

Innovative Treatments in Neurotology and Mental Health Supportive Care



Strategy & Business Update Third Quarter 2018 Financial Results

November 15, 2018

NASDAQ: EARS

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Clinical Highlights

- Reported positive outcomes from second Phase 1 trial with intranasal betahistine
 - Provided further evidence for betahistine's preventive effects in antipsychotic-induced weight gain
 - Progressing intranasal betahistine program towards proof-of-concept studies

Partnering Highlights

- Initiated partnering process for AM-111 program

Commercial Highlights

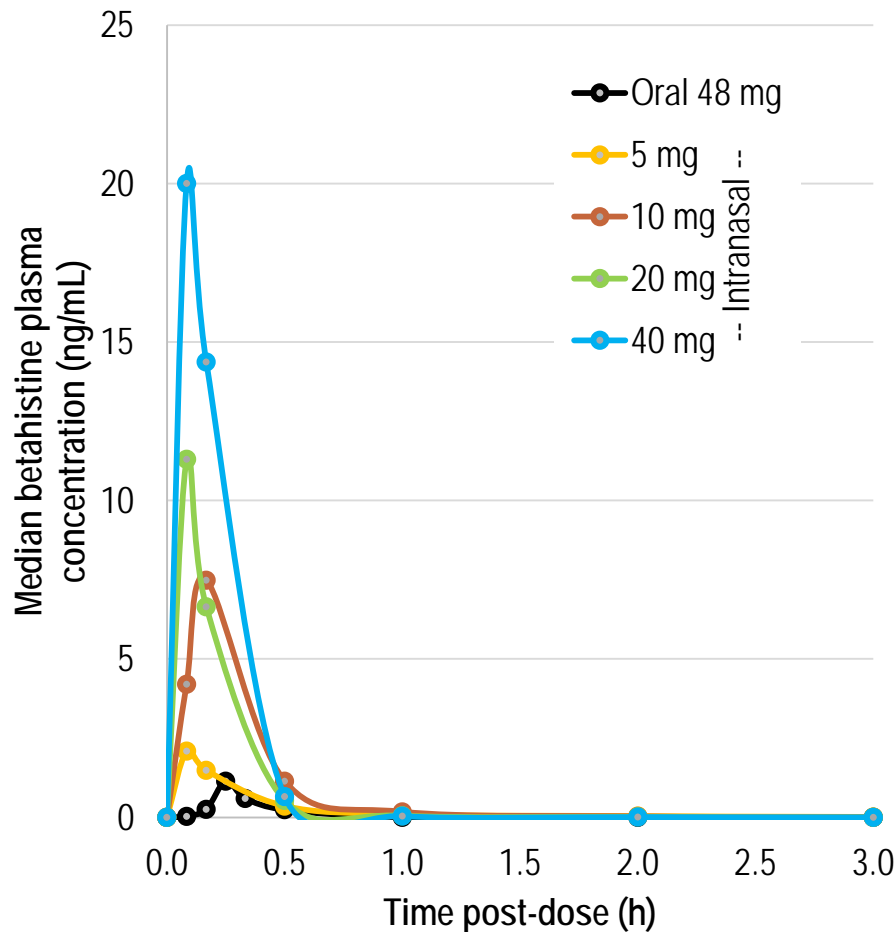
- Announced acceptance of Sonsuvi[®] as brand name for AM-111



Intranasal Betahistine Program Update

Superior Bioavailability Confirmed

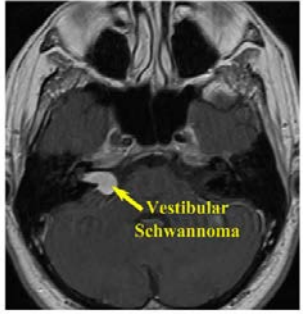
Betahistine concentration in human plasma



