



COMMITTED TO CNS DRUG DEVELOPMENT

INNOVATIVE TREATMENTS TO IMPROVE QUALITY OF LIFE

Full Year Results 2024 and Outlook 2025

Tuesday, April 1, 2025, 3:00 pm CET/2:00 pm UK/9:00 am EDT



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FULL YEAR RESULTS 2024 AND OUTLOOK 2025 TELEPHONE CONFERENCE

Please dial in five to ten minutes prior to the beginning of the call using one of the following telephone numbers:

Switzerland/Europe: +41 (0)58 310 50 00

United Kingdom: +44 (0)207 107 0613

United States: +1 (1)631 570 56 13

For other countries, please see [HERE](#)

Speakers:

Stefan Weber, CEO

Ravi Anand, CMO

Roberto Galli, CFO

Evenamide – Schizophrenia

- Exceptional data from study 014/015 and study 008A
 - Significant and increasing efficacy of evenamide as an add-on therapy on multiple measures of psychopathology in treatment-resistant schizophrenia (TRS) and chronic schizophrenia
 - Confirmed evenamide's favorable safety and tolerability profile
- Adds to the growing evidence that evenamide's glutamatergic inhibition MoA offers innovative therapeutic option to schizophrenia patients who are not benefiting from current antipsychotic treatments



Evenamide – Schizophrenia

- Licensing agreement with EA Pharma / Eisai Group, to develop, manufacture and commercialize evenamide in Japan and other designated Asian territories
 - up to a maximum total of EUR 117 million, including EUR 44 m upfront, financial contributions to upcoming pivotal Phase III study, milestone payments, and tiered royalties up to a double-digit percentage of net sales for evenamide
- Licensing agreement with Myung In Pharm to develop, manufacture and commercialize evenamide in South Korea
 - Myung In to contribute 10% of the total patient population to be enrolled into Newron's upcoming Phase III trial and cover the costs related to this population
 - Other standard licensing terms



2024 – BUILDING ON SUCCESS (3/3)

Corporate

- Board of Directors renewal
 - Dr. Chris Martin proposed for election as Independent, Non-Executive Director and Chairman of the Board of Directors, at the Company's upcoming AGM, to succeed Dr. Ulrich Köstlin
 - Margarita Chavez as an Independent, Non-Executive Director and Chair of the Board's Business Development Committee
- Agreement for the subscription of up to 2.05 million newly issued shares with institutional investor, with total proceeds generated of EUR 15 million
- Agreement with the European Investment Bank to extend the near-term tranche repayment dates



2025 – WHAT TO EXPECT ?



Evenamide – Schizophrenia

- Initiation of pivotal Phase III randomized, double-blind, one-year trial in Q2 2025 that will compare evenamide to placebo as an add-on treatment in patients with TRS
- Further development opportunities for evenamide in other territories

Corporate

- Strengthening of institutional shareholder base
- Preparation for US uplisting
- Upcoming shareholders' meeting (April 23, 2025)



EVENAMIDE – CHANGING THE TREATMENT PARADIGM IN SCHIZOPHRENIA



TPP

- Large market opportunity
- Differentiated MoA and positioning
 - **First add-on drug**
 - Changes a non-responder into a responder
 - No need to change current therapy, minimizing risk of patient relapse
 - Ease-of-use for patients & physicians
 - **First/only TRS (treatment resistant schizophrenia) drug since/beyond clozapine**
 - 30-50% of total population
 - 20-30% poor responders



CLINICAL EVIDENCE

- **TRS patients:** Positive results from 1-year pilot study 014/015 in 161 TRS patients
- **NON-TRS patients:** Positive results from pivotal Phase II/III Study 008A



NEXT STEPS

- **Next step:** Pivotal 1-year study in TRS
- **Regulatory strategy:** Approval in TRS - Chance for early market access
- **Strong IP position:** Exclusivity: 2034 (COMP, US), 2033 (COMP, RoW) and beyond (10 yrs exclusivity post approval in the EU); additional patents under review: up to 2044
- **Validation by:** EA Pharma / Eisai

EVENAMIDE'S DIFFERENTIATED MODE OF ACTION DEMONSTRATED

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

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



Inhibition of native sodium channels expressed in rat cortical neurons

K_{rest} (μM)

25

K_{inact} (μM)

