with further upside potential from OTO-311's blockbuster potential.

- **OTIC's sustained exposure technology addresses an unmet need in otic drug delivery.** Despite the large number of patients who suffer from maladies of the ear, current treatments (i.e. local delivery of drug in solution) leave something to be desired on convenience and efficacy given the anatomical challenges of administering a liquid drug solution to the targeted area. OTIC's technology uses a polymer that turns from liquid to gel at body temp. The gel form allows the drug suspension to be retained in the desired location for an extended period of time, providing higher and more sustained drug exposure directly to the affected area.
- **AuriPro (antibiotic) and OTO-104 (steroid) are largely de-risked late-stage assets based on early-stage data and familiarity of the active compounds.** Both AuriPro and OTO-104 have generated promising data thus far, with AuriPro successfully completing two Phase 3 trials and OTO-104 showing positive Phase 1b data. Both products use common and well-characterized active ingredients (ciprofloxacin in AuriPro, dexamethasone in OTO-104) that are currently used by ENTs to treat OTIC's target indications for each product.
- **Doctors we spoke with were unilaterally positive on sustained delivery of compounds via techniques that they already use.** We spoke with four ENTs, all of whom were involved in one or both of OTIC's clinical trials. All agreed that the products were easy to use logistically/procedurally, which we think will be important for adoption (doctors won't have to change any practice habits). Additionally, the four doctors noted the benefit of increased compliance should be key in pediatric patients for AuriPro, and fewer repeat office visits for steroid injections would be an important benefit for Ménière's patients.
- **Initiating at OW.** Our YE15 PT of \$32 is based on an avg of our NPV and scenario analysis (50% each). AuriPro and OTO-104 are the key value drivers. On a sum-of-the-parts basis, we assign ~\$14/shr to AuriPro (85% prob of approval) and ~\$12/shr to OTO-104 (70% prob of approval) plus ~\$6/shr for the pipeline and YE15E cash.

Otonomy, Inc. (OTIC;OTIC US)

FYE Dec	2012A	2013A	2014E	2015E	2016E
EPS Reported (\$)					
Q1 (Mar)	-	(1.04)	(3.65)A	-	-
Q2 (Jun)	-	-	(3.40)A	-	-
Q3 (Sep)	-	-	(0.77)	-	-
Q4 (Dec)	-	-	(0.75)	-	-
FY	(3.38)	(7.64)	(4.51)	(3.09)	(3.11)

Source: Company data, Bloomberg, J.P. Morgan estimates.

Initiation Overweight

OTIC, OTIC US

Price: \$18.79

Price Target: \$32.00

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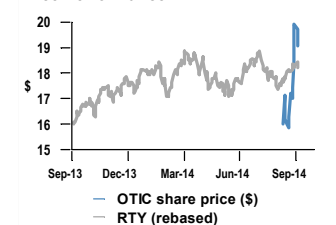
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Price Performance



Company Data

Price (\$)	18.79
Date Of Price	05 Sep 14
52-week Range (\$)	20.45-15.19
Market Cap (\$ mn)	58.70
Fiscal Year End	Dec
Shares O/S (mn)	3
Price Target (\$)	32.00
Price Target End Date	31-Dec-15

See page 33 for analyst certification and important disclosures.

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Investment Thesis

Otonomy (OTIC)

Overweight

OTIC's proprietary polymer meets an unmet need in otic drug delivery by providing sustained drug exposure with a single-dose administration

Millions of patients in the US suffer from various ear diseases (e.g. infection, hearing loss, Ménière's disease), and current treatment methods leave something to be desired both on convenience and efficacy given anatomical challenges of treating the issues locally. Drug solution delivered via drops and/or injection into the middle ear cavity essentially "runs out of the ear" fairly quickly, limiting the amount of drug delivered/necessitating repeat doses. OTIC's proprietary tech platform involves a drug suspension in a thermosensitive polymer that is injected into the desired location within the ear where it then gels at body temperature. This state change allows the drug suspension to be retained in the desired location for an extended period of time, providing higher and more sustained drug exposure directly to the affected area.

AuriPro, OTIC's lead candidate, is a sustained exposure antibiotic that provides significant compliance advantages over currently used drops

AuriPro contains ciprofloxacin (a commonly used antibiotic in ear drops) and is in development for the treatment of middle ear effusion in pediatric patients requiring TTP (tube placement) surgery. Ear drops typically prescribed (off label) after surgery require multiple doses per day for several days which 1) is challenging for caregivers/parents and 2) is worrisome for docs as missed doses can affect efficacy. With a single injection administered by the doc during surgery, AuriPro provides a full course of antibiotics while eliminating compliance struggles/concerns. AuriPro has successfully completed two RCTs, and an NDA is anticipated in 1H15.

NDA filing for AuriPro is anticipated in 1H15; we model launch in 2016 with peak US sales of ~\$250M

Otonomy estimates off-label antibiotic ear drops are used in ~1M TTP procedures in the US each year, and its market research (and our doc conversations) has indicated a high level of interest in AuriPro's product profile. Otonomy plans to commercialize its products itself in the US (with ~30-40 reps initially), and we model launch in 2016. We conservatively assume AuriPro is used in 55% of the target TTP procedures at peak. Based on physician commentary we also assume some off-label use in other middle ear indications (e.g. swimmer's ear, prophylaxis in other middle ear surgeries) prior to their actual inclusion on the label. We assume a launch price of \$250 per administration, giving peak revenues of \$250M in the US. Given the lack of clarity on the ex-US strategy, we currently do not model/assign value to any ex-US revenues, which could provide potential upside to our estimates.

OTO-104 is a sustained exposure steroid currently in Phase 2b in Ménière's disease, for which there are currently no FDA-approved therapies

OTO-104 contains dexamethasone, a steroid that is currently widely used off label (in liquid form) in the treatment of inner ear disorders. Ménière's disease is a chronic condition characterized by acute vertigo attacks, tinnitus, fluctuating hearing loss and a feeling of aural fullness. While there are currently no FDA-approved drug therapies, off-label steroids are often used to help manage symptoms. Currently used liquid formulations require repeat administrations as the injections provide less than a day of drug exposure with each dose. With a single administration by the physician, OTO-104 provides a full course of steroid treatment by providing sustained exposure of the drug in the inner ear over several weeks. OTO-104 is currently being evaluated

in a Phase 2b trial in 140 patients to assess reductions in vertigo frequency and improvements in tinnitus in patients with Ménière's disease. OTO-104 has been granted Fast Track designation by the FDA.

Phase 2b data for OTO-104 is anticipated in 1H15; we model launch in 2018 with peak US sales of ~\$500M

OTIC estimates there are more than 600,000 patients diagnosed with Ménière's disease in the US. Based on the company's market research and our conversations with docs, there is a high level of interest in OTO-104 for this disease given the lack of existing approved/effective therapies and the convenience for both the doc and patient with a single dose. Additionally, the four docs with whom we spoke repeatedly mentioned they would likely use OTO-104 in the treatment of other inner ear disorders (sudden hearing loss was most often mentioned) ahead of label inclusion. We model launch in 2018 and assume that OTO-104 is used in 55% of the target Ménière's pts at peak, plus some off label use in other indications. We assume a launch price of \$1,000/administration, giving a peak US revenue estimate of ~\$500M. As with AuriPro, we do not currently model/assign value to any ex-US revenues.

OTO-311, currently in preclinical development for the treatment of tinnitus, has an estimated >\$1B revenue potential and is a free call option, in our view.

Tinnitus is a condition wherein patients hear noise when there is no outside source of the sound (i.e. ringing in the ear), and patients with severe symptoms can have trouble sleeping, working and hearing, among other issues. There are currently no FDA-approved drugs to treat the condition. OTO-311 contains the NMDA receptor antagonist gacyclidine, which preclinical data suggest is active at the NMDA receptor subtype believed to be relevant to tinnitus. OTO-311 is currently in preclinical development, and the company plans to file an IND in 2015. With an estimated 16M Americans (according to the American Tinnitus Association) suffering from tinnitus symptoms severe enough to seek treatment (and ~2M unable to function normally on a day-to-day basis), OTO-311 has the potential to be a blockbuster product with an estimated >\$1B in revenue potential, in our view.

Otonomy has global commercialization rights to all of its pipeline candidates and has a strong IP position with initial patent expiry ranging from 2029-2031.

Otonomy has a broad IP portfolio, with rights to 55 issued patents and 85 pending patent applications directed to AuriPro, OTO-104, and OTO-311, as well as towards a broad range of active ingredients delivered through their proprietary technology (potential future indications). AuriPro, OTO-104, and OTO-311 have patent protection until at least 2030, 2029, and 2031, respectively.

Balance sheet: OTIC appears well positioned financially

OTIC ended 2Q14 with ~\$71M in cash and subsequently raised ~\$104M from an IPO in August (J.P. Morgan acted as a joint book-runner). We estimate OTIC will end 2014 with ~\$145M in cash and believe the company has sufficient cash through the expected approval of AuriPro in early 2016.

Initiate at Overweight: OTIC's clinical pipeline represents a compelling opportunity with an attractive free call option in pre-clinical development.

We are initiating coverage of OTIC with an OW rating and YE15 PT of \$32. We believe the unmet need in otic drug delivery will drive uptake of AuriPro and OTO-104 given their compliance (and thus likely efficacy) benefits vs. currently used therapies. Our target price is based on a blended average of our risk-adjusted NPV

model (50%) and proprietary scenario analysis (50%). On a sum-of-the-parts basis, we assign ~\$14/shr to AuriPro (85% prob of approval) and ~\$12/shr to OTO-104 (70% prob of approval) plus ~\$3/shr for the remaining pipeline/tech and \$3/shr in estimated YE15 cash.

Risks to Rating and Price Target

Otonomy is susceptible to the standard risks that apply to the entire biotech industry, including development, regulatory, commercial, manufacturing, financing, and IP pitfalls. Risks more specific to Otonomy are outlined below:

Clinical Risk

Though Otonomy has successfully completed two randomized, controlled clinical trials with AuriPro, the indication evaluated for this product represents the smallest potential revenue opportunity of the pipeline candidates, based on our estimates. It is also possible that later stage trials with OTO-104 may not produce data consistent with earlier studies. With any of the product candidates, it is possible that longer term/additional trials may not meet their primary endpoints, or that new/unexpected side effects could emerge with greater numbers of patients.

Regulatory Risk

Otonomy believes data from the two Phase 3 trials for AuriPro will be sufficient to support approval. However, the risk remains that AuriPro will not be approved by the FDA or EMA. Regulatory agencies may want to see additional data before approving the drug. If approved, it is possible that the label may not be as the company anticipates, potentially limiting the use of AuriPro. Further, regulatory agencies could remove the drug from the market if it shows additional/more severe AEs in a real-world setting. The same holds true for additional pipeline products OTO-104 and OTO-311.

Commercial risk

The rate of uptake and/or pricing could limit sales of AuriPro or OTO-104. AuriPro would be Otonomy's first commercial drug, and it is possible that product adoption by physicians may be slower than expected. There are competitive products (standard ear drops) that are fairly widely used. Physicians may be slower than expected to try new products in these indications. Further, there are generic antibiotic and steroid drops which could affect pricing power and could limit Otonomy's ability to price favorably and/or remain competitive.