- Relative bioavailability of intranasal betahistine in blood plasma vs. oral betahistine 48 mg
 - 6-29 x (p values 0.056 to <0.0001)
- Overall, good safety profile confirmed; transient, dose-dependent nasal tolerability signals as expected
- Maximum tolerated dose with repeated dosing (3 x daily for 3 days): 40 mg
- Safety package ready for requesting approvals for one-month studies



Project AM-125 Update



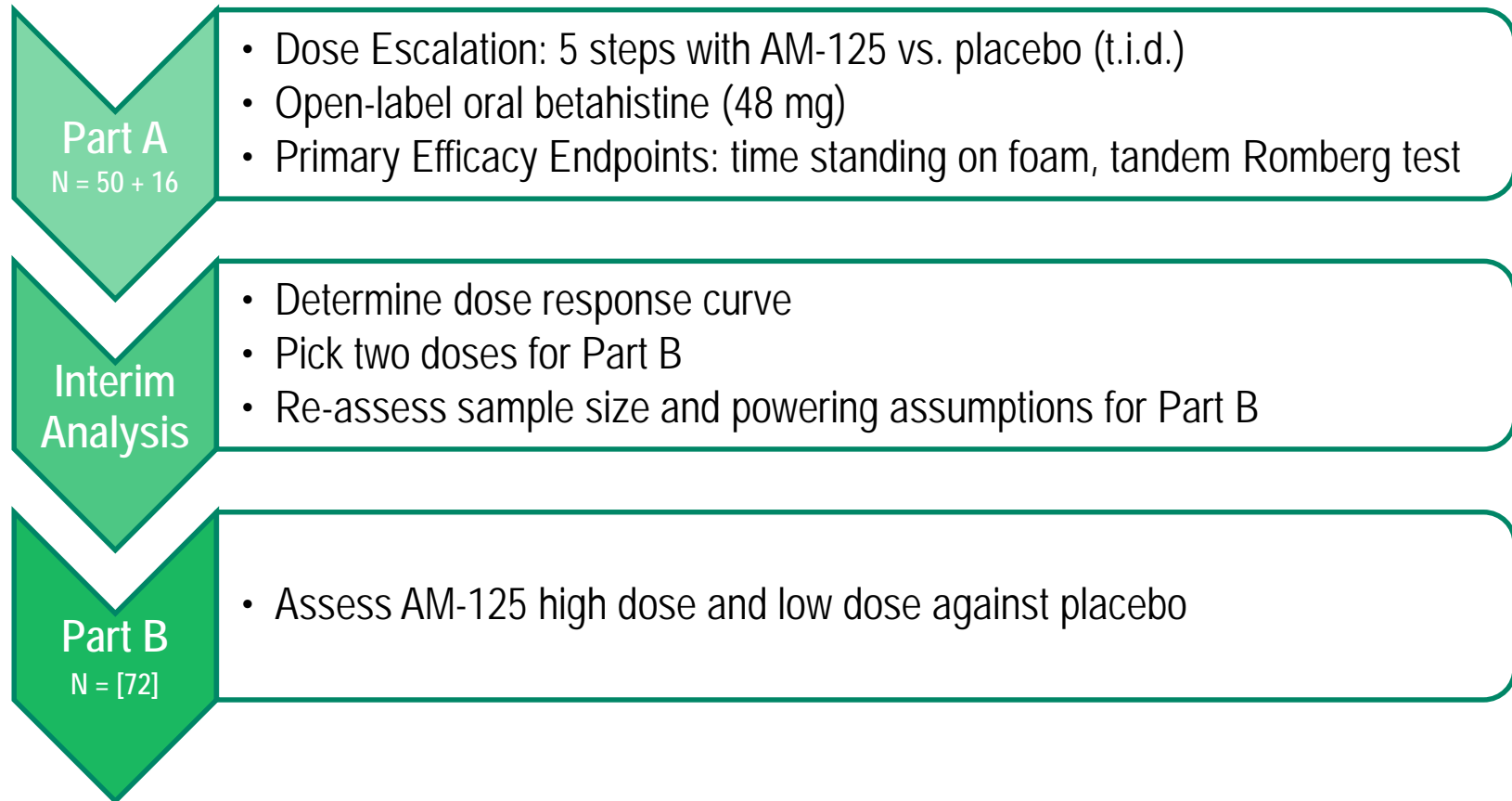
Expect to initiate Phase 2 trial with AM-125 (TRIVERS) in Q1 2019