0.4

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



High frequency firing

Control

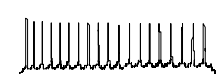


Evenamide 1 μM



Low frequency firing

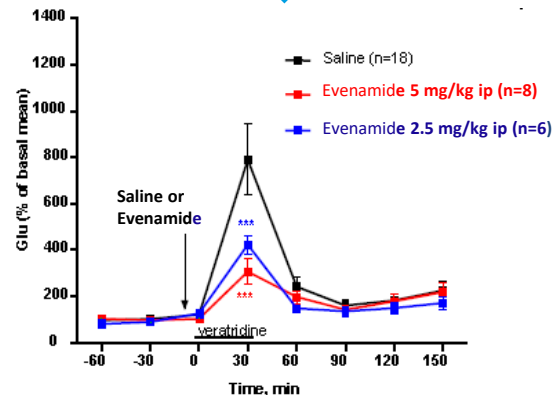
Control



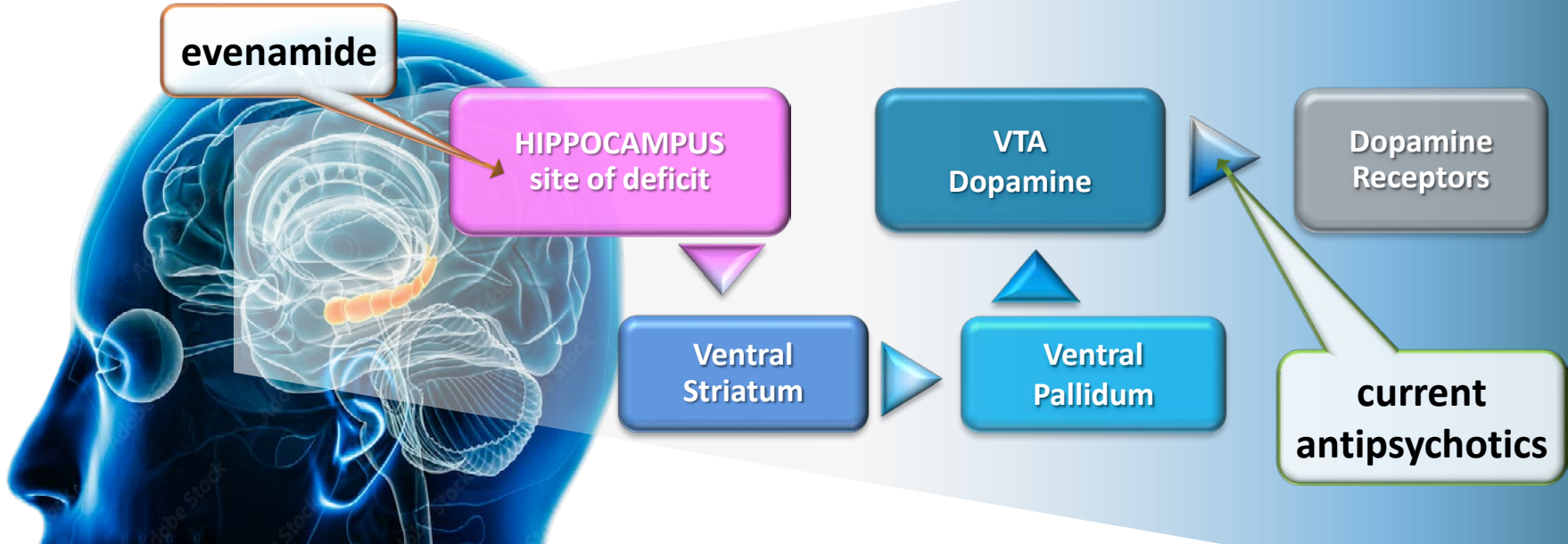
Evenamide 1 μM



Inhibits Glutamate Release



STRAIGHT TO THE HEART OF THE BRAIN



EVENAMIDE*: SIGNIFICANT EFFICACY IN THE MAM MODEL

DOMAIN	KEY FINDINGS ON EVENAMIDE
Neuronal Activity	Reverses Hippocampal Pyramidal Neuron Hyperactivity
	Normalizes VTA Dopamine Neuron Population Activity
	Impacts Primarily Lateral VTA Dopamine
	Effects of evenamide outlast its presence in the brain → Induction of Long-Term Plasticity (after a single dose) → Potential for disease modification
Cognition	Normalizes Novel Object Recognition Model of Cognition
Negative symptoms	Normalizes Social Approach/Interaction Model of Negative Symptoms

*Monotherapy; 3 mg/kg i.p.

PILOT STUDY 014/015: DESIGN AND KEY CHARACTERISTICS

Study design:

A pilot, randomized, open-label, rater-blinded, parallel-group, 6 weeks, multi-center study followed by an extension up to **1 year of treatment with Evenamide**

Objectives:

Evaluate the safety, tolerability and preliminary efficacy of three add-on fixed doses of Evenamide (7.5, 15 and 30 mg bid) in patients with treatment resistant schizophrenia (TRS) not responding adequately to their stable, therapeutically active dose of a single antipsychotic medication, treatment for **up to 1-year in the extension study (Study 015)**

Efficacy measures: :

PANSS, CGI-S, CGI-C, LOF rated by psychiatrists certified for the study

The efficacy rater was blinded to the dose of Evenamide and to any safety findings

Study Population:

- **Treatment-Resistance** with documented non-response to at least 2 antipsychotics from two different chemical classes including at least one atypical antipsychotic, for at least 6 weeks of treatment each
- **PANSS total 70-90; PANSS positive total score ≥ 20 , CGI-S of moderately to severely ill (4-6);**
- **Antipsychotic monotherapy** (except clozapine) for 4 weeks prior to screening, with current symptoms present for at least one month
- **NO** Patients at high risk of suicide/ other psychiatric disorders/ severe or unstable disease

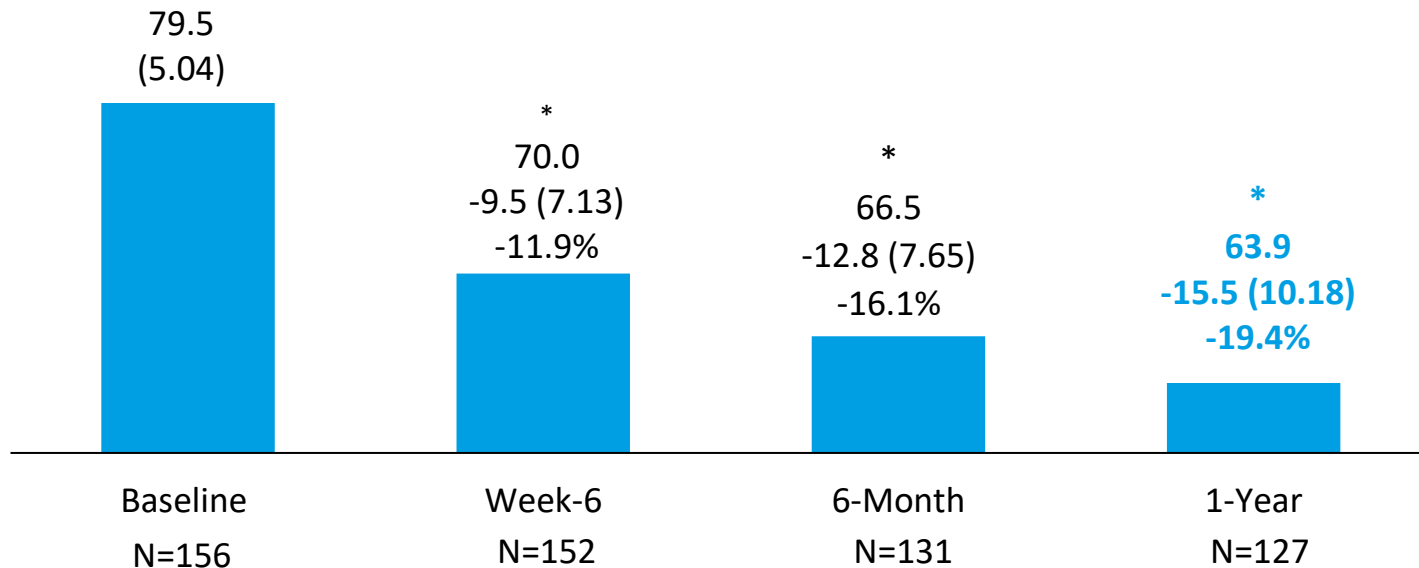
Countries:

India | Italy | Sri Lanka

STUDY 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

MEAN CHANGE FROM BASELINE (SD) – mITT

% Change from baseline

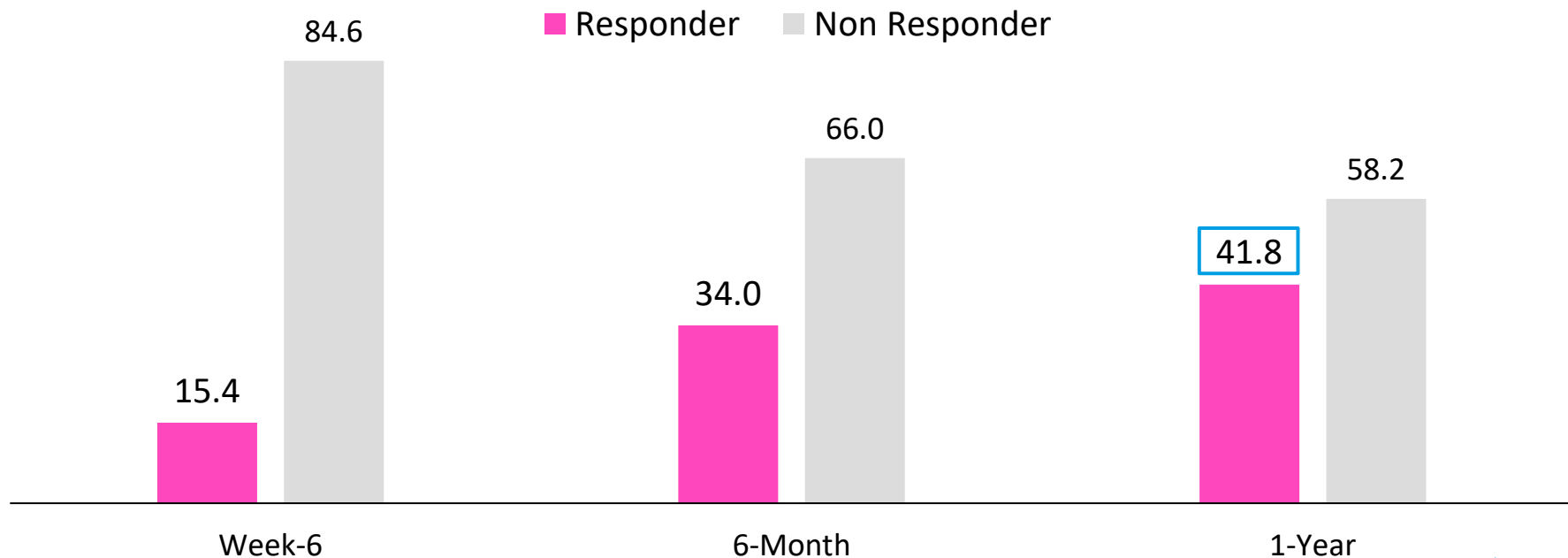


* p-value vs baseline < 0.001, paired t-test, OC

STUDY 015 – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

PANSS RESPONDER ANALYSIS (%) – mITT

PANSS Total $\geq 20\%$ Improvement from baseline



STUDY 015 - PATIENTS NO LONGER MEETING SEVERITY CRITERIA FOR TRS (mITT; LOCF/OC)

SEVERITY CRITERIA	VISIT	WEEK 6		6-MONTH		1-YEAR	
	STAT N	LOCF 156	OC 152	LOCF 156	OC 131	LOCF 156	OC 120
1. PANSS <70	n (%)	72 (46.1)	72 (47.3)	93 (59.6)	84 (64.1)	99 (63.5)	84 (70.0)
2. Core items* <20	n (%)	60 (38.4)	60 (39.4)	83 (53.2)	76 (58.0)	93 (59.6)	80 (66.7)
3. CGI-S < 4	n (%)	52 (33.3)	52 (34.2)	73 (46.7)	66 (50.4)	89 (57.1)	76 (63.3)
4. Score of > 4 in max 1 core symptom of psychosis#	n (%)	75 (48.1)	75 (49.3)	96 (61.5)	87 (66.4)	104 (66.7)	87 (72.5)
All combined	n (%)	40 (25.6)	40 (26.3)	57 (36.5)	51 (38.9)	76 (48.7)	66 (55.0)

*P1 (delusions), P2 (conceptual disorganization), P3 (hallucinatory behavior), P4 (excitement), P6 (suspiciousness), P7 (hostility), G9 (unusual thought content); #P2, P3, P6, G9

***Data on file at Newron Pharmaceuticals



STUDY 014/015 – PROPORTION OF PATIENTS WHO MEET PROPOSED REMISSION CRITERIA

Method	Criteria	Maintenance requirement	N=156 n (%) of patients meeting remission criteria
Lieberman et al, 1993	P1, P2, P3, P6, G5 ≤ 3 CGI-S «mildly ill»; CGI-C «much improved»	8 weeks	43 (27.6%)
Andreasen et al, 2005	P1, P2, P3, N1, N4, N6, G5, G9 ≤ 3	24 weeks	39 (25.0%)

STUDY 008A - DESIGN AND KEY CHARACTERISTICS

Study design:

A potentially pivotal, phase II/III, 4-week, international randomized, double-blind, placebo-controlled study

Objectives:

to evaluate the efficacy, safety, tolerability, of evenamide 30 mg bid vs placebo in patients who are inadequate responders to SGAs

Sample size: 291 patients randomized in a 1:1 ratio →
Evenamide 30 mg bid OR matching Placebo

Efficacy measures: :

PANSS, CGI-S, CGI-C, LOF

Study Population:

- Outpatients with chronic schizophrenia (DMS-5) on therapeutic doses of SGAs who are still symptomatic, despite ≥ 4 weeks of treatment at a stable dose (adherence confirmed by plasma levels)
- Current symptoms present for at least one month
- Total PANSS 70-85
- CGI-S rating of moderately (4) to severely ill (6)
- Patients with ≥ 2 core positive symptoms (hallucinations, suspiciousness, conceptual disorganization and unusual thought content) rated moderately severe or higher

Countries:

EU (CZ, EST, HUN, ITA, RO, SPA), IND, MEX, ARG

STUDY 008A - USAGE OF BACKGROUND ANTIPSYCHOTIC MEDICATION

Antipsychotic	Evenamide 30 mg bid N=132; n (%)	Placebo N=159; n (%)	Overall N=291; n (%)
Risperidone	51 (38.6)	63 (39.6)	114 (39.2)
Olanzapine	32 (24.2)	32 (20.1)	64 (22.0)
Clozapine	19 (14.4)	17 (10.7)	36 (12.4)
Paliperidone	15 (11.4)	24 (15.1)	39 (13.4)
Aripiprazole	11 (8.3)	14 (8.8)	25 (8.6)
Quetiapine	2 (1.5)	7 (4.4)	9 (3.1)
Cariprazine	2 (1.5)	2 (1.3)	4 (1.4)