Company Description

Otonomy is a San Diego-based biopharmaceutical company focused on the development and commercialization of therapeutics that treat disorders and diseases of the ear. OTIC went public in August (J.P. Morgan acted as a joint book-runner). The company's proprietary technology has been designed to overcome challenges with delivering drugs to the middle and inner ear, and allow for sustained exposure after a single, local administration. Otonomy currently has three products in development using this technology, including Phase 3 AuriPro, Phase 2 OTO-104, and pre-clinical OTO-311. AuriPro, OTIC's sustained exposure antibiotic therapeutic, has successfully completed two Phase 3 trials in pediatric patients with

middle ear effusion at the time of tympanostomy tube placement. An NDA is anticipated in 1H15. OTO-104 is a sustained exposure steroid currently in a Phase 2b trial for the treatment of Ménière's disease, with data anticipated in 1H15. OTO-311 is in pre-clinical development for the treatment of tinnitus. Otonomy has global commercialization rights to all three product candidates.

Upcoming Events

Figure 1: OTIC News Flow Highlights

Anticipated Newsflow Highlights				
Program	Event		Expected Timing	Significance
AuriPro	Submit NDA		1H15	Medium
	Initiate clinical trials in other indications	✓	2015	Low
	Potential US Launch	✓	2016	High
OTO-104	Phase 2b results in Ménière's disease		1H15	Medium
	Initiate single-dose Phase 3 study		2H15	Medium
	Initiate multiple-dose safety studies		4Q14	Medium
OTO-311	File IND	✓	2015	Medium
	Initiate Phase 1b study	✓	2015	Medium

Source: Company reports and J.P. Morgan estimates.

For Otonomy in the next 12-18 months, the key upcoming catalysts include Phase 2b data from the ongoing Phase 2b trial of OTO-104 Ménière's disease in 1H15.

Otonomy also plans to submit an NDA for AuriPro in 1H15 for potential approval and launch in 2016. We also expect the company to file an IND and initiate clinical development of OTO-311 in tinnitus.

Pipeline

Figure 2: OTIC's Pipeline

Program	P/C	Ph 1	Ph 2	Ph 3	FDA	Mkt.	Partner	Comments
AuriPro								ciprofloxacin
OTO-104								dexamethasone
OTO-311								gacyclidine
Tinnitus								

Source: Company reports.

AuriPro is OTIC's lead drug candidate. It is a suspension of the antibiotic ciprofloxacin in OTIC's proprietary polymer that is currently in development for the treatment of middle ear effusion (fluid build up in the middle ear) in pediatric patients requiring TTP surgery. The company also plans to explore possible additional indications (e.g. acute otitis media with tubes in place, acute otitis externa, chronic suppurative otitis media, and prophylaxis following various middle ear surgeries). OTIC's second product candidate is OTO-104, a suspension of the steroid dexamethasone. It is currently in Phase 2b for the treatment of Ménière's disease and other inner ear conditions. OTO-104 has been granted Fast Track designation from

the FDA.OTIC's preclinical candidate, OTO-311, is a suspension of the NMDA receptor antagonist gacyclidine and is currently in development for the treatment of tinnitus.

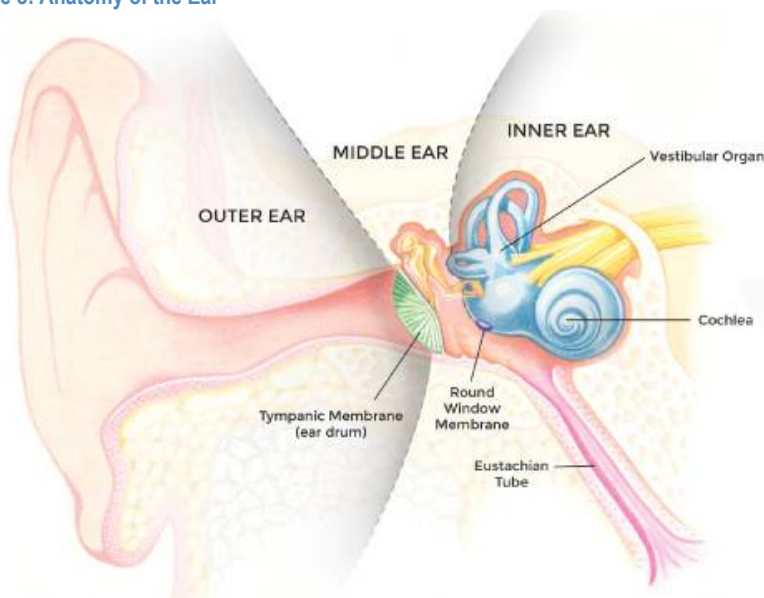
The Ear: A Brief Overview

Anatomy and Function

Otology is the branch of medicine that focuses on the structure, function and pathology of the ear, as well as diseases and disorders of the ear. Structurally, there are three main parts of the ear: the outer, inner and middle ear.

The ear consists of three main segments; the outer, middle and inner ear.

Figure 3: Anatomy of the Ear



Source: Otonomy reports.

Looking from the outside in, the outer ear describes the external portion of the ear (the cartilage flap that works to funnel sound waves into the auditory canal) up to the ear drum (tympanic membrane). When sound waves that have traveled down the auditory canal hit the tympanic membrane, it vibrates. On the other side of the tympanic membrane lies the middle ear, also known as the tympanic cavity. This air-filled cavity is connected to the upper throat area at the back of the nose via the Eustachian tube. This is a narrow, ~1.5-inch long tube that allows the air pressure in the middle ear to equalize with atmospheric pressure via periodic opening of the tube (e.g. when yawning or swallowing). The middle ear also contains the three small bones, known as ossicles, which transmit sound (the vibration of the tympanic membrane) to the inner ear. The inner ear is liquid filled and contains the cochlea, where sound waves passed into the inner ear fluid are converted to neural signals. The inner ear also contains the vestibular complex, which is responsible for the maintenance of equilibrium/balance.

Infections are common in the outer and middle ear, and are known as otitis externa (e.g. swimmer's ear) and otitis media.

Middle ear infections that do not respond to initial treatment, or that are recurrent, are often treated with tube placements (TTP surgery) wherein small tubes are inserted through the ear drum to help ventilate/drain the middle ear cavity.

Inner ear diseases include Ménière's disease, tinnitus, hearing loss, and balance disorders.

Drug solutions currently used to treat ear disorders (e.g. antibiotic ear drops during TTP surgery or injections of steroids to treat diseases of the inner ear) require multi-dose, multi-day dosing to deliver enough drug to the desired site because the liquid tends to run out of the ear.

Otonomy has developed a polymer that turns into a gel at body temperature, which can be injected into the ear where it will remain to deliver an entire course of therapy with a single administration.

Pathophysiology

Otonomy estimates that there are more than 50M people in the US who are affected by disorders of the ear – i.e. otic disorders – of whom approximately 20M people seek treatment for the most common of conditions, including infections of the outer and middle ear, and balance disorders and tinnitus which are disorders of the inner ear. The company estimates that ~2.5M people per year are affected with infection in the outer ear – acute otitis externa or swimmer's ear – in the US alone. In the middle ear, it is estimated that ~75% of children suffer from infection, also known as otitis media, by the age of three. In patients whose middle ear infections do not go away with treatment or those that have recurrent infections, ear tubes may be inserted through the eardrum to ventilate the middle ear via surgical procedure (tympanostomy tube placement, or TTP), which can help prevent hearing loss and reduce the risk of infections.

Moving to the inner ear, it is estimated that more than 600,000 Americans have been diagnosed with Ménière's disease, a chronic disorder that causes spontaneous episodes of vertigo, fluctuating hearing loss, tinnitus (ringing in the ear), and a feeling of fullness/pressure within the ear. The American Tinnitus Association estimates that approximately 16M patients in the US experience tinnitus symptoms severe enough to seek treatment, and of those, ~2M have such severe symptoms that they are unable to function normally on a day-to-day basis. Interestingly, tinnitus is the most prevalent military service-related disability among veterans, and the cost of treating the condition among veterans is estimated to be greater than \$2B annually according to the US DoD. Also related to the inner ear, an estimated 36M adults in the US report some degree of hearing loss.

Current Treatment Limitations

Despite the large number of patients that suffer from these various maladies of the ear, current treatment methods leave something to be desired both in the way of convenience and efficacy given the anatomical challenges of treating the issues locally. Specifically, antibiotic ear drops used in the middle ear cavity post-surgery to prevent infection and steroid injections into the middle ear to help treat inner ear disorders, essentially “run out of” the middle ear (are cleared from the tympanic cavity via the Eustachian tube). In the case of antibiotic drops administered post ear surgery, drops can be difficult to administer (especially in children) and again require multiple doses/day over multiple days to deliver an entire course of antibiotics. The frequency with which these treatments must be administered also raises compliance concerns, which could have read through to efficacy when patients miss doses.

Otonomy's Approach

Otonomy believes there is significant unmet need related to drug delivery techniques in otology and has developed a proprietary drug delivery technology to allow for sustained exposure of a given drug in the ear after a single administration. OTIC's technology platform makes use of a thermosensitive polymer in which various drugs can be suspended. The polymer + drug combination is then injected into the desired location within the ear and turns from liquid to gel at body temperature. This change from a liquid to a solid state allows the drug suspension to be retained in the desired location (the middle ear) for an extended period of time, providing higher levels of drug to the affected area.

AuriPro

AuriPro is a suspension of the antibiotic ciprofloxacin in OTIC's polymer; it is currently being developed for use during TTP surgery.

Ear drops currently used during/post TTP surgery require multi-dose, multi day regimens, which is burdensome for caregivers, and missed doses can affect efficacy.

Ciprofloxacin is the antibiotic ingredient in the most commonly prescribed branded ear drops, which are currently used off label in this condition.

AuriPro is a suspension of the antibiotic ciprofloxacin in OTIC's proprietary polymer. It is currently in development for the treatment of middle ear effusion (fluid buildup in the middle ear) in pediatric patients requiring TTP surgery. AuriPro has successfully completed two randomized, double-blind controlled trials, wherein the drug met the primary efficacy endpoint, reducing the incidence of treatment failures ($p < 0.001$) vs. a sham simulated injection. Based on these results, Otonomy plans to submit an NDA for AuriPro in 1H15 and has retained global commercialization rights for the product with patent protection until at least 2030. The company also plans to explore possible additional indications for AuriPro, including the treatment of acute otitis media with tubes in place, acute otitis externa, chronic suppurative otitis media, and prophylaxis following various middle ear surgeries.

Disorders of the Middle Ear and Current Treatment

As highlighted above, infection and inflammation of the middle ear – otitis media – is a common problem in young children. Middle ear infections are typically treated first line with oral antibiotics, which can lead to systemic side effects (as well as increased risk of bacterial resistance). Patients with recurrent infections are generally treated surgically, wherein tubes (tympanostomy tubes) are inserted through the eardrum to ventilate the middle ear cavity – a process known as TTP surgery. In addition to the tympanostomy tubes, which are generally not effective on their own, antibiotic ear drops are used (off label) during and after the procedure. These antibiotic eardrops, commonly branded CIPRODEX drops, require repeat administration over several days, which lead to compliance concerns and therefore efficacy concerns when patients miss doses.

