SUCCESS IN CNS DRUG DEVELOPMENT – INNOVATION IN RARE DISEASES

Full Year Results 2018 and Outlook 2019

Tuesday, March 5, 2019, 3 pm CET

Newron
Pharmaceuticals

FULL YEAR RESULTS 2018 AND OUTLOOK 2019 TELEPHONE CONFERENCE

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2018 - Year of fundamental progress (1/2)

Sarizotan in Rett Syndrome

- Newron successfully completed enrolment for the STARS phase III study (Results from the study are expected in Q4 2019).
- Newron presented, at its R&D day in New York City, baseline data from more than 100 patients treated in the STARS trial, suggesting, amongst other findings, that up to 70 percent of patients suffering from Rett syndrome experience clinically significant apneas.
- Newron participated at the international conference: “Rett Syndrome Research, Towards the Future” in Rome and provided an update on the first ever international Burden Of Illness (BOI) study in Rett syndrome.

Evenamide in schizophrenia

- Newron has completed discussions with and gained agreement from the regulatory authorities in Europe and the United States for a Phase III program, consisting of two pivotal studies and is on track to commence these trials in Q2 2019:
  - one study in patients with schizophrenia experiencing worsening of psychosis on atypical antipsychotics
  - the other study investigating Evenamide as an add-on therapy for patients with treatment-resistant schizophrenia, not responding adequately to clozapine.

2018 - Year of fundamental progress (2/2)

Xadago® (safinamide) in PD:

- Zambon and its regional partners have gained approval for Xadago/safinamide in Australia, Canada, Brazil and Colombia; launches in these territories are expected within the next 12 months.
- Dossiers for marketing authorization of Xadago® are currently under review in Mexico and Israel.
- Zambon is engaged in discussions for additional Xadago® distribution agreements in Southern Europe, Middle East, Africa and South America.
- Meiji Seika Pharma announced that the primary endpoint was met in a Phase II/III study of safinamide in patients with Parkinson's disease in Japan and has subsequently filed for marketing authorisation in this territory.
- Zambon has completed discussions with US FDA on the design of a potentially pivotal efficacy study to evaluate the effects of Xadago/safinamide in patients with levodopa induced dyskinesia (PD LID); study is expected to start in H1 2019.

Corporate

- Newron has secured a long term funding of up to EUR 40 million from the European Investment Bank to boost its R&D activities and support pivotal and post-approval CNS development programs.
- As a result, the Company disposes of total available funds of up to EUR 84 million, which will cover the pursuit of its development programs and operations beyond 2020.
- Newron's shareholders approved all resolutions at the 2018 Annual General Meeting, including granting the Board of Directors
  - the ability to issue shares and/or convertible bonds, up to EUR 1,426,987.60
  - powers to create American Depositary Shares and to list them on the Nasdaq or on any other market in the United States of America.
- The Company hosted a well-attended R&D day in New York City featuring John Kane, MD and Daniel Glaze, MD, leading experts in the fields of schizophrenia and Rett syndrome, alongside Newron's management team.

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Successful Track Record in CNS Product Development

Xadago® (safinamide)

Commercialized by partner in 15 European markets and the US for Parkinson's disease ("PD")

- Newron receives milestone and royalty payments from sales of safinamide in PD
  - EUR40m received to date

Sarizotan

Close to completion of Phase III program in Rett syndrome (orphan disease)

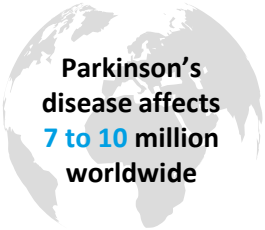
- Newron will commercialize Sarizotan for Rett syndrome in the US and – if viable – in key EU territories

Evenamide (NW-3509)

Phase IIa trial demonstrated PoC

- Phase III program to start in QII 2019: opportunities for commercialization by Newron (Clozapine TRS population) and partnering (major indication)

Xadago®: 1st New Chemical Entity Approved in a Decade for Parkinson's Disease



Parkinson's disease affects 7 to 10 million worldwide

A progressing disorder, no cure available yet

- 2nd most common chronic progressive neurodegenerative disorder in the elderly
- Affecting 1-2% of individuals aged ≥ 65 years worldwide
  - **20%** to **30%** in early stage
  - **70%** to **80%** percent in mid to late stage
  - **>$4 billion** worldwide market