STUDY 008A - MOST COMMON TEAEs BASED ON EVENAMIDE INCIDENCE

System Organ Class (SOC) ≥4.5% on Evenamide	Evenamide 30 mg bid N=132; n (%)	Placebo N=159; n (%)	Overall N=291; n (%)
Nervous system disorders	9 (6.8)	12 (7.5)	21 (7.2)
Psychiatric disorders	6 (4.5)	12 (7.5)	18 (6.2)
Gastrointestinal disorders	9 (6.8)	5 (3.1)	14 (4.8)
Infections and infestations	7 (5.3)	4 (2.5)	11 (3.8)

Preferred Term (PT) ≥1.5% on Evenamide	Evenamide 30 mg bid	Placebo	Overall
Nasopharyngitis	3 (2.3)	1 (0.6)	4 (1.4)
Headache	3 (2.3)	4 (2.5)	7 (2.4)
Vomiting	3 (2.3)	1 (0.6)	4 (1.4)
Diarrhoea	2 (1.5)	0 (0.0)	2 (0.7)
Somnolence	2 (1.5)	5 (3.1)	7 (2.4)

STUDY 008A - PRIMARY, KEY SECONDARY EFFICACY ENDPOINT – ITT POPULATION

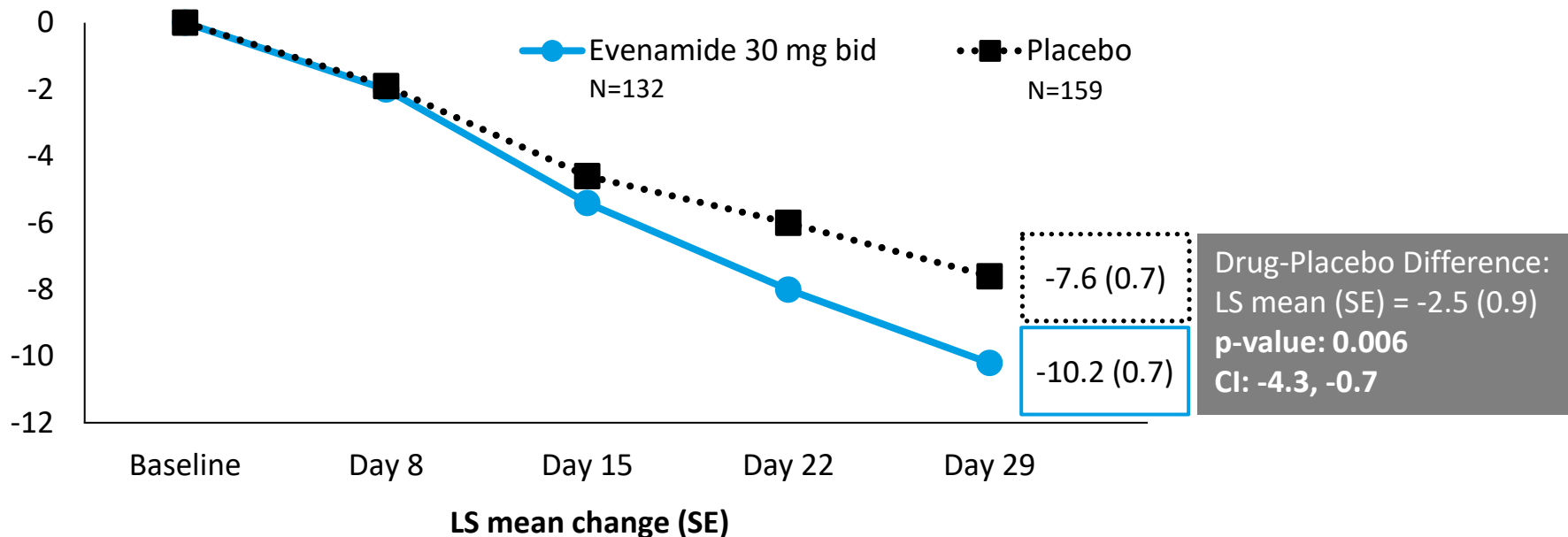
PRIMARY ESTIMAND – TREATMENT POLICY, MEAN CHANGE FROM BL – DAY 29

Scale	Visit	Evenamide 30 mg bid N=132	Placebo N=159
PANSS total score	Baseline – mean (SD)	78.4 (4.1)	78.7 (4.0)
	Day 29 – LS mean (SE)	-10.2 (0.7)	-7.6 (0.7)
	LS mean difference (SE)	-2.5 (0.9)	
	<i>p-value [CI]</i>	0.006 [-4.3, -0.7]	
CGI of Severity (CGI-S)	Baseline – mean (SD)	4.4 (0.6)	4.5 (0.6)
	Day 29 – LS mean (SE)	-0.6 (0.1)	-0.5 (0.1)
	LS mean difference (SE)	-0.16 (0.08)	
	<i>p-value [CI]</i>	0.037 [-0.3, -0.0]	