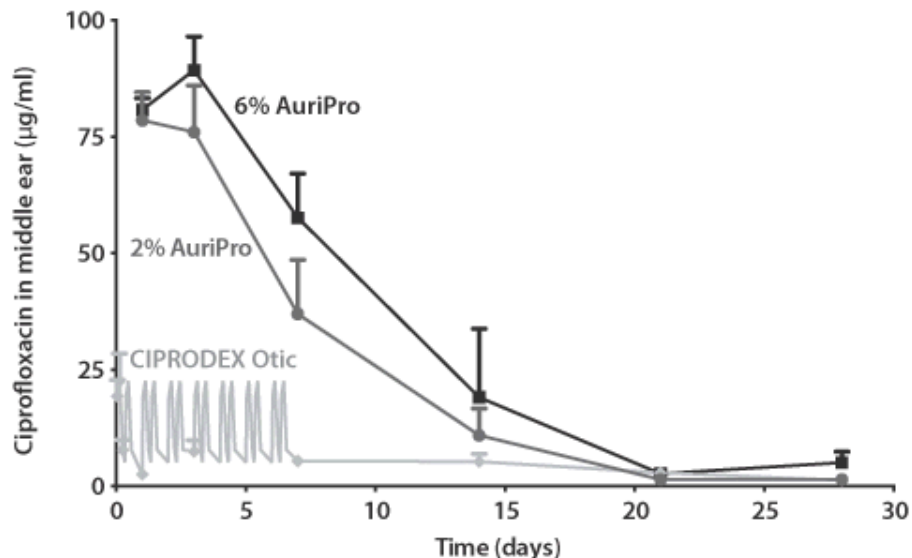
AuriPro Overview

AuriPro is a suspension of the antibiotic ciprofloxacin in OTIC's proprietary thermosensitive polymer. Ciprofloxacin is widely used and known to be active against many of the pathogens common in ear infections. Additionally, ciprofloxacin is an ingredient in several FDA-approved antibiotic ear drops, including branded CIPRODEX, which is one of the most common ear drops used in TTP surgery (per our doc conversations). Of note, though antibiotic ear drops are currently widely used in this indication, none has received FDA approval such that their use is off label. With a single administration by the physician, AuriPro provides a full course of antibiotic treatment by providing sustained exposure of the drug over one to two weeks.

Otonomy believes a single-use, doctor-administered antibiotic gel has several key advantages over currently used ear drops. First, as noted above, ear drops require multi-dose, multi-day administration, which doctors we have spoken with note is worrisome as compliance is often an issue when patients miss doses. CIPRODEX currently requires BID dosing for seven days, and generic ofloxacin requires TID dosing for 10 days. As ~50% of TTP surgeries are in pediatric patients ≤ 3 years of age (and 75% in patients ≤ 5 years of age), compliance can be even more of an issue given challenges that may be associated with administering ear drops to young children. Docs note that lack of compliance with these regimens leads to decreased efficacy and can also increase the potential for bacterial resistance. In contrast, AuriPro is administered by the physician at the time of surgery, and this single

administration provides a full course of antibiotic treatment, facilitating a sustained and clinically relevant level of antibiotic at the desired location.

Figure 4: Ciprofloxacin Drug Concentration Measured in Middle Ear Following Single Administration of AuriPro vs. Twice Daily Dosing of Ear Drops for 7 Days through Ear Tube



Source: Company reports.

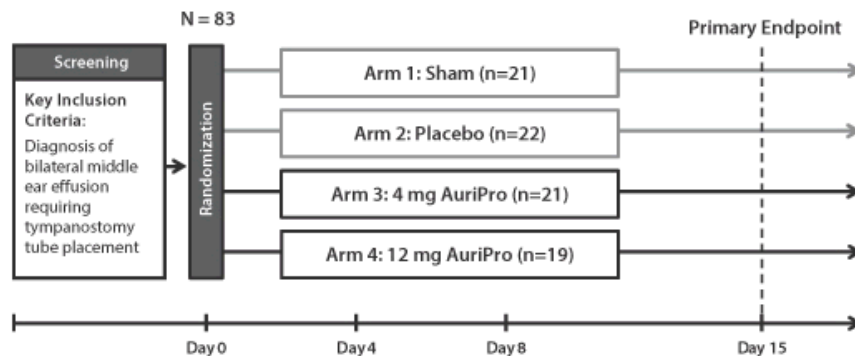
Clinical Data Review

AuriPro has completed a Phase 1b and two Phase 3 trials; an NDA is anticipated in 1H15.

AuriPro has successfully completed various clinical trials, including a Phase 1b and two Phase 3 trials in the TTP surgery indication. After successful completion of the Phase 1b trial, the drug proceeded directly into Phase 3 trials.

Phase 1b. Otonomy conducted a Phase 1b trial of AuriPro in pediatric patients with middle ear effusion requiring TTP surgery. Patients aged 6 months to 12 years were eligible to enroll if they presented with bilateral effusion at the time of TTP surgery. Eighty-three patients were enrolled and were randomized to receive no treatment (sham), a placebo injection, 4mg of AuriPro, or 12mg of AuriPro. Treatment was administered in the operating room before tube placement but after the eardrum incision and suctioning; follow-up visits were conducted on days 4, 8, 15, and 29 post surgery. The primary endpoint of the trial was the percentage of treatment failures, defined as otorrhea (discharge from the external ear, or fluid draining through the tubes) observed by a blinded assessor from day 4 to day 15, or the use of rescue antibiotics from day 1 to day 15.

Figure 5: Design of AuriPro Phase 1b Clinical Trial in Pediatric Patients

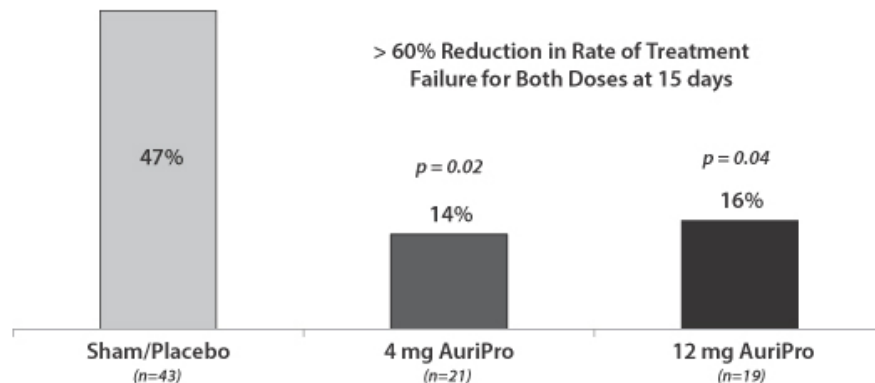


Source: Company reports.

In the Phase 1b, AuriPro was shown to be safe and well tolerated, and demonstrated a significantly lower number of treatment failures than in the sham/placebo group.

All patients enrolled completed the trial except for one who was classified as lost to follow-up because he/she did not return for the final visit. The percentage of treatment failures was similar between the sham and placebo arms, thus these groups were combined into a single group per the pre-specified statistical analysis plan. Both doses of AuriPro showed statistically significant reduction in the number of treatment failures through day 15, with both showing a >60% reduction vs. sham/placebo ($p < 0.05$). Of note, the magnitude of effect was similar between the low and high dose AuriPro arms, which Otonomy notes was expected based on the preclinical pharmacokinetic data.

Figure 6: Phase 1b Clinical Trial Results for AuriPro vs. Sham/Placebo: Cumulative Proportion of Treatment Failures through Day 15



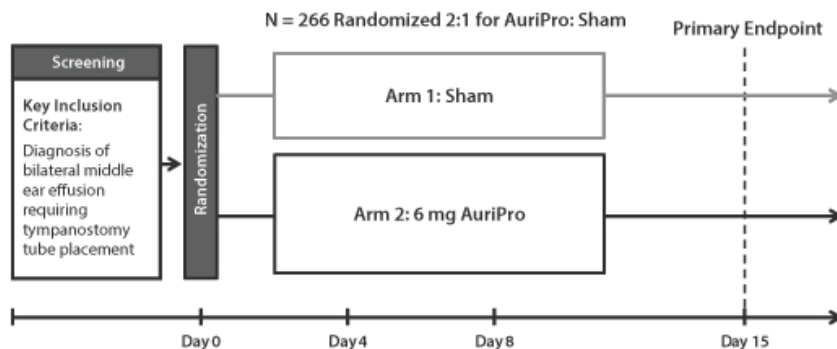
Source: Company reports.

In the trial, AuriPro was shown to be safe and well tolerated, with no serious AEs related to AuriPro treatment. Additionally, there were no adverse findings demonstrated on physical examination or vital signs. Other safety assessments included treatment-emergent adverse events, including hearing function testing and tympanometry (middle ear function); AuriPro did not have a negative impact on hearing, tympanometry, or otoscopy. Importantly, there was no evidence of tube clogging with AuriPro. Most reported AEs were mild to moderate in severity.

Phase 3. The multi-center Phase 3 trials (study 302 and 303) were identical and evaluated AuriPro as a single IT injection for intra-operative treatment of middle ear effusion in pediatric patients requiring TTP surgery. Patients ages 6 months to 17

years old were eligible for enrollment in the trials if they presented with bilateral effusion at the time of TTP surgery. The trials were conducted across ~60 centers in the US and Canada, and were randomized, double-blind, and sham controlled; patients were randomized 2:1 to receive 6mg AuriPro vs. a sham injection. Treatment was administered in the operating room following the small incision made in the ear drum and suctioning but before tube placement, as in the Phase 1b trial. Follow-up visits occurred on day 4, day 8, day 15, and day 29. The trials enrolled a total of 532 patients.

Figure 7: AuriPro Phase 3 Trial Design (Two Identical Trials Conducted)



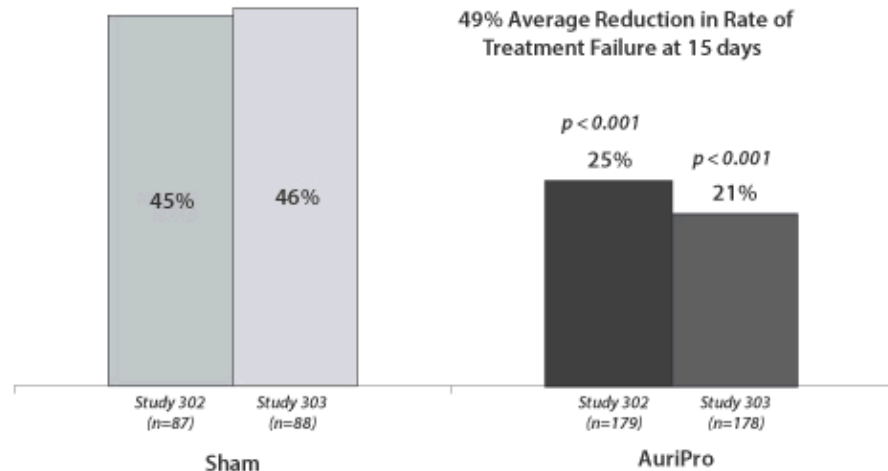
Source: Company reports.

Baseline characteristics of enrolled patients were balanced between treatment arms, and all enrolled patients completed the day 15 study visit, except two patients (one in each treatment arm) that were enrolled but never received treatment. The primary endpoint of the trials was the proportion of treatment failures, which was defined as otorrhea as assessed by a blinded assessor at any point from day 4 to day 15, or use of rescue antibiotics at any point during the 15-day period.

In Phase 3, AuriPro met its primary efficacy endpoint with statistical significance, showing a ~50% reduction in the incidence of treatment failures vs. sham injection.

Top-line data from the trials was announced in July 2014, showing that AuriPro met the primary efficacy endpoint, as well as key secondary endpoints. The drug demonstrated an average 49% reduction in the incidence of treatment failures through day 15 in all patients. The reduction was statistically significant in both trials ($p < 0.001$).