Fast and sustained efficacy, well tolerated

MID- TO LATE-STAGE PD PATIENTS –
add-on to L-Dopa dopamine replacement

- Significant improvement of
  - ON Time/OFF Time – regulatory endpoint
  - UPDRS II – activities of daily living
  - UPDRS III – motor function
  - CGI (clinical global impression) – severity and improvement
- Additional ON Time without any increase in troublesome dyskinesia

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Xadago®: New Label Study in Patients with Levodopa Induced Dyskinesia

- Newron and partner Zambon have completed designing a potentially pivotal study to evaluate Xadago® in patients with levodopa induced dyskinesia (PD LID)
- Study to be performed in Europe and US
- Supportive evidence of Xadago's anti-dyskinetic effect:
  - Mechanism, i.e. glutamate release inhibition
  - LID models
  - PD patient data: significant benefit on DRS (Dyskinesia Rating Scale) in 223 dyskinetic PD patients in a 2 year-placebo-controlled study
- Advanced discussions with US regulators on study design ongoing
- Study expected to start HY I 2019

Significant Commercial Opportunity in Xadago® (Safinamide)

US / Canada

Launched in US in July 2017
Regulatory approval for Canada

EU / Latin America

Launched in Germany, UK, Italy, Spain and other EU territories, and Switzerland; regulatory approval for Brazil and Colombia, application for regulatory approval filed for Mexico

Israel

Application for regulatory approval filed

Japan / Asia

Phase II/III completed in Jan. 18; application for regulatory approval filed

Australia /New Zealand

Regulatory approval for Australia

- Parkinson's disease affects 7 to 10 million people worldwide
- Long period of Xadago® market exclusivity (patent life: 2029 in EU, 2031 in the US)
- Milestone and royalty revenues to Newron since 2012

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Rett Syndrome: A Severe Neuro-Developmental Orphan Disease

25% of sudden deaths in Rett syndrome may be due to cardio-respiratory abnormalities

- Estimated 36,000 patients in US and EU combined
- Focus on symptom management

No Approved Treatment Options

Spontaneous mutations in the X-chromosome linked MeCP2 gene

- Disease manifests almost exclusively in females with one affected X-chromosome
- Normal development until 6-18 months of age, then loss of skills and ability for social interaction
- Respiratory abnormalities, motor and severe intellectual impairment, sleep abnormalities and seizures in most patients (70-90%)

Sarizotan: Targeting Respiratory Disturbances in Rett Syndrome Patients

- First Rett syndrome drug candidate targeting respiratory disturbances as primary efficacy outcome
- Deficits in serotonergic transmission due to the MeCP2 mutation in the mid-brain nucleus may underlie the respiratory abnormalities in MeCP2 deficit mice
- Sarizotan, a full agonist at the serotonergic 5HT1A receptor, has demonstrated dramatic improvement of respiration in genetic knockout (MeCP2) mouse model of RTT
- Development plan addressing regulatory requirements as discussed with FDA/EMA/HPB
- Orphan drug designation in EU and US
- Rare Pediatric Disease Priority Review Voucher Program

EFFECTS OF ACUTE ADMINISTRATION WITH SARIZOTAN IN RETT FEMALE MICE (MECP2R168X/+). BENEFIT PERSISTS IN LONG LASTING TREATMENTS (14-DAYS-MECP2$^{R168X/+}$)

Apnea in MeCP2-deficient mice

Apnea in MeCP2-deficient mice treated with Sarizotan 5.0 mg/kg

Ref: **Abdala AP, Lioy DT, Garg SK, Knopp SJ, Paton J F, Bissonnette JM**. Effect of Sarizotan, a 5-HT1A and D2-Like Receptor Agonist, on Respiration in Three Mouse Models of Rett Syndrome. *American Journal of Respiratory Cell and Molecular Biology, 50(6): 1031-1039.*