Significant results were also obtained using the mITT population; N=287
CI= 95% confidence interval

STUDY 008A - PANSS TOTAL SCORE

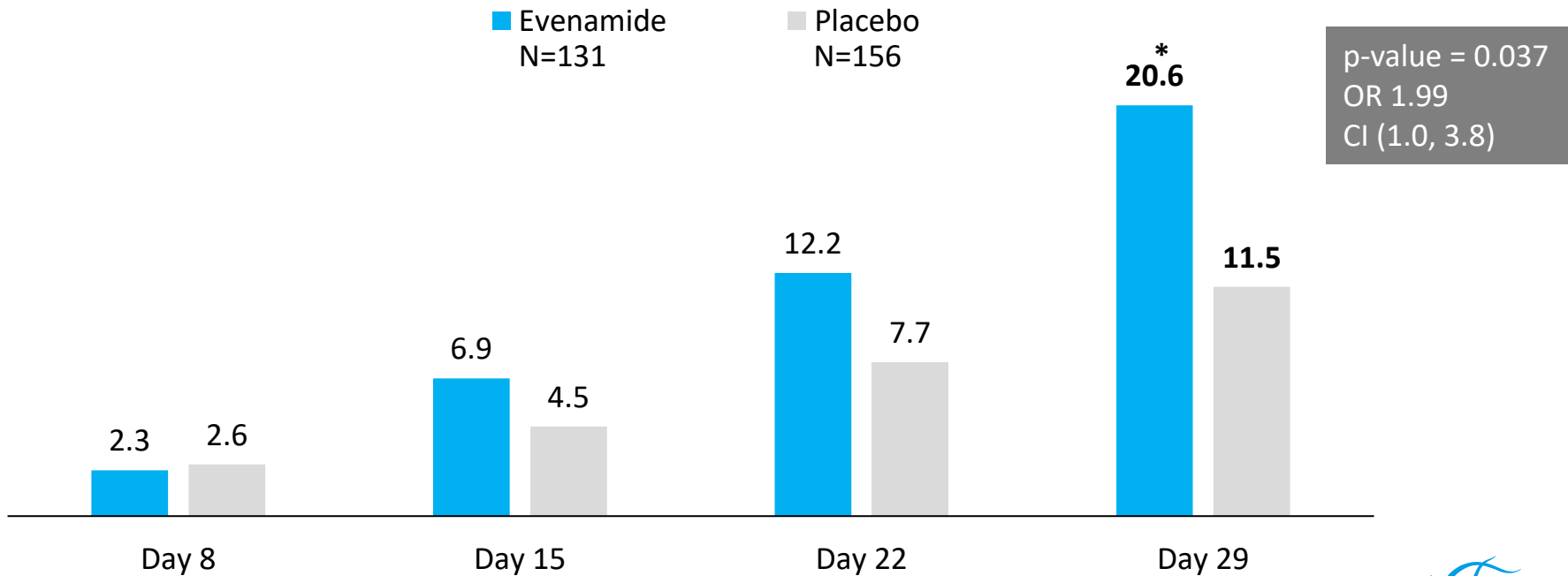
MEAN CHANGE FROM BASELINE TO DAY 29; ITT POPULATION;
PRIMARY ESTIMAND – TREATMENT POLICY; MMRM