Figure 8: Phase 3 Results for AuriPro vs. Sham (All Patients): Cumulative Proportion of Treatment Failures through Day 15

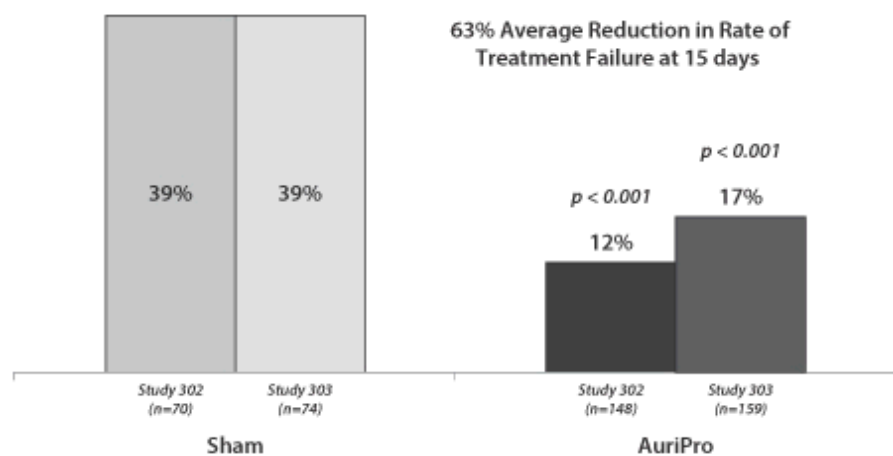


The symbol "n" is used to denote sample size per group.

Source: Company reports.

On a per-protocol basis, AuriPro demonstrated an average 63% ($p < 0.001$) reduction in the incidence of treatment failures in all enrolled patients who did not have a major protocol deviation (>80% of patients in each arm).

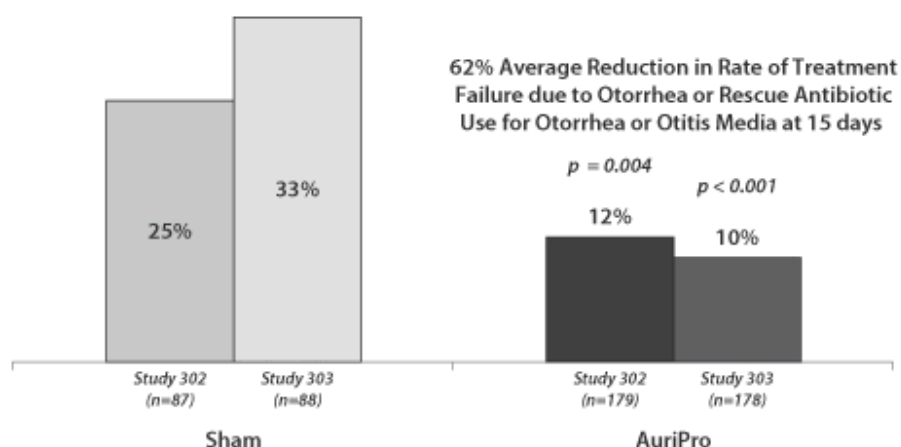
Figure 9: Phase 3 Results for AuriPro vs. Sham (Per-Protocol Analysis): Cumulative Proportion of Treatment Failures through Day 15



Source: Company reports.

In a post-hoc analysis, the proportion of patients considered treatment failures due to observation of otorrhea by the blinded observer or use of either otic or systemic antibiotics with documentation of otorrhea or otitis media through day 15 was analyzed. In this case, AuriPro reduced the rate of post-op otorrhea or use of rescue antibiotics by an average of 62% ($p \leq 0.004$) across both trials.

Figure 10: Phase 3 Results for AuriPro vs. Sham: Cumulative Proportion of Treatment Failures due to Otorrhea or Rescue Antibiotic Use for Otorrhea or Otitis Media through Day 15



Source: Company reports.

In Phase 3, AuriPro continued to be safe and well tolerated, with no SAEs attributable to the drug.

In both trials, AuriPro was shown to be safe and well tolerated, with no serious AEs related to drug. Additionally, no patients discontinued the trial due to AEs, and there were no adverse findings on physical examinations or vital signs. Generally, there were no differences between AuriPro and sham in the incidence of treatment-emergent AEs, and most were mild to moderate. AuriPro use did not have an adverse impact on hearing, tympanometry, or otoscopy, and there was no incidence of the drug clogging the tympanostomy tubes.

Figure 11: Treatment-Emergent Adverse Events (Patients from Combined 302 and 303 Studies)

System Organ Class: Number of Patients (%)	Sham (N=174)	AuriPro (N=356)
Total patients with at least one TEAE reported	95 (54%)	189 (53%)
Infections and infestations	40 (23%)	85 (24%)
General disorders and administration site conditions	30 (17%)	62 (17%)
Gastrointestinal disorders	17 (10%)	41 (11%)
Respiratory, thoracic and mediastinal disorders	23 (13%)	38 (11%)
Injury, poisoning and procedural complications	20 (11%)	26 (7%)
Ear and labyrinth disorders	11 (6%)	25 (7%)
Skin and subcutaneous tissue disorders	4 (2%)	13 (4%)
All others	≤2%	≤2%

Note: two patients were randomized but not treated (one patient in the sham group and one in the AuriPro group)

Source: Company reports.

Competitive Landscape

We think AuriPro could have advantages over currently used liquid antibiotic formulations, and we are not aware of any other gel/sustained release antibiotic products in development.

As indicated, CIPRODEX is the leading branded ear drop used during TTP surgery, although it (or any other antibiotic eardrop) has not been approved for use in this indication. Though CIPRODEX drops will go generic in 2020, the efficacy, convenience and route of administration highlighted above for AuriPro are likely to be key competitive factors for AuriPro vs. existing treatments. Alcon (Novartis, covered by JPM analyst Richard Vossler) does have antibiotic ear drops in later stage clinical trials for various otic diseases, though for the reasons outlined above, we think OTIC's gel formulation will likely also prove to have benefits over any future liquid formulations.

Market Opportunity and Commercial Strategy

If approved, AuriPro's initial labeled indication will be for use during TTP procedures. Of all TTP procedures conducted, Otonomy estimates that off-label antibiotic ear drops are used in ~1M. Otonomy conducted market research amongst ENTs who perform TTP surgeries, and 69% of those docs expressed a strong interest in using AuriPro instead of antibiotic ear drops during TTP procedures. When asked various questions about AuriPro relative to antibiotic ear drops, 80% of responders think AuriPro's product profile is better for compliance/adherence, 50% said it was better for patient tolerability and achieving adequate drug exposure and >1/3 of docs thought it would be better in reducing the incidence of otorrhea, post operative tube clogging, and the frequency of complications.

We assume AuriPro launch in 2016 in the US, and model peak sales of ~\$250M. We do not currently give OTIC credit for ex-US revenues given the lack of clarity around the plans in that geography.

Otonomy plans to commercialize AuriPro on its own in the US with ~30-40 sales reps. We model launch in 2016 and assume that AuriPro is used in 55% of the target TTP procedures at peak. Based on our doc conversations, we also assume some off-label use in other middle ear indications prior to their actual inclusion into the label. We assume a launch price of \$250 per administration (a premium to the ~\$150/Rx cost for branded CIPRODEX drops, which has been rising). Together, these assumptions give peak revenues of \$250M for AuriPro in the US. Given the lack of clarity on the ex-US strategy, we currently do not model/assign value to any ex-US revenues (although we see no reason why future value should not eventually be generated internationally).

Figure 12: AuriPro Revenue Build

		2016	2017	2018	2019	2020	2021	2022	2023
US AuriPro									
Antibiotic Rx for Otic Uses	0.50%	20,200,500	20,301,503	20,403,010	20,505,025	20,607,550	20,710,588	20,814,141	20,918,212
Antibiotic for Middle Ear Uses	11.60%	2,343,258	2,354,974	2,366,749	2,378,583	2,390,476	2,402,428	2,414,440	2,426,513
Rx for TTP	42.63%	998,915	1,003,909	1,008,929	1,013,973	1,019,043	1,024,139	1,029,259	1,034,406
AuriPro Rx in TTP		29,967	120,469	201,786	304,192	407,617	512,069	566,093	568,923
AuriPro TTP Share	3.00%		12.00%	20.00%	30.00%	40.00%	50.00%	55.00%	55.00%
Rx for AOMT	40.13%	940,333	945,035	949,760	954,509	959,281	964,078	968,898	973,743
AuriPro Rx in AOMT		-	9,450	47,488	95,451	191,856	318,146	319,736	321,335
AuriPro Other Share	0.00%		1.00%	5.00%	10.00%	20.00%	33.00%	33.00%	33.00%
Rx for Other Middle Ear	17.24%	404,010	406,030	408,060	410,101	412,151	414,212	416,283	418,364
AuriPro Rx in Other Middle Ear		-	4,060	12,242	24,606	37,094	82,842	83,257	83,673
AuriPro Other Share	0.00%		1.00%	3.00%	6.00%	9.00%	20.00%	20.00%	20.00%
Total Patients on AuriPro		29,967	129,919	249,274	399,643	599,474	830,215	885,829	890,258
% of Total Middle Ear Pts		1.3%	5.5%	10.5%	16.8%	25.1%	34.6%	36.7%	36.7%
Gross WAC	3%	\$250	\$258	\$265	\$273	\$281	\$290	\$299	\$307
Net WAC	8%	\$230	\$237	\$244	\$251	\$259	\$267	\$275	\$283
Total US Revenue (\$m)		\$6.89	\$30.78	\$60.82	\$100.44	\$155.18	\$221.36	\$243.28	\$251.83
TTP		\$6.89	\$28.54	\$49.24	\$76.45	\$105.52	\$136.53	\$155.47	\$160.93
AOMT		\$0.00	\$2.24	\$11.59	\$23.99	\$49.67	\$84.83	\$87.81	\$90.90
Other		\$0.00	\$0.96	\$2.99	\$6.18	\$9.60	\$22.09	\$22.86	\$23.67

Source: J.P. Morgan and Company estimates.

OTO-104

OTO-104 is a suspension of the steroid dexamethasone in OTIC's proprietary polymer; it's currently in a Phase 2b trial as a treatment for Ménière's disease.

Ménière's disease is a chronic condition characterized by acute vertigo attacks, tinnitus, fluctuating hearing loss, and a feeling of aural fullness.

There are no FDA-approved therapies to treat the disorder, and repeat steroid injections into the middle ear are often used.

Unlike currently used steroid solutions which require multiple injections (at a doctor's office) over the course of treatment, OTO-104 can provide an entire course of therapy after a single administration.

OTO-104 is a suspension of the steroid dexamethasone in OTIC's proprietary polymer, and it is currently in development for the treatment of Ménière's disease and other inner ear conditions. OTO-104 is currently being evaluated in a Phase 2b trial in 140 patients to assess reductions in vertigo frequency and improvements in tinnitus in patients with Ménière's disease. Data from this trial is anticipated in 1H15, and if positive, Otonomy plans to start another pivotal trial in 2015. OTO-104 has been granted Fast Track designation from the FDA, and Otonomy has retained global commercialization rights to this product which has patent protection in the US until at least 2029.