STARS: First Ever Global Phase III Study in Rett Syndrome

- Protocol/program approved by HA in UK, Germany, Sweden, Spain, Canada, CHMP, and US
- Randomized, double-blind, placebo-controlled, six-month study evaluating efficacy and safety of sarizotan in at least 129 Rett syndrome patients with respiratory symptoms
  - Females and males ≥ 4 years, body weight ≥ 10 kg meeting RTT consensus clinical criteria, confirmed by MECP2 mutations
  - Patients meet all criteria related to breathing abnormalities:
    - ≥10% of the time with abnormal breathing
    - At least 10 episodes of breathing dysrhythmia (≥10 seconds of breath holding, apnea)/hour during cardiorespiratory monitoring (home/ambulatory monitoring system - BioRadio™)
- 14 Centers of excellence in the United States, Italy, UK, Australia and India
- Primary endpoint:
  - Percent reduction in number of apnea episodes/hour
    - Primary efficacy variable to be calculated from data from home cardiorespiratory monitoring
  - Measurements to be performed for 6-hr per day, during time awake, on any 3 days during the week
    - Weeks 2, 8, 16 and 24
- Enrollment completed
- Results expected QIV 2019

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Natural history study and new learnings from the STARS clinical trial

- The **natural history** points to the fact that respiratory symptoms start early in these patients (minimum 0.7 years: median 3 years), quickly become prominent and dramatic, but wane over time; they are correlated with worsening of the core symptoms and with Long QTc interval
  - but there has been no systematic attempts to quantitate these breathing abnormalities, their time course, the associated effects on SpO2 saturation
- **STARS data suggest** that the proportion of patients with respiratory abnormalities **does not decline with age**
- Quantitative recordings for over 18 hours in the home setting **indicate that up to 70% of patients evaluated experience clinical significant apnea**
- Oxygen saturation goes below 90% 4.2 times per hr, duration may last a long as **48 minutes/hr**
- Definitive data will be available late next year, however anecdotal data from investigators suggest that greater awareness of surroundings, increased attempt at non-verbal communication, greater alertness noted in patients who experience some improvement in apnea'

Sarizotan Market Opportunity and Commercialization Strategy

Initiation of a Health Economic Outcome Research Study (HEOR)
→ ”burden of illness”

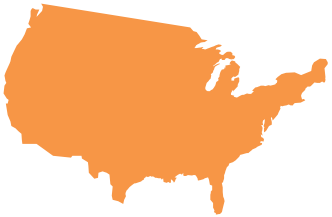
- Partnerships and collaborations with Rett advocacy, thought leaders & governing payers
- Global survey to quantify the ways in which patient “respiratory breathing abnormalities” affect daily life
- Meets Health Technology Assessment (HTA) requirements

Goals

- Align economic & clinical outcomes
- Create awareness to breathing abnormality burden
- Optimize market uptake, access, reimbursement
- Build Newron leadership

Rare Pediatric Disease Priority Review Voucher Program

US 16,000 patients



Orphan exclusivity
7.5 years post approval

EU 20,000 patients

Orphan exclusivity
12 years post approval

Small team ~ 25-30 medical liaison managers required to commercialize sarizotan in US and Europe

Schizophrenia: No Effective Treatment that Reduces Burden of Disease in Last 20 Years

Globally over 4 million patients

- Disease onset in 20s, need for life long treatment
- Cost to society (direct cost US only): $63bn p.a.

Efficacy of current treatment options is insufficient

Onset of disease occurs in early adulthood affecting 1% of the population worldwide

- Efficacy of typicals and atypicals limited and wanes over 18 months; severe side effects; 64-82% of patients switch but without additional benefits
- Treatment-resistant schizophrenia (TRS)
  - Min. 30% of patients after 3-5 years are TRS: only clozapine shows efficacy
  - 30-50% of these patients show resistance to clozapine; no therapeutic option left
- Outcomes for 1-year treated young US first episode patients: 24 times greater mortality than age matched (16-30 year olds) controls despite use of antipsychotics (40%) and mental health services (Schoenbaum, 2017)

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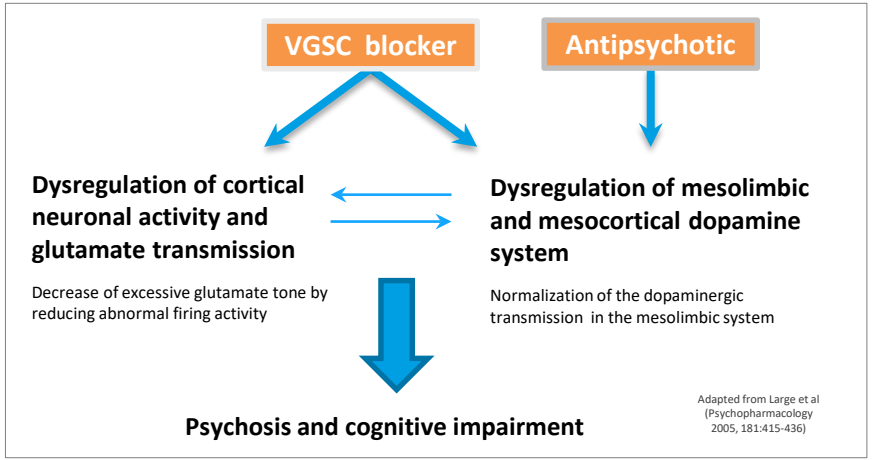
Evenamide Novel MoA: Synergistic with Marketed Antipsychotics