STUDY 008A – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

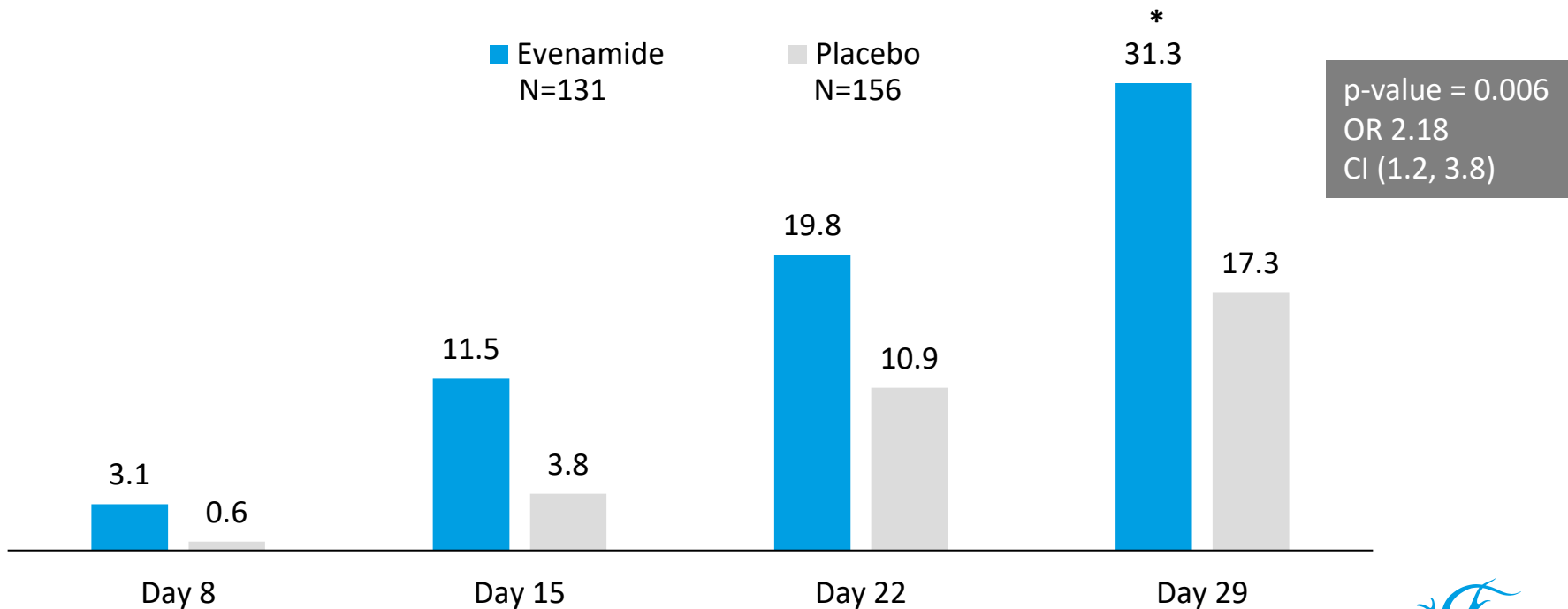
PANSS RESPONDER ANALYSIS –

Proportion of patients (%) improving $\geq 20\%$ from baseline; mITT; OC



STUDY 008A – POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

CGI-C Responder Analysis –
Proportion of patients (%) “At least much improved”; mITT



STUDY 008A – SUMMARY OF EFFICACY RESULTS – MEAN CHANGE FROM BASELINE TO ENDPOINT

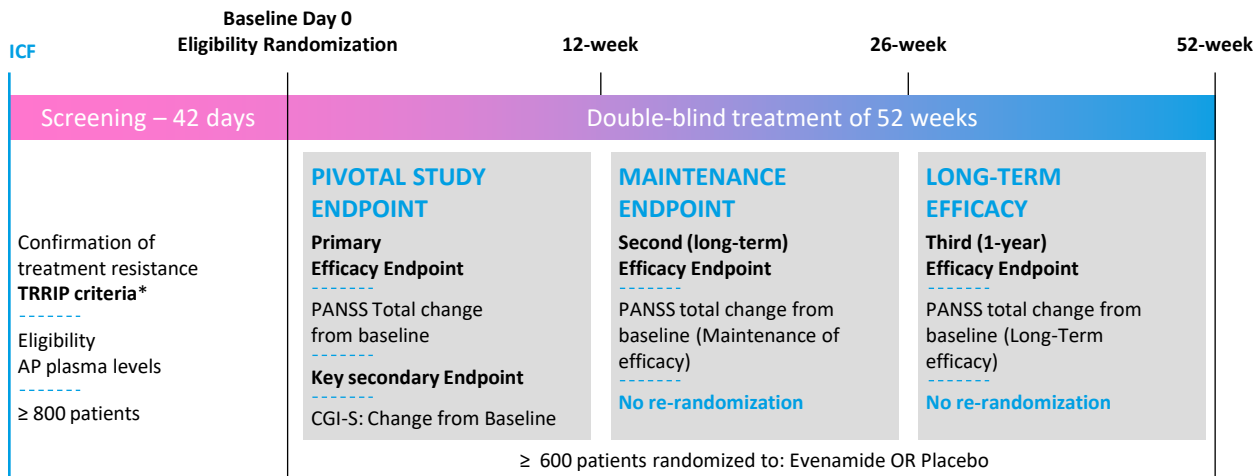
Efficacy Parameter/ Analysis/ Population	LS Mean Difference (SE)*	95% CI	p-value
PANSS Total Score MMRM (Primary Estimand Treatment Policy) ITT Population	-2.5 (0.90)	-4.3, -0.7	0.006
CGI-S MMRM ITT Population	-0.16 (0.08)	-0.3, -0.0	0.037
CGI-C mean rating at endpoint ANOVA mITT Population	-0.2 (0.04)	-0.3, -0.1	<0.001
PANSS Subscales score ANCOVA Using LOCF mITT Population	POS: -1.16 (0.36) NEG: -0.63 (0.26) GP: -0.59 (0.44)	-1.9, -0.5 -1.1, -0.1 -1.5, 0.3	0.001 0.016 0.184