Disorders of the Inner Ear and Current Treatment

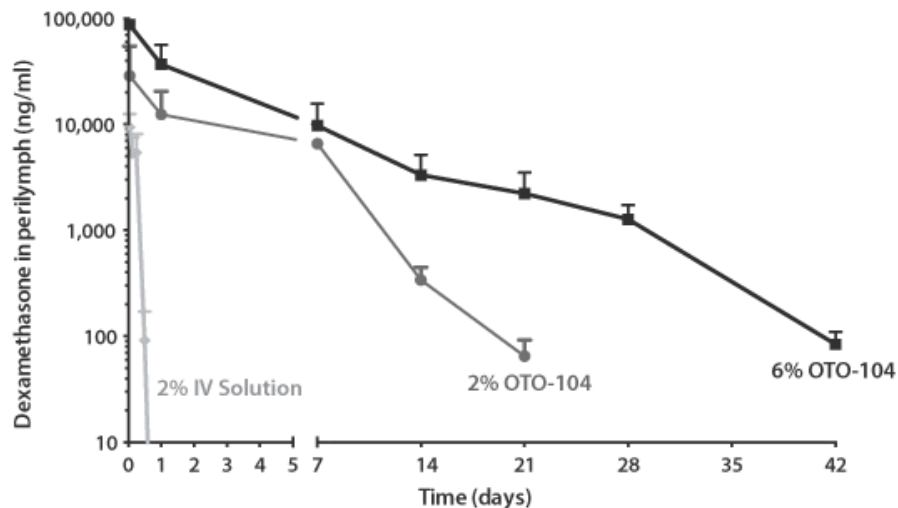
Ménière's disease, as noted above, is a condition characterized by acute vertigo attacks, tinnitus, fluctuating hearing loss, and a feeling of aural fullness. Vertigo tends to be the highest burden symptom given 1) it is difficult to anticipate, 2) it is disruptive to daily activities, and 3) it is difficult to manage. Ménière's is a chronic condition, with patients generally being diagnosed during middle age with symptoms lasting for decades. The cause of Ménière's is not well understood, and there is currently no cure (and no FDA-approved drug treatments), though clinical evidence supports the use of steroids to help manage Ménière's symptoms, in addition to other inner ear disorders such as balance disorders, sudden sensorineural hearing loss, other types of sensorineural hearing loss, and tinnitus. Both oral and IT injection steroids are currently used to help manage conditions, with the latter involving repeat office visits for injections in a given treatment regimen. For patients who do not respond to steroidal treatment, additional treatment options include surgical or chemical ablation procedures, but these high-risk treatments can cause irreversible hearing loss.

OTO-104 Overview

OTO-104 is a suspension of the steroid dexamethasone in OTIC's proprietary thermosensitive polymer. Dexamethasone is widely used for IT injection as a solution currently in the treatment of inner ear disorders. With a single administration by the physician, OTO-104 provides a full course of steroid treatment facilitating sustained exposure of the drug in the inner ear fluid over several weeks. As with AuriPro, the suspension is liquid at room temperature allowing for injection into the middle ear, and then gels at body temperature, ensuring that the suspension stays in the middle ear, and in this case, in contact with the round window membrane so drug can diffuse across the membrane into the inner ear fluid.

As previously indicated, currently used IT steroid injections require repeat administrations in a given treatment course as the liquid formulations are cleared from the middle ear cavity via the Eustachian tube. Preclinical trials have shown that a single IT injection of OTO-104 gives a full course of treatment, providing measurable levels of drug in the inner ear fluid more than one month after the injection. This is in contrast to steroid solution injections, which provide less than a day of drug exposure with each injection.

Figure 13: Dexamethasone Drug Concentration in Perilymph Following Single IT Injection of OTO-104 vs. IV Solution



Source: Company reports.

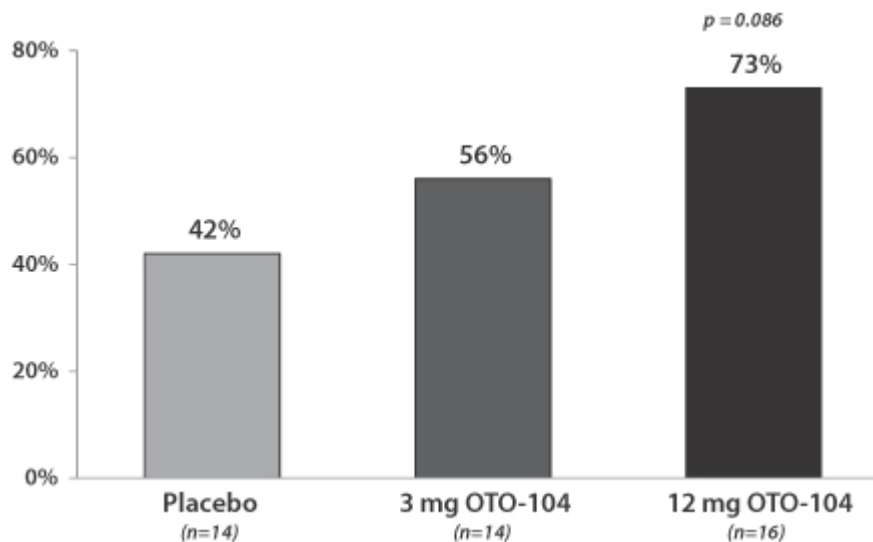
Clinical Data Review

Phase 1b. Otonomy conducted a randomized, double-blind, controlled Phase 1b trial to evaluate the safety and preliminary efficacy of a single IT injection of OTO-104 in patients with Ménière's disease. Forty-four patients were enrolled and randomized to receive either 3mg OTO-104, 12mg OTO-104, or placebo (gel vehicle). Patients were followed for three months following the injection, and the primary endpoint was the frequency of vertigo within the three-month period.

In a Phase 1b trial, treatment with OTO-104 reduced the frequency of vertigo, the highest-burden Ménière's symptom, by ~60-70% vs. placebo.

The small number of patients enrolled in the trial prevented statistical significance on efficacy endpoints, but trends in activity were observed. The high dose OTO-104 cohort experienced an average 73% reduction in the frequency of vertigo at month 3 vs. a mean 56% in the low dose and a mean 42% reduction in the placebo group. The high-dose OTO-104 cohort also experienced a reduction in the number of days with a vertigo episode from 8 days to 2 days from base line to month 3.

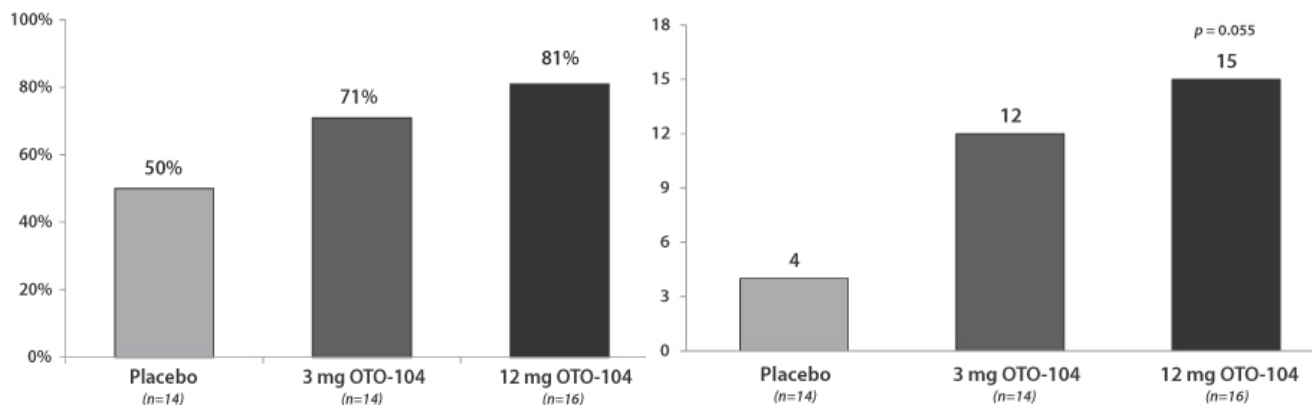
Figure 14: Phase 1b Clinical Trial Results for OTO-104 vs. Placebo: % Reduction in Vertigo Frequency from Baseline to Month 3



Source: Company reports.

When data was evaluated on a responder basis, 81% of patients in the high-dose OTO-104 group had at least a 50% improvement in vertigo frequency during month 3 vs. baseline, compared to 71% of patients in the low-dose group, and 50% of the patients in the placebo cohort. Additionally, treatment with OTO-104 was also associated with improvements in tinnitus, as measured by the Tinnitus Handicap Inventory (THI-25) patient questionnaire. The mean change in the THI-25 score from baseline to month 3 was 15 for the 12mg OTO-104 cohort, 12 for patients in the 3mg cohort, and 4 for patients in the placebo arm.

Figure 15: Left: Phase 1b Clinical Trial Results for OTO-104 vs. Placebo: % of Patients with $\geq 50\%$ Improvement in Vertigo Frequency from Baseline to Month 3; Right: Phase 1b Clinical Trial Results for OTO-104 vs. Placebo: Mean Reduction in THI-25 Score from Baseline to Month 3



Source: J.P. Morgan and Company estimates.

OTO-104 was also safe and generally well tolerated.

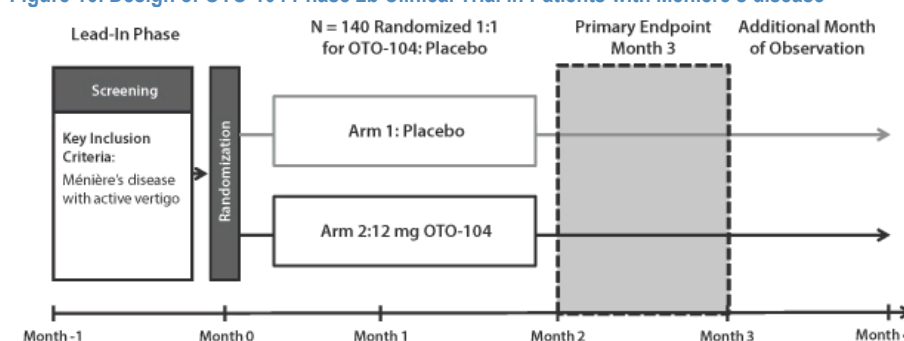
The drug was well tolerated at both dosage levels, and there were no serious AEs reported during the trial. Importantly, there were no cases of persistent conductive hearing loss related to the drug. Three AEs of interest (protocol pre-specified) occurred during the trial: injection site perforation of the tympanic membrane, a patient reporting vertigo during the procedure, and a placebo patient experienced otitis media. The most common drug related AE was described as a pinhole perforation observed following the procedure and most resolved spontaneously (all mild to moderate). In all, the AEs reported in the trial were consistent with those reported in clinical trials of other IT injected steroids. Based on the persistent pinhole perforations observed, Otonomy modified the topical anesthetic used to numb the eardrum for subsequent trials.

After completion of this trial, the OTO-104 program was placed on full clinical hold on the basis of *preclinical* safety findings during repeat doses of OTO-104. Otonomy generated additional data (that showed the issue was species specific) which resulted in the removal of the full clinical hold in July 2013 and a partial clinical hold prohibiting initiation of multi-dose studies in the US pending submission/review of additional data. The additional data was subsequently submitted, and OTO-104 was removed from partial clinical hold in June 2014. It turned out that this was a species-specific issue.

A Phase 2b trial is currently ongoing and is similar in design to the successful Phase 1b trial. Data from this trial is anticipated in 1H15.

Phase 2b. On the basis of the Phase 1b results, Otonomy initiated a Phase 2b trial of 12mg OTO-104 in Ménière's patients, the design of which is similar to the Phase 1b. The trial is being conducted at more than 50 centers in the US and Canada and is intended to serve as one of the two required pivotal trials. The randomized, double-blind, placebo controlled trial study will enroll ~140 patients with Ménière's disease. Upon screening, patients will enter into a 1-month observational period to establish baseline vertigo and tinnitus symptoms (via daily diary). Eligible patients will then be enrolled in the trial and will be randomized 1:1 to receive 12mg OTO-104 or gel vehicle via a single IT injection. Patients will be observed for up to four months after injection, and month 3 will be used to evaluate efficacy.

Figure 16: Design of OTO-104 Phase 2b Clinical Trial in Patients with Ménière's disease



Source: Company reports.

The primary endpoint of the trial is the same as in the Phase 1b trial: the reduction in vertigo frequency during month 3 vs. a one-month baseline period. The trial was designed to have 90% power to detect a 30% treatment effect (based on the effect size seen in Phase 1b) with $p < 0.05$. Effect on tinnitus is an exploratory endpoint in the trial. The trial is currently enrolling, and Otonomy expects to announce results in 1H15.