- Evenamide, a Voltage-Gated Sodium Channels (VGSC) blocker has the potential to target the abnormal neuronal activity and glutamate transmission in patients with schizophrenia
- Evenamide may add to or synergize with antipsychotic drugs to bring about a combined therapeutic effect on glutamate and dopamine systems
  - Effects seen in combination with haloperidol, risperidone, aripiprazole, and clozapine
- Composition of matter – USPTO, 2013 – patent life 2028 plus extension

Voltage-Gated Sodium Channels (VGSC) blockers may act synergistically with antipsychotics in schizophrenia therapy



Evenamide's Unique MOA Demonstrated

Selectively blocks native sodium channels, showing no off target effect on >130 CNS receptors, enzymes, transporters, etc.

Selectively blocks VGSCs in a voltage-and use-dependent manner

Modulates sustained repetitive firing without inducing impairment of the normal neuronal excitability

Inhibits Glutamate Release

Inhibition of native sodium channels expressed in rat cortical neurons

K_{rest} (µM)

25

K_{inact} (µM)

0.4

High frequency firing

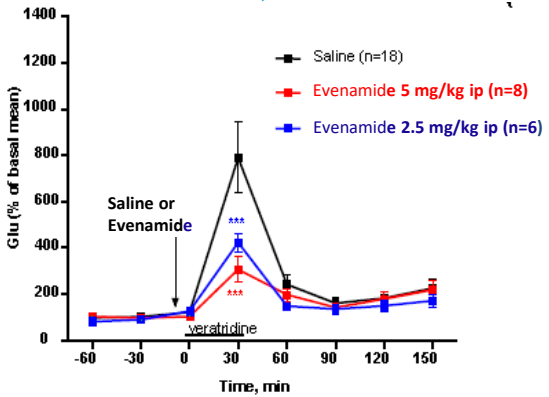
Control

Evenamide 1µM

Low frequency firing

Control

Evenamide 1µM



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Evenamide is Active in a Wide Range of Schizophrenia and Psychiatric Animal Models as a Monotherapy and as an Add-on to Existing Antipsychotics

		Monotherapy	Add-on
Information Processing Deficit	Pre-pulse inhibition (PPI) disrupted by dopamine activation (amphetamine -rat)	✓	✓
	Pre-pulse inhibition (PPI) disrupted by NMDA antagonists (MK-801, PCP, -rat)	✓	
	Pre-pulse inhibition (PPI) disrupted by natural stimuli (sleep deprivation -rat)	✓	
	Pre-pulse inhibition spontaneous deficit (C57 mice)	✓*	✓
	Pre-pulse inhibition (PPI) disrupted by Ketamine in rat	✓	✓
Negative Symptoms	PCP-induced deficit in Social Interaction in the rat	✓	✓
	Saccharin preference test (anhedonia) in prenatal poly:IC exposed mice (ongoing)	✓	
	Three-chamber sociability test in prenatal poly:IC exposed mice (ongoing)	✓	
	Forced swimming test (avolition) in prenatal poly:IC exposed mice (ongoing)	✓	
Psychosis and Mania	Amphetamine induced hyperactivity in mice	✓	✓
	Amphetamine plus Chlordiazepoxide induced hyperactivity in mice	✓	✓
Cognitive Impairment	Novel object recognition in the rat: short term scopolamine impairment	✓	
	Novel object recognition in the rat: long term 24 hr natural forgetting	✓	
Impulse Control and Mood Symptoms	Resident–Intruder test in mice (Impulsivity)	✓	
	Tail suspension test in mice (Depression)	✓	
	Marble burying test in mice (Obsessive Compulsive Disorders)	✓	

*Trend
Blank cells = not evaluated

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Evenamide: PoC in Patients with Schizophrenia Demonstrated