Trial Details

- Patients with loss of vestibular function following vestibular schwannoma resection
- Model endorsed by EMA for proof-of-concept through Scientific Advice
- To be conducted in several European countries and potentially, Canada
 - Site selection ongoing: 12-15 sites
- Initiation planned for Q1 2019
- Target enrollment = 138 patients
- Primary objective = accelerate and improve vestibular recovery



Design of TRAVERS Phase 2 Trial





Project AM-201 Update

Expect to initiate pharmacokinetic/pharmacodynamic (PK/PD) trial with AM-201 in first quarter of 2019



Trial Details

- 50 healthy volunteers
- Single European site
- Olanzapine treatment + AM-201 or placebo over four weeks
- Start planned for Q1 2019

Trial Objectives

- Primary objective = reduction in weight gain
- Secondary objective = reduction in daytime sleepiness
- Test potential interaction olanzapine / betahistine

Screening

- Healthy male or female volunteers 18-50 years of age
- BMI 18-25 kg/m²
- **Dose escalation:** 5 steps with AM-201 vs. placebo (t.i.d.)

Titration OLZ

- Titrate OLZ up to 10 mg (7.5 mg) q.d. within first week
- Subjects who do not tolerate OLZ or who gain clinically relevant amount of weight or high glucose level to be replaced

Maintenance

- Maintain OLZ dose for three weeks



- Recent publication providing further evidence for betahistine's preventive effects on antipsychotic-induced weight gain
- Oral betahistine 36-48 mg per day or placebo over 12 weeks
- 51 adolescent and adult patients who received at the same time various antipsychotic drugs
- In sub-group of patients treated with olanzapine or clozapine (n=26), betahistine was significantly better than placebo in preventing increases in:
 - weight (3.1 kg less weight gain than placebo)
 - body mass index
 - waist circumference

Smith RC et al. (2018). Betahistine effects on weight-related measures in patients treated with antipsychotic medications: a double-blind placebo-controlled study. *Psychopharmacology (Berl)*, in press.



Project AM-111 Update



- Target indication = treatment of acute sensorineural hearing loss
 - Orphan Drug Designation, Fast Track
- Sonsuvi® ("son-SUE-vee") conditionally approved by FDA as brand name for AM-111
- Follows previous endorsement by EMA
- Subject to final review at the time of marketing approval
- Registered as trademark in various countries
- FDA guidance on AM-111 development program through type C meeting
- FDA endorsed
 - proposed choice of primary and secondary efficacy endpoints
 - the safety endpoints
 - planned sample size
 - statistical methodology

Partnering Process Initiated

- Refocus development activities on intranasal betahistine program
- Seek partners or other sources of non-dilutive funding for late-stage development programs
- Mandated JSB Partners, Boston, an international transaction advisory firm
 - Identify potential partners for AM-111 development program
 - Provide support for partnering discussions and negotiations
- Process started
- “First-in-class” drug for treating acute inner ear hearing loss



Financial Update

Third Quarter 2018 Financial Update

CHF	Q3 2018	Q3 2017
Net Income (Loss)	(3.0 million)	(6.0 million)
EPS	(0.14)	(1.36)
R&D Expenses	1.7 million	4.2 million
General & Administrative Expenses	1.2 million	1.3 million

Operating Expenses 2018 (Guidance)