In addition to two pivotal trials, Otonomy anticipates the FDA will require multi-dose safety data for approval, given the chronic nature of the disease/likelihood of repeat treatments. As such, OTIC plans to conduct additional clinical trials lasting up to one year in at least 300 patients in order to satisfy this requirement. OTIC plans to initiate one or more of these open-label, multi-dose safety studies in Ménière's patients by the end of 2014.

Competitive Landscape

With no currently approved treatments for Ménière's disease, initial treatment methods involve a low-salt diet and off-label use of various medications including diuretics, oral and IT injected steroids. On the future potential competitive landscape, Otonomy has noted that a Phase 2/3 trial of IT injected latanoprost (Symphora AB, private) in Ménière's patients. In addition, Auris Medical Holding AG (not covered) has indicated it intends to evaluate AM-111 (a gel formulation of a JNK inhibitor) for the treatment of Ménière's disease.

Market Opportunity and Commercial Strategy

If approved, the initial labeled indication for OTO-104 will be for use in the treatment of Ménière's disease, of which Otonomy estimates there are more than 600,000 patients diagnosed in the US. As with AuriPro, Otonomy has conducted market research on the treatment of Ménière's disease and impression of OTO-104 via an online survey of 100 ENTs. Of the physicians surveyed, 57% of docs indicated a high level of interest in using OTO-104. Additionally, in our conversations with four ENTs who have experience using the product in Ménière's patients, there is a high level of interest in using the product in the treatment of other inner ear disorders. Specifically, docs we spoke with indicated they would likely use the product off label in the treatment of sudden hearing loss, which they indicated is a fairly common diagnosis in their respective practices.

We assume OTO-104 launches in 2018, and model peak sales of ~\$500M in the US, and do not currently assign value to potential ex-US revenues.

Otonomy plans to commercialize OTO-104 on its own in the US with the existing AuriPro sales force given the same target physician audience (though we model an gradual doubling in the number of reps as we assume some incremental infrastructure will be needed). We model launch in 2018, and assume that OTO-104 is used in 55% of the target Ménière's disease patients at peak. Based on our doc conversations, we also assume some off-label use in other inner ear indications prior to their actual inclusion into the label. We assume a launch price of \$1,000 per administration, and in the Ménière's indication, we assume that half of the patients treated require two treatments per year. Together, these assumptions give peak revenues of ~\$500M for OTO-104 in the US. As with AuriPro, we do not currently model/assign value to any ex-US revenues (although we once again assume the product eventually has utility in international markets).

Figure 17: OTO-104 Revenue Build

		2016	2017	2018	2019	2020	2021	2022	2023
US OTO-104									
Patients Treated in Target Indications	1.00%	3,876,380	3,915,144	3,954,295	3,993,838	4,033,777	4,074,114	4,114,855	4,156,004
Treated Meniere's Patients	6.18%	239,724	242,121	244,542	246,987	249,457	251,952	254,471	257,016
Steroid Treated Meniere's	1.5	71,917	72,636	73,363	79,036	84,815	90,703	96,699	102,806
% of treated		30.00%	30.00%	30.00%	32.00%	34.00%	36.00%	38.00%	40.00%
OTO-104 Patients		-	-	7,336	15,807	25,445	36,281	48,350	56,544
OTO-104 Share		0.00%	0.00%	10.00%	20.00%	30.00%	40.00%	50.00%	55.00%
Vertigo Patients	25.68%	995,618	1,005,574	1,015,630	1,025,786	1,036,044	1,046,404	1,056,868	1,067,437
Steroid Treatment Vertigo	20.00%	199,124	201,115	203,126	205,157	207,209	209,281	211,374	213,487
OTO-104 Patients		-	-	-	6,155	16,577	27,207	38,047	42,697
OTO-104 Share		0.00%	0.00%	0.00%	3.00%	8.00%	13.00%	18.00%	20.00%
Sudden HearingLoss Patients	1.97%	76,508	77,273	78,045	78,826	79,614	80,410	81,214	82,026
Steroid Treated SHL Pts	70.00%	53,555	54,091	54,632	55,178	55,730	56,287	56,850	57,418
OTO-104 Patients		-	-	-	8,277	13,932	22,515	31,267	40,193
OTO-104 Share		0.00%	0.00%	0.00%	15.00%	25.00%	40.00%	55.00%	70.00%
Sensorineural HearingLoss Patients	50.45%	1,955,532	1,975,087	1,994,838	2,014,786	2,034,934	2,055,283	2,075,836	2,096,595
Steroid Treated SHL Pts	18.00%	351,996	355,516	359,071	362,662	366,288	369,951	373,651	377,387
OTO-104 Patients		-	-	-	10,880	29,303	48,094	67,257	75,477
OTO-104 Share		0.00%	0.00%	0.00%	3.00%	8.00%	13.00%	18.00%	20.00%
Tinnitus Patients	15.71%	609,000	615,090	621,241	627,453	633,728	640,065	646,465	652,930
Steroid Treated Tinnitus	18.00%	109,620	110,716	111,823	112,942	114,071	115,212	116,364	117,527
OTO-104 Patients		-	-	-	18,824	50,698	83,208	116,364	130,586
OTO-104 Share		0.00%	0.00%	0.00%	3.00%	8.00%	13.00%	18.00%	20.00%
Total OTO-104 Treatments per year		-	-	11,004	67,846	148,677	235,445	325,460	373,769
% of Total Inner Ear		0.0%	0.0%	0.3%	1.7%	3.7%	5.8%	7.9%	9.0%
Gross WAC	3%	\$1,000	\$1,030	\$1,061	\$1,093	\$1,126	\$1,159	\$1,194	\$1,230
Net WAC	8%	\$920	\$948	\$976	\$1,005	\$1,035	\$1,067	\$1,099	\$1,131
Total US Revenue (\$m)		\$0.00	\$0.00	\$10.74	\$68.21	\$153.95	\$251.11	\$357.53	\$422.91
Meniere's		\$0.00	\$0.00	\$10.74	\$23.84	\$39.52	\$58.04	\$79.67	\$95.97
Vertigo		\$0.00	\$0.00	\$0.00	\$6.19	\$17.16	\$29.02	\$41.80	\$48.31
Sudden Hearing Loss		\$0.00	\$0.00	\$0.00	\$8.32	\$14.43	\$24.01	\$34.35	\$45.48
Sensorineural Loss		\$0.00	\$0.00	\$0.00	\$10.94	\$30.34	\$51.29	\$73.88	\$85.40
Tinnitus		\$0.00	\$0.00	\$0.00	\$18.92	\$52.50	\$88.74	\$127.83	\$147.76

Source: J.P. Morgan and Company estimates.

OTO-311

OTO-311 is a suspension of an NMDA receptor antagonist in OTIC's polymer, and is currently in preclinical development for the treatment of tinnitus. An IND is anticipated in 2015.

Tinnitus is a condition wherein patients hear noise that has no outside source (e.g. ringing in the ear), which can be debilitating and interfere with work, sleep, and normal day-to-day function.

OTO-311 contains the NMDA receptor antagonist gacyclidine, which Otonomy believes has some unique characteristics that could be beneficial in the treatment of tinnitus.

OTO-311 is a suspension of the NMDA receptor antagonist gacyclidine in OTIC's proprietary polymer and is currently in development for the treatment of tinnitus. OTO-311 is currently in preclinical development, and OTIC plans to file an IND to initiate clinical trials in 2015. As with its other products, Otonomy has global commercialization rights to this product, which has patent protection in the US until at least 2031.

Background on Tinnitus and Current Treatment

Tinnitus is a condition where patients hear noise when there is no outside source of the sound. Most commonly it manifests as hearing ringing in the ear, but can also sound like roaring, clicking, hissing or buzzing. The most common cause of the disorder is exposure to a loud noise, but several other factors can contribute – e.g. heart or blood vessel problems, hormonal changes in women, ear and sinus infections, certain medications and thyroid problems, among others. Symptoms range in severity, and patients with severe symptoms can have difficulty sleeping, working and hearing. There is currently no cure for the condition, and there are no FDA-approved drugs to treat the condition.

OTO-311 Overview

OTO-311 is a suspension of the NMDA receptor antagonist in OTIC's proprietary thermosensitive polymer. Emerging clinical data has indicated that NMDA antagonists may have efficacy in the treatment of tinnitus, potentially via their ability to reduce the dysfunctional activity of the receptor caused by injury to the cochlea. Gacyclidine is a potent and selective NMDA receptor antagonist, with data suggesting it is active at the NMDA receptor subtype believed to be relevant to tinnitus, and pre-clinical studies have shown the compound to have efficacy in models of tinnitus. Additionally, gacyclidine's binding kinetics are slower than some other NMDA receptors, which Otonomy believes could be beneficial in achieving sustained drug levels in the inner ear after a single injection.

Gacyclidine was originally developed for the treatment of traumatic brain and spinal cord injuries in the early 1990s, though it has never been approved or commercialized. However, previously conducted clinical trials have evaluated the compound systemically in over 300 patients, which OTIC believes could be helpful in the development of OTO-311. For example, the previously established MTD provides an upper limit for OTIC's dose selection work, though the company expects limited systemic exposure with the IT injection route of administration.

A third-party clinical trial (Wenzel et al., Eur Arch Otorhinolaryngol. 2010 May;267(5):691-9) evaluated local administration of gacyclidine delivered via micro-pump in patients with tinnitus. While the trial was in a small number of patients and not sized to demonstrate efficacy, Otonomy believes it provides evidence of clinical activity for gacyclidine in patients with tinnitus.

There are several other products currently in development for the treatment of tinnitus.

If approved, we think OTO-311 has >\$1B in revenue potential, though we do not currently include that revenue in our valuation, thus OTO-311 represents significant potential upside to our estimates.

Competitive Landscape

Currently there are no approved drugs to treat tinnitus, and the four docs we spoke with repeatedly highlighted the challenges with managing this condition. Current treatment options include white noise machines or other devices to mask the perceived noise, hearing aids, as well as off-label use of anti-depressants, anti-anxiety medications and steroids. Relative to future competition, Otonomy has noted that there are several other therapies currently in development for the treatment of tinnitus, including Auris' AM-101 (gel formulation of an NMDA receptor antagonist) which is currently in Phase 3 trials, Autifony Therapeutics, which intends to initiate a Phase 2 trial for an oral product candidate, and Novartis (covered by JPM analyst Richard Vossler), which has completed a Phase 2 trial in tinnitus.

Market Opportunity and Commercial Strategy

If approved, the initial labeled indication for OTO-311 would likely be for the treatment of tinnitus. The treatment of this condition represents a significant market opportunity given the large patient population and high-burden symptoms. The American Tinnitus Association estimates that ~16M people in the US have tinnitus symptoms severe enough to seek medical attention. Of these patients, it estimates that ~2M patients cannot function on a day-to-day basis. If approved, Otonomy would commercialize OTO-311 with the same sales force used to commercialize their other products. We currently do not include any OTO-311 revenues in our valuation of OTIC.

Otonomy owns or has rights to a significant patent portfolio, providing coverage for AuriPro until at least 2030, for OTO-104 until at least 2029, and for OTO-311 until at least 2031.

Intellectual Property

Otonomy has a broad intellectual property (IP) portfolio, with rights to 55 issued patents and 85 pending patent applications directed to AuriPro, OTO-104, and OTO-311, as well as towards a broad range of active ingredients delivered through their proprietary technology (potential future indications). Specific to each product candidate as well as potential future product candidates, OTIC co-owns patent families with UC (The Regents of the University of California) having acquired the rights through an exclusive license agreement. Additionally, Otonomy solely owns certain patents/patent applications around each product. More details on each candidate's IP are below.

AuriPro. The co-owned UC patent family includes one issued US patent, which will expire in April 2030 without extensions, and two pending US applications. The patent family also includes issued patents/allowed applications in various ex-US markets. Additionally, Otonomy has filed its own application directed towards methods of manufacturing AuriPro with the USPTO.