- 4-week, placebo-controlled, add-on study of evenamide (15-25mg BID/day) in 89 patients on stable doses of aripripazole or risperidone showing signs of worsening when compared to standard of care, at every assessment during the study (starting day 8)

  - **Significant improvement of**
    - PANSS positive, both mean change AND responder rate
    - CGI-C

  - **Superior benefit on**
    - PANSS total
    - LOF total
    - CGI-S

- Glutamatergic MoA seems to improve symptoms of psychosis in patients not responding to D2/5HT2 blockade

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Evenamide: Applicability in Clozapine Resistant Treatment Resistant Schizophrenia (TRS)

- 30% of TRS patients on clozapine do not respond adequately to this treatment, or develop resistance to its effects
- Outcomes/service utilization data indicate TRS is a categorically different illness to treatment-responsive schizophrenia
  - 10-20% of patients already show symptoms of resistance in first episode
- TRS is associated with some of the highest rates of hospitalization and costs to society - $34bln. in direct healthcare costs in the United States
- No drug other than clozapine has shown efficacy in these patients
- NIMH/ FDA/ ECNP/ EMA have raised this as an issue of grave concern
- TRS patients show normal dopaminergic, but abnormal glutamatergic transmission
- Evenamide antagonizes (in vivo)
  - effect of ketamine (glutamate antagonist) on PPI
  - effects of MK-801 and PCP (glutamate releasers)
- Results with Evenamide in animal models of schizophrenia mimic effects of clozapine

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Evenamide: Regulatory Interactions and Phase III Clinical Development Plan

Discussed with Health Authorities in:

- Spain, Denmark, Sweden, Germany, UK, CHMP, US, Canada: end of Phase II

All Health Authorities accepted pharmacokinetics, metabolism, toxicology, safety pharmacology, human safety, and efficacy data from Study 002
Indications, selection criteria, study designs, dose-range, safety/efficacy measures agreed on Phase III
Efficacy program will be comprised of 2 populations:

- **Non-treatment resistant patients**: chronic schizophrenics experiencing inadequate benefit for symptoms of their psychosis, on current atypical antipsychotic monotherapy (risperidone, aripripazole, paliperidone, olanzapine, or quietapine) **– Planned Study 003**
- **Treatment resistant schizophrenia**: Patients whose psychotic symptoms are not responding adequately to treatment with clozapine - **Planned Study 004**

Positive results of both studies would meet efficacy criteria for both indications
Positive result of study 004 only would lead to approval of clozapine-resistant population only
Positive result of study 003 only would lead to need for another similarly designed study
Start of Phase III program expected HI 2019 – appr. 18 months to results

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Study 003: Study Design

A Phase IIb/III, prospective, randomized, double-blind, placebo-controlled, parallel-group, multi-center, 6-week study to evaluate the efficacy, safety, and tolerability of three add-on fixed doses of Evenamide (7.5, 15 and 30 mg BID) or placebo in patients with established schizophrenia not responding adequately to their current single atypical antipsychotic medication.

Patients/centers/countries: 520 patients (130/group) ~30 centers in Canada, Europe, India, Latin America and North America

- **Population:**
  - Male/female (not of CBP) outpatients, age $\geq$ 18 Y, chronic schizophrenia (DSM-5) on a stable dose of an atypical antipsychotic (min. 4 weeks prior to screening);
  - Total score $\geq$ 20, and a score of 4 (moderate) or more on at least 2 of 4 core symptoms of psychosis (conceptual disorganization, hallucinatory behaviour, suspiciousness and unusual thought content);
  - CGI-S of moderately to severely ill (4-6); functional deficits (GAF < 50)
  - Patient has achieved remission or “good response” to any antipsychotic within past 5 years

Screening 3-21 days; patients meeting all selection criteria at screening and baseline will be randomized to treatment and receive their first dose in the clinic on Day 1. Return for scheduled visits on Days 8, 15, 29 and 43 (endpoint)

Extension (Study 005): Separate 46-week, double-blind, placebo-controlled, extension; continue double-blind treatment on same dose/treatment.

Study 004: Study Design

A phase IIb/III, prospective, randomized, double-blind, parallel-group, multi-center, 8-week study to determine the efficacy, safety and tolerability of add-on treatment with Evenamide (15 or 30 mg BID) or placebo in patients with treatment-resistant schizophrenia (TRS) not responding adequately to clozapine.