- CHF 10 to 12.9 million

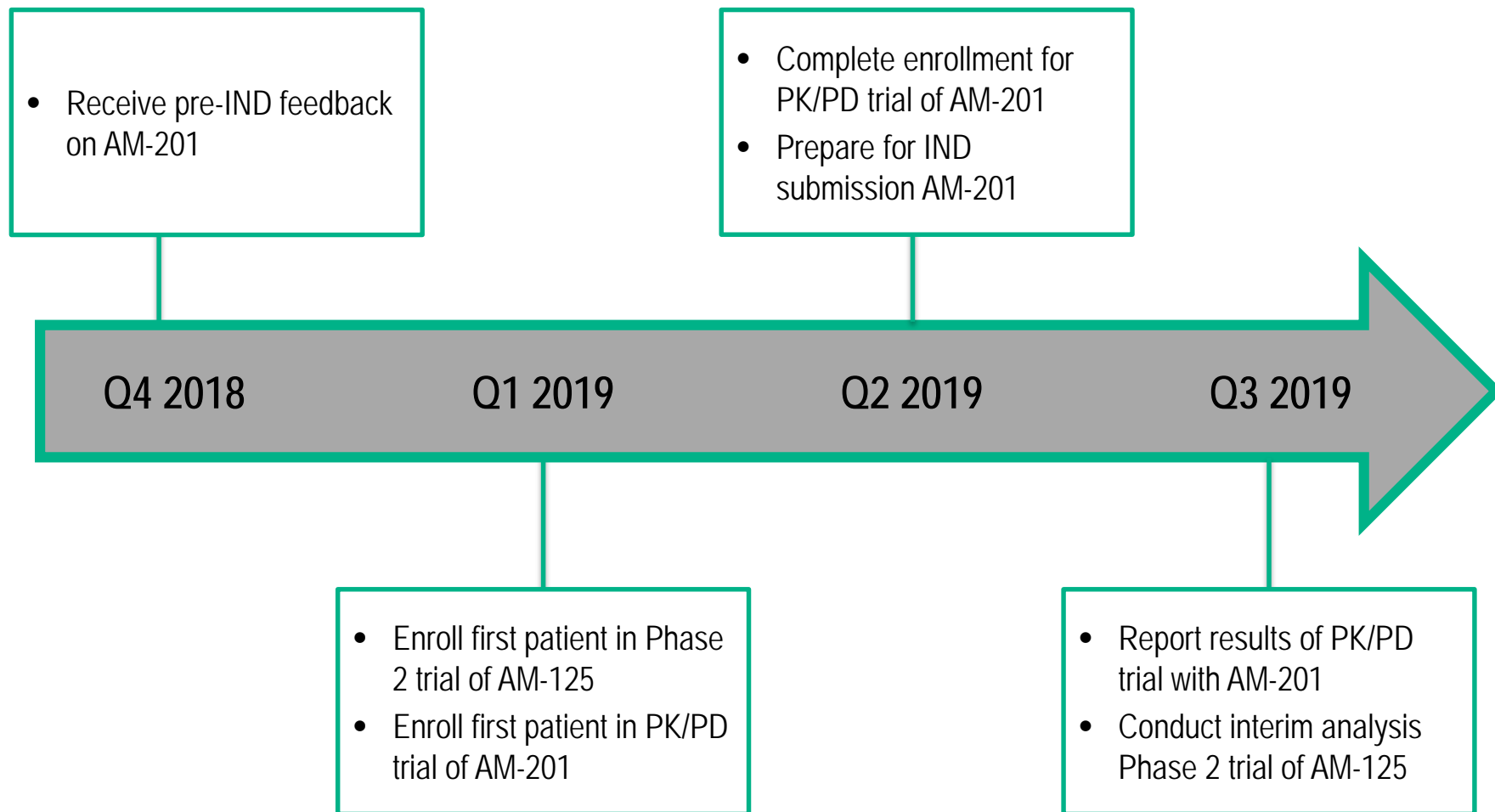
Cash Position

- Cash and cash equivalents (at September 30, 2018) totaled CHF 5.3 million
- Cash runway into second quarter of 2019
- Exercise of warrants from the July 2018 offering as well as the sale of shares under the equity line with LPC since end of Q3 have increased cash and cash equivalents by approximately CHF 2.7 million.



Outlook and Conclusions

Upcoming Milestones





Take care of your ears!

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