OTO-104. The co-owned patent family is directed towards the composition and therapeutic use of OTO-104. Within the patent family there are four issued US patents, one allowed US patent, and one pending US patent, the expirations of which range from May 2029 to September 2029. This patent family also contains several issued or allowed applications in various ex-US markets. OTIC also solely owns a patent family directed towards additional therapeutic uses of OTO-104, as well as an issued US patent with claims on the manufacturing methods for OTO-104 which will expire in April 2030 (without extension).

OTO-311. OTIC co-owns with UC two patent families directed towards the composition and therapeutic use of OTO-311. The families include one issued US patent and one pending US patent application. Without extension, the expiry of the issued patent is April 2031. The patent families also include issued or allowed applications in various ex-US markets.

Future Candidates. OTIC co-owns eight patent families directed towards a broad range of other active ingredients, including anti-TNF agents, auris pressure modulators, CNS modulators, cytotoxic agents, anti-apoptotic agents, bone-remodeling modulators, free radical modulators and ion channel modulators. Additionally, OTIC solely owns a patent family directed towards alternative formulations and has also acquired rights to patent families directed towards formulations or devices that deliver active agents into the ear through alternative delivery technologies from IncuMed, LCC.

Financial Outlook

Otonomy is a developmental-stage biopharmaceutical company with upcoming clinical and regulatory events (NDA filing for AuriPro in 1H15, Phase 2b data for OTO-104 in 1H15). Currently, we do not model profitability until 2019 (second year of sales for OTO-104). Otonomy has retained worldwide rights to all of its product candidates, though ex-US strategies are still undecided, and we currently do not assign any value to ex-US opportunities for any of the pipeline products.

OpEx Expectations. Below we briefly highlight our assumptions for Otonomy's key operating spend line items.

- **COGS.** Given OTIC's products are made of generically available compounds and commercially available materials (to manufacture the proprietary polymer), we anticipate COGS at peak will be <10% (we currently assume 7%), which takes into account the various royalties owed related to IP licenses.
- **R&D trends.** We assume R&D will continue to ramp as Otonomy executes on the ongoing Phase 2b trial of OTO-104 and the additional development of the pipeline. In the outer years, we assume the company will continue to invest in R&D on additional products given their technology platform and eventual commercial infrastructure.
- **SG&A trends.** We anticipate OTIC will begin to build commercial infrastructure in 2015, ahead of the launch of AuriPro which we expect in 2016. Our model reflects a field force of 40 reps at AuriPro launch, which we assume eventually doubles to 80 to support the ongoing commercialization of both AuriPro and OTO-104 leading to continued growth in SG&A over time.

Otonomy ended 2Q14 with ~\$71 million in cash

The company's cash, cash equivalents and marketable securities totaled \$71 million as of June 30, 2014. In August, Otonomy raised ~\$104M from an initial public offering of common stock (J.P. Morgan acted as a joint book runner). We believe the current cash position is sufficient to get through the expected 1H16 approval of AuriPro, and we estimate that OTIC will end 2014 with ~\$145M in cash.

OTIC's current cash position should be sufficient through the expected 1H16 approval of AuriPro.

Share count

We estimate Otonomy currently has ~23 million fully diluted shares outstanding (including ~21 million common shares and ~2 million stock options post offering).

Figure 18: OTIC Key Financial Metrics

Key Financial Metrics	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E
In \$ M								
December financial year-end								
Cash	4.7	37.3	145.3	73.1	95.4	20.2	122.2	156.5
Debt								
CFOp + CapEx (burn)	(11.0)	(20.0)	(50.7)	(66.8)	(77.7)	(75.2)	(48.0)	33.3
Expected financing	-	0.0	153.3	-	100.0	-	150.0	-
Revenue		-	-	-	6.9	30.8	71.6	168.6
EPS (GAAP diluted)		(7.6)	(4.5)	(3.1)	(3.1)	(2.7)	(1.6)	0.9
Consensus EPS								
Average shares outstanding		2.6	11.3	21.7	25.2	28.7	31.7	34.7
Fully diluted shares outstanding		46.1	51.6	80.8	23.4	23.5	13.4	23.8

Source: Company reports and J.P. Morgan estimates.

Valuation

We are initiating coverage of OTIC with an Overweight rating and a December 2015 price target of \$32 per share.

Our December 2015 price target of \$32 per share is based on a blended average of our proprietary probability-adjusted scenario analysis (50%) and a risk-adjusted NPV model (50%).

Figure 19: OTIC Valuation Summary

Otonomy Valuation Summary				
Discount rate	13%			
4Q15 Fully Diluted Shares (mm)	23.8			
Main value drivers	Prob of approval	Peak WW sales est (avg. scenario)	Avg peak yr	
US AuriPro	85%	\$ 249	2022	
US OTO-104	70%	\$ 497	2023	
Valuation methodology	Value / share	Weighting	Adj. value/ share	
Real options scenario analysis	\$ 36.57	50%	18.28	
Risk adjusted NPV analysis	\$ 27.85	50%	13.92	
Total			\$ 32.21	
Catalyst/liquidity discount			0%	
YE15 Price Target			\$ 32	

Source: J.P. Morgan estimates.

Risk-adjusted NPV analysis (50% weighting)

In our risk-adjusted NPV analysis, we estimate AuriPro and OTO-104 revenues and associated expenses (including taxes) over the expected patent life of the products. We complete this exercise for conservative, moderate, and aggressive sales scenarios and then assign a range of probabilities to each of these outcomes as well as to the possibility that the products are ineffective and generate zero value (which is 15% and 30%, respectively, in our model). We apply a discount rate of 13%, based on OTIC's weighted-average cost of capital (WACC). We believe this is appropriate given the applied probability adjustments.

Figure 20: AuriPro and OTO-104 rNPV Analysis

US AuriPro					
	Peak Sales/Royalty	NPV	NPV/Share	Probability	Value/Share
Not Approved	-	-	-	15%	-
Aggressive	374.1	662.9	27.4	25%	6.9
Base	249.4	386.2	16.0	45%	7.2
Disappointing	82.3	107.4	4.4	15%	0.7
Total				100%	14.70
US OTO-104					
	Peak Sales/Royalty	NPV	NPV/Share	Probability	Value/Share
Not Approved	-	-	-	30%	-
Aggressive	975.7	422.2	17.5	15%	2.6
Base	507.5	211.1	8.7	30%	2.6
Disappointing	243.9	105.6	4.4	25%	1.1
Total				100%	6.33

Source: J.P. Morgan estimates.

Management

Below we highlight key executives at Otonomy.

David A. Weber, Ph.D. - Chief Executive Officer, President and Board Member

Dr. Weber joined Otonomy in November 2010 as president and CEO, prior to which he served as CEO of MacuSight, an ophthalmology company that developed sustained-delivery formulations of sirolimus for the treatment of severe ophthalmic diseases, which he joined in February 2004. Prior to MacuSight, Dr. Weber was the CEO and EVP of Oculex Pharmaceuticals, a specialty pharmaceutical company focused on the development and commercialization of intraocular pharmaceuticals and drug delivery systems (was acquired by Allergan in 2003). Before joining Oculex, Dr. Weber held various management positions with Oral-B Laboratories and Proctor & Gamble.

Paul E. Cayer - Chief Financial and Business Officer

Mr. Cayer is Otonomy's CFO and CBO, and has held each role since October 2010 and October 2008, respectively. Before joining Otonomy, he served as SVP of Corporate Development at Verus Pharmaceuticals, a specialty pharmaceutical company focused on the treatment of pediatric allergic and respiratory disorders, from 2005 to 2008. From 2001 to 2005, Mr. Cayer served as the CFO and SVP of Business Development of Targeted Molecules Corporation (biopharmaceuticals). He has also held various management positions with Gensia Pharmaceuticals (biopharmaceuticals), Acuson (medical ultrasound systems), and Castle & Cooke (consumer products).

Carl LeBel, Ph.D - Chief Scientific Officer

Dr. LeBel is Otonomy's CSO and has held the role since April 2009. Prior to joining Otonomy, he served as Executive Director at Amgen from 2003 to 2007, and held a variety of other positions there from 1993 to 2003. From 1990 to 1991, Dr. LeBel served as a consultant at Arthur D. Little, Inc. (management and technology consulting firm). Dr. LeBel is also a scientific fellow of the American Academy of Otolaryngology—Head & Neck Surgery, a member of the Association for Research in Otolaryngology and a member of both the American Association for the Advancement of Science and the Society of Toxicology.

Robert Michael Savel, II - Chief Technical Officer

Mr. Savel joined Otonomy in January 2014, prior to which he served as general manager and SVP of Operations for Optimer Pharmaceuticals from 2011 to 2013. Before Optimer, he served as SVP and CTO for Inspire Pharmaceuticals, an ophthalmic pharmaceutical company, from 2010 to 2011. From 2008 to 2010, he served as President of Savel Enterprises, a management consulting firm. Prior to Savel, he served as the SVP of Technical Operations for PDL BioPharma (antibody manufacturer). He has also held leadership operating positions with Johnson & Johnson.

Models

Figure 22: OTIC Income Statement

Otonomy Income Statement

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	2012A	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E
AuriPro Revenues								-	6.9	30.8	60.8	100.4
OTO-104 Revenues								-	-	-	10.7	68.2
Total Product Revenue							-	-	6.9	30.8	71.6	168.6
License & Milestone	-	-	-	-	-	-	-	-	-	-	-	-
Contract, Grant & Collaboration	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	-	-	-	-	-	-	-	-	6.9	30.8	71.6	168.6
COGS								-	1.0	4.0	7.9	15.2
R&D	8.5	16.3	9.0	8.3	11.6	13.6	42.5	48.9	50.4	55.5	60.5	68.1
SG&A	2.4	3.5	1.6	1.6	2.1	2.6	7.8	18.5	34.0	47.6	52.8	54.2
Total Operating Expenses	10.9	19.9	10.6	9.8	13.7	16.2	50.3	67.4	85.4	107.1	121.2	137.5
Operating Income	(10.9)	(19.9)	(10.6)	(9.8)	(13.7)	(16.2)	(50.3)	(67.4)	(78.6)	(76.3)	(49.6)	31.2
Other income (expense)	(0.4)	(2.5)	0.1	(0.8)	0.1	0.2	(0.4)	0.3	0.2	0.2	0.2	0.4
Change in fair value of convertible pref. stock	3.8	2.8	(0.3)	(0.0)	-	-	(0.3)	-	-	-	-	-
Income Tax (benefit)	-	-	-	-	-	-	-	-	-	-	-	-
GAAP Net Income	(7.6)	(19.6)	(10.717)	(10.615)	(13.6)	(16.0)	(51.0)	(67.1)	(78.3)	(76.2)	(49.4)	31.5
Accretion to redemption value of convertible pref. stock	(0.8)	(0.5)	(0.0)	-	-	-	-	-	-	-	-	-
GAAP Net Income attributable to common stockholders	(8.4)	(20.1)	(10.7)	(10.6)	(13.6)	(16.0)	(51.0)	(67.1)	(78.3)	(76.2)	(49.4)	31.5
Non-GAAP Net Income	(8.4)	(20.1)	(10.6)	(10.4)	(13.4)	(15.8)	(50.2)	(66.2)	(77.2)	(74.7)	(47.4)	33.8
GAAP Basic EPS	(3.38)	(7.64)	(3.65)	(3.40)	(0.77)	(0.75)	(4.51)	(3.09)	(3.11)	(2.65)	(1.56)	0.91
GAAP Diluted EPS	(3.38)	(7.64)	(3.65)	(3.40)	(0.77)	(0.75)	(4.51)	(3.09)	(3.11)	(2.65)	(1.56)	0.86
Non-GAAP Basic EPS			(3.59)	(3.32)	(0.75)	(0.74)	(4.44)	(3.05)	(3.06)	(2.60)	(1.49)	0.97
Non-GAAP Diluted EPS			(3.59)	(3.32)	(0.75)	(0.74)	(4.44)	(3.05)	(3.06)	(2.60)	(1.49)	0.92
Basic Shares Outstanding	2.5	2.6	2.9	3.1	17.7	21.4	11.3	21.7	25.2	28.7	31.7	34.7
Diluted Shares Outstanding	2.5	2.6	2.9	3.1	17.7	21.4	11.3	21.7	25.2	28.7	31.7	36.8
Margin Analysis:												
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	85%	87%	89%	91%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	18.48%
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	18.70%
Tax Rate	0%	0.0%	0%	0%	0%	0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Cost Analysis:												
COGS as % of tot. prod. sales	NM	NM	NM	NM	NM	NM	NM	0.00%	15.00%	13.00%	11.00%	9.00%
R&D as % of tot. revenue	NM	NM	NM	NM	NM	NM	NM	NM	731.82%	180.27%	84.58%	40.37%
SG&A as % of tot. revenue	NM	NM	NM	NM	NM	NM	NM	NM	492.85%	154.75%	73.77%	32.15%
Year-over-year growth:												
Total revenue		NM	NM	NM	NM	NM	NM	NM	NM	346.54%	132.52%	135.66%
R&D Expense		91.67%	189.57%	NM	NM	NM	159.89%	15.18%	3.15%	10.00%	9.10%	12.48%
SG&A Expense		45.93%	119.50%	NM	NM	NM	122.79%	136.30%	83.62%	40.21%	10.85%	2.69%
Total operating expenses		81.59%	176.48%	NM	NM	NM	153.32%	34.04%	26.77%	25.36%	13.15%	13.43%
Operating income		NM	NM	NM	NM	NM	153.32%	34.04%	16.55%	-2.82%	-34.98%	-162.79%
Net income		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
EPS		NM	NM	NM	NM	NM	-41.01%	-31.46%	0.50%	-14.60%	-41.23%	-154.99%
Basic Shares		6.28%	14.14%	NM	NM	NM	329.89%	92.16%	16.11%	13.88%	10.44%	9.46%
Diluted Shares		NM	NM	NM	NM	NM	#DIV/0!	52.45%	2.33%	29.58%	1.76%	18.98%