Patients/centers: 450 patients (150/group), 30 centers in Canada, Europe, India, Latin America and US

- **Population:**
  - Male/female (not of CBP) outpatients with chronic schizophrenia (DSM-5) with a TRS diagnosis of at least 2 yrs, despite an adequate trial of clozapine (≥ 12 wks, with a dose of ≥ 300 mg/day for 8 weeks), and a plasma clozapine concentration of ≥ 300 ng/ml
  - Total score ≥ 20, and a score of 4 (moderate) or more on at least 2 of 4 core symptoms of psychosis (conceptual disorganization, hallucinatory behaviour, suspiciousness and unusual thought content);
  - CGI-S of moderately to severely ill (4 – 6); functional deficits (GAF < 41).

Screening 3-21 days; patients meeting all selection criteria at screening and baseline will be randomized to treatment and receive their first dose in the clinic on Day 1. Return for scheduled visits on Days 8, 15, 36, and 57 (endpoint).

Extension (Study 006): Separate 44-week open-label extension study; to maintain the blind in Study 004, all patients will have Evenamide dose titrated.

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Company Highlights

Diversified portfolio of innovative CNS product candidates

- Xadago® for Parkinson's disease – validation of Newron's development expertise – from research to market
- Sarizotan for Rett syndrome – in late Phase III development
- Evenamide – Re-defining the treatment of poor/non-response in schizophrenia

Significant near-term value drivers

Management team with proven track record

Fully funded beyond key value inflexion points

- Cash balance of € 44 (Dec 31, 2018)
- Access to long term funding facility of up to € 40 (European Investment Bank)

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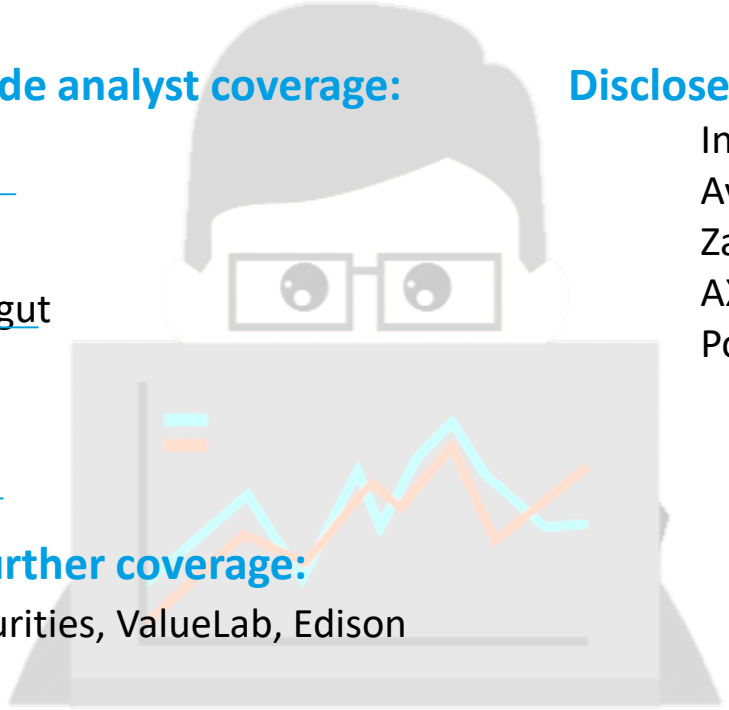
Analysts and most Recent Info on Shareholdings

Sell-side analyst coverage:

Jefferies Peter Welford

Kempen Alexandru Cogut

VONTOBEL Stefan Schneider



Disclosed* material shareholders (>3%)