Source: Company reports and J.P. Morgan estimates.

Figure 23: OTIC Balance Sheet

Otonomy Balance Sheet (\$ millions)

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	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E
Assets								
Cash and cash equivalents	\$ 4.7	\$ 37.3	\$ 139.9	\$ 73.1	\$ 95.4	\$ 20.2	\$ 122.2	\$ 156.5
Restricted cash	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1
Prepaid Expenses	\$ 0.7	\$ 1.7	\$ 1.8	\$ 2.0	\$ 2.2	\$ 2.4	\$ 2.7	\$ 2.9
Total Current Assets	5.4	39.0	141.8	75.2	97.7	22.7	125.0	159.5
PPE, Net	0.4	0.7	0.8	0.8	0.9	1.0	1.1	1.2
Other	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total Assets	5.90	39.76	142.61	76.11	98.67	23.75	126.13	160.77
Liabilities & Equity								
Accrued expenses/compensati	0.5	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Accounts payable	1.1	2.0	2.2	2.4	2.7	2.9	3.2	3.6
Current portion of deferred ren	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total Current Liabilities	1.7	2.7	2.9	3.2	3.4	3.7	4.0	4.3
Convertible preferred stock wa	2.9	0.6						
Convertible notes payable and	7.1	-						
Deferred rent, net of current	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Total Liabilities	11.92	3.58	3.14	3.37	3.63	3.90	4.21	4.55
Preferred stock	33.0	95.2						
Common Stock	0.0	0.0						
Additional Paid in capital	0.4	0.6	104.6	104.6	204.6	204.6	354.6	354.6
Accumulated Deficit	(39.5)	(59.6)	34.9	(31.8)	(109.5)	(184.7)	(232.7)	(198.4)
Total Shareholders' Equity	(6.0)	36.2	139.5	72.7	95.0	19.8	121.9	156.2
Total Liabilities & Equity	5.90	39.76	142.61	76.11	98.67	23.75	126.13	160.77

Source: Company reports and J.P. Morgan estimates.

Figure 24: OTIC Cash Flow Statement

Otonomy Cash Flow Statement (\$ millions)

Cory W. Kasimov

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	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E
Cash Flow from Operations								
Net Income	\$ (7.6)	\$ (19.6)	\$ (51.0)	\$ (67.1)	\$ (78.3)	\$ (76.2)	\$ (49.4)	\$ 31.5
<u>Adjustments to reconcile net loss to net operating cash</u>								
Depreciation & Amortization	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.5
Share-based compensation	0.2	0.2	0.8	0.9	1.1	1.5	2.0	2.3
Others	(3.0)	(0.3)	(0.4)	(0.4)	(0.4)	(0.5)	(0.5)	(0.6)
<u>Changes in operating assets and liabilities</u>								
Prepaid expenses and other	(0.5)	(1.0)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.3)
Accounts payable	0.6	0.9	0.2	0.2	0.2	0.3	0.3	0.3
Accrued expenses & compen	(0.7)	0.1	-	-	-	-	-	-
Cash Flow from Operations	\$ (10.8)	\$ (19.5)	\$ (50.2)	\$ (66.3)	\$ (77.2)	\$ (74.7)	\$ (47.5)	\$ 33.8
Purchase of PPE	(0.2)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)
Other	-	(0.0)	-	-	-	-	-	1.0
Cash Flow from Investing	\$ (0.2)	\$ (0.5)	\$ (0.5)	\$ (0.5)	\$ (0.5)	\$ (0.5)	\$ (0.5)	\$ 0.5
Issuance of common stock, net	0.0	0.0	104.0	-	100.0	-	150.0	-
Proceeds from convertible not	8.0	7.0						
Proceeds from issuance of con	-	45.6	49.3					
Cash Flow from Financing	\$ 8.0	\$ 52.6	\$ 153.3	\$ -	\$ 100.0	\$ -	\$ 150.0	\$ -
Total Change in Cash	(3.0)	32.6	102.6	(66.8)	22.3	(75.2)	102.0	34.3
Beginning Cash Balance	7.7	4.7	37.3	139.9	73.1	95.4	20.2	122.2
Ending Balance: Cash and Investme	\$ 4.7	\$ 37.3	\$ 139.9	\$ 73.1	\$ 95.4	\$ 20.2	\$ 122.2	\$ 156.5

Source: Company reports and J.P. Morgan estimates.

Otonomy: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E	Income Statement - Quarterly	1Q14A	2Q14A	3Q14E	4Q14E
Revenues	0	0	0	7	Revenues	0A	0A	0	0
Cost of products sold	0	0	0	(1)	Cost of products sold	0A	0A	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(4)	(8)	(19)	(34)	SG&A	(2)A	(2)A	(2)	(3)
R&D	(16)	(42)	(49)	(50)	R&D	(9)A	(8)A	(12)	(14)
Operating income	(20)	(50)	(67)	(79)	Operating income	(11)A	(10)A	(14)	(16)
EBITDA	(20)	(50)	(67)	(79)	EBITDA	(11)A	(10)A	(14)	(16)
Net interest (income) / expense	-	-	-	-	Net interest (income) / expense	-	-	-	-
Other income / (expense)	(3)	(0)	0	0	Other income / (expense)	0A	(1)A	0	0
Income taxes	0	0	0	0	Income taxes	0A	0A	0	0
Net income - GAAP	(20)	(51)	(67)	(78)	Net income - GAAP	(11)A	(11)A	(14)	(16)
Net income - recurring	(20)	(51)	(67)	(78)	Net income - recurring	(11)A	(11)A	(14)	(16)
Diluted shares outstanding	3	11	22	25	Diluted shares outstanding	3A	3A	18	21
EPS - excluding non-recurring	(7.64)	(4.51)	(3.09)	(3.11)	EPS - excluding non-recurring	(3.65)A	(3.40)A	(0.77)	(0.75)
EPS - recurring	(7.64)	(4.51)	(3.09)	(3.11)	EPS - recurring	(3.65)A	(3.40)A	(0.77)	(0.75)
Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E	Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	37	140	73	95	Sales growth	-	-	-	-
Accounts receivable	-	-	-	-	EBIT growth	81.6%	153.3%	34.0%	16.5%
Inventories	-	-	-	-	EPS growth - recurring	125.9%	(41.0%)	(31.5%)	0.5%
Other current assets	2	2	2	2	Gross margin	-	-	-	-
Current assets	39	142	75	98	EBIT margin	-	-	-	(1139.7%)
PP&E	1	1	1	1	EBITDA margin	-	-	-	(1139.7%)
Total assets	40	143	76	99	Tax rate	0.0%	0.0%	0.0%	0.0%
Total debt	0	0	0	0	Net margin	-	-	-	(1136.4%)
Total liabilities	4	3	3	4	Net Debt / EBITDA	187.8%	278.2%	108.5%	121.5%
Shareholders' equity	36	139	73	95	Net Debt / Capital (book)	3365.0%	32014.0%	17862.8%	25161.2%
Net income (including charges)	(20)	(51)	(67)	(78)	Return on assets (ROA)	(88.0%)	(55.9%)	(61.4%)	(89.6%)
D&A	0	0	0	0	Return on equity (ROE)	(133.3%)	(58.0%)	(63.3%)	(93.4%)
Change in working capital	(0)	0	0	0	Enterprise value / sales	-	-	-	NM
Other	(0)	0	1	1	Enterprise value / EBITDA	NM	1.6	0.2	0.5
Cash flow from operations	(19)	(50)	(66)	(77)	Free cash flow yield	(40.4%)	(23.9%)	(16.4%)	(16.4%)
Capex	(0)	(0)	(0)	(0)					
Free cash flow	(20)	(51)	(67)	(78)					
Cash flow from investing activities	(1)	(0)	(0)	(0)					
Cash flow from financing activities	53	153	0	100					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.

Note: \$ in millions (except per-share data). Fiscal year ends Dec

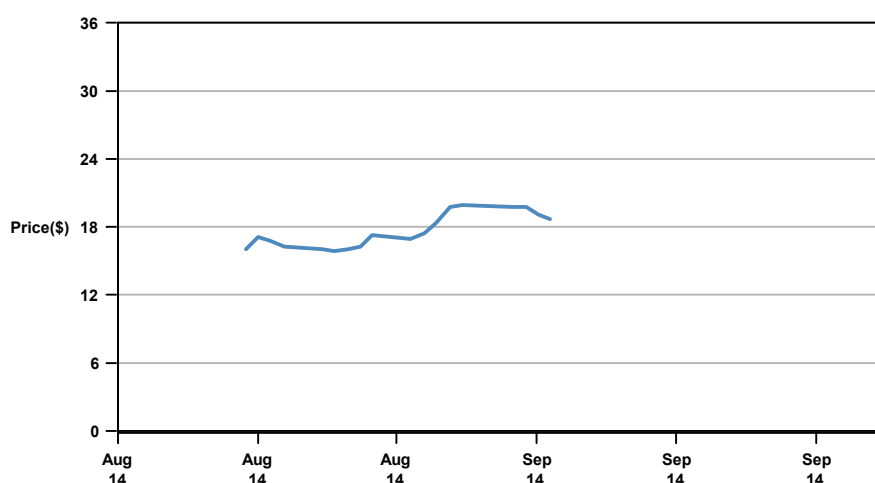
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Otonomy (OTIC, OTIC US) Price Chart



Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.

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