Investor AB	> 9%
Aviva	> 7%
Zambon	> 4%
AXA	> 3%
Polar	> 3%

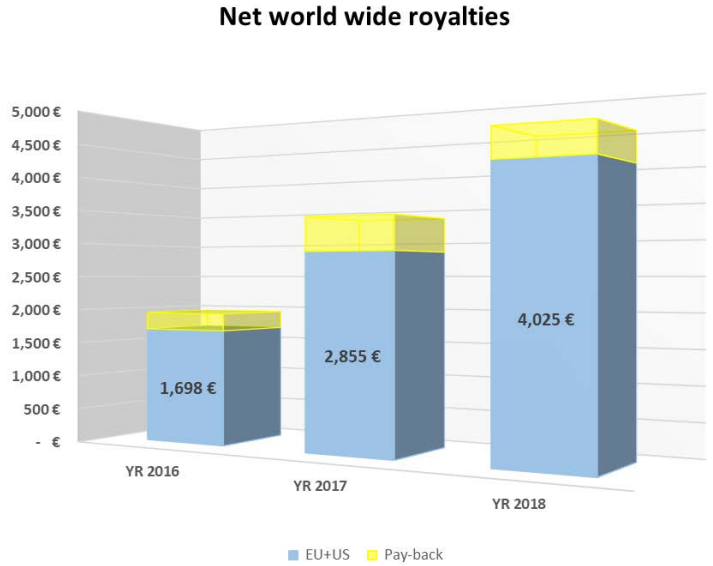
Further coverage:

RX Securities, ValueLab, Edison

*: to the best of Newron' knowledge https://www.six-exchange-regulation.com/en/home/publications/significant-shareholders.html?companyId=NEWRONPH

Group Consolidated Financials (IFRS) FY 2018 – Income statement

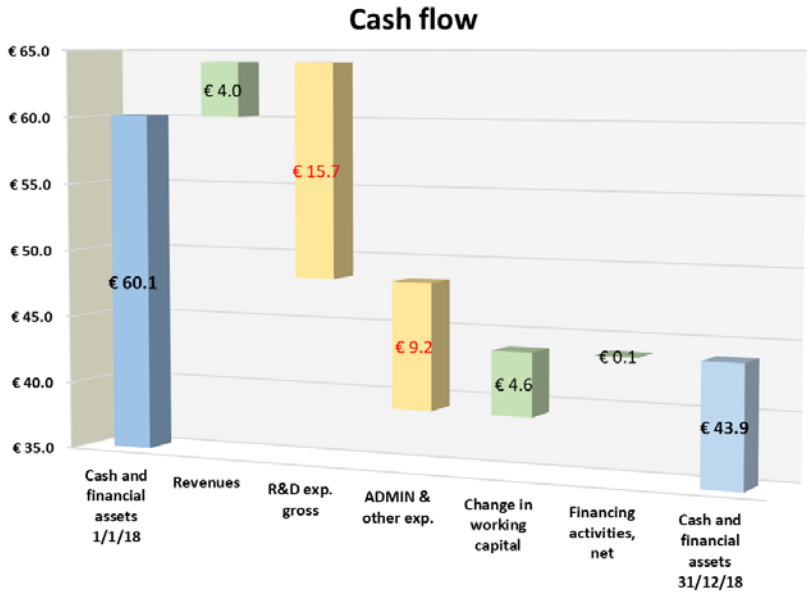
EUR/000	2018	2017
Licence income	0	10,430
Royalties	4,025	2,855
Other income	0	143
Research and development expenses	(9,835)	(8,596)
Marketing and advertising expenses	(406)	(708)
General and administrative expenses	(8,762)	(8,470)
Operating loss	**(14,978)**	**(4,346)**
Net loss	**(15,035)**	**(5,282)**
Net loss per share - in EUR	(0.84)	(0.32)



- Licence income refers to milestones cashed in at: i) FDA approval and ii) identification of Australian, Canadian and Israeli partners
- Royalties increased by 41% despite AIFA (Italian authority) imposing a ceiling on sales (impact shown by yellow box)
- R&D expenses are net by Italian R&D Tax Credit (2018 equal to 5,9m€)

Group Consolidated Financials (IFRS) FY 2018 – Balance sheet and Cash flow statements

EUR/000	2018	2017
Non-current assets	219	224
Current assets	15,659	12,719
Cash and other financial ass	43,853	60,081
Total shareholders' equity	54,844	67,721
Non current liabilities	606	576
Current liabilities	4,887	4,727



- Current assets include 13.6m€ of R&D tax credit
  - ✓ In 2018, Newron used 1.9m€ of R&D Tax Credit to reimburse social contribution (no cash disbursement)
- Cash, other financial assets and EIB facility are sufficient to finance Newron' development activities beyond 2020

AGM April 2, 2019 – 10.00 am CET - Newron premises

AGENDA

1. Approval of the financial statements as at December 31st, 2018. Related and consequent resolutions.
2. Appointment of Auditors for the 3-years period 2019-2021
3. Appointment of Statutory Auditors for the 3-years period 2019-2021

CONTACT DETAILS

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Q&A