STUDY 008A – SUMMARY OF EFFICACY RESULTS – RESPONDER ANALYSES

Efficacy Parameter/ Analysis/ Population	Responder Category	Responders [n/N (%)]	Odds Ratio (95% CI)	p-value*
PANSS OC (mITT N as denominator) mITT Population	≥ 20% improvement from baseline	EVE: 27/131 (20.6) PBO: 18/156 (11.5)	1.99 (1.0, 3.8)	0.037
CGI-C OC (mITT N as denominator) mITT Population	Any improvement at endpoint	EVE: 94/131 (71.8) PBO: 90/156 (57.7)	1.86 (1.1, 3.1)	0.014
CGI-C OC (mITT N as denominator) mITT Population	At least “Much improved” at endpoint	EVE: 41/131 (31.3) PBO: 27/156 (17.3)	2.18 (1.2, 3.8)	0.006

UPCOMING PIVOTAL (PHASE III), PLACEBO-CONTROLLED, 1-YEAR STUDY IN PATIENTS WITH TRS

A *Phase III, 52-week, prospective, randomized, double-blind, placebo-controlled, parallel-group, multi-center study, with a primary efficacy endpoint at 12 weeks, to determine the efficacy, safety, and tolerability of Evenamide as add-on in patients with documented treatment-resistant schizophrenia (TRS), which is not adequately controlled by a stable therapeutic dose of the patient's current antipsychotic medication(s)*



* TRRIP Working Group Howes et al., 2017

KEY SELECTION CRITERIA

- Treatment resistance (TRS) according to TRRIP working group (Howes et al., 2017)
- Antipsychotic treatment as per 'Standard of Care', minimally one oral or depot antipsychotic at a stable therapeutic dose
- BPRS total score ≥ 45 at Screening
- Prominent positive symptoms as measured by the BPRS
- CGI-S rating of mildly ill to severely ill (score of 3 to 6)
- Antipsychotic (AP) plasma levels tested at screening and throughout the study to confirm adherence to the background AP therapy and Evenamide therapy

NEWRON SHARE INFORMATION



LISTING PROFILE AS OF DECEMBER 31, 2024

- Newron is listed at
 - SIX since December 2006 and
 - Since June 26, 2019, traded also at the Dusseldorf Stock Exchange (XETRA)
- Newron issues ordinary shares (nominal value 0.20€), only
- Number of outstanding shares as of Dec. 31, 2024: 19,958,859
 - Senior managers and Directors hold 129,472 shares (0.6%)
- Number of outstanding call options/derivative holding as of Dec. 31, 2024: 1,038,052 / 1,845,221
 - Senior managers and Directors hold 579,345 call options (2.8%*)
 - EIB holds 807,169 warrants (4.0%*); at current exchange ratio 892,589 shares

Additional info can be found in Corporate Governance section of 2024 annual report: <https://www.newron.com/investors/reports-and-presentation/year/2024>

*: fully diluted



ANALYST

Sell-side analyst coverage:

Baader Helvea/Thomas Meyer

Further coverage:

RX Securities, ValueLab, Edison



MOST RECENT INFO ON SHAREHOLDINGS

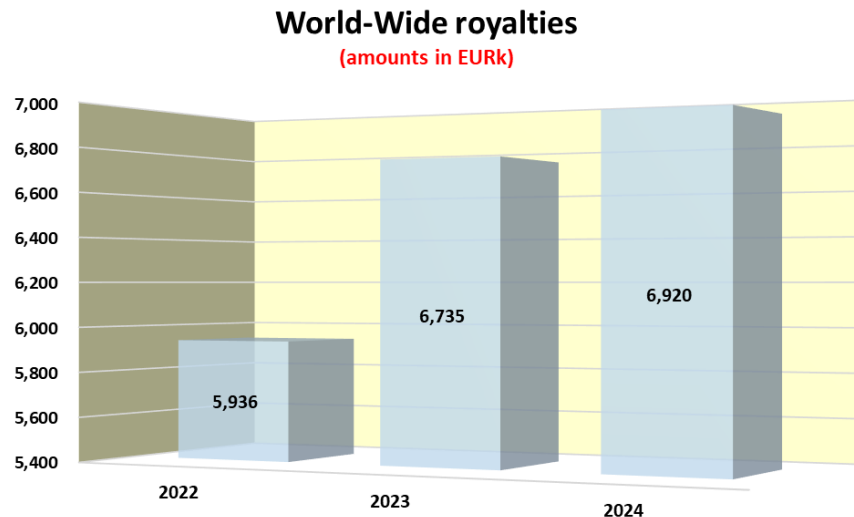
Disclosed** material shareholders (>3%)

Tobias Scherer > 8%

** : to the best of Newron' knowledge <https://www.ser-ag.com/en/resources/notifications-market-participants/significant-shareholders.html#/>

GROUP CONSOLIDATED FINANCIALS (IFRS) FY 2024 – INCOME STATEMENT

EUR/000	2024	2023
Licence income	44,470	58
Royalties	6,920	6,735
Research and development expenses	(13,642)	(13,152)
General and administrative expenses	(11,575)	(7,534)
Operating profit/(loss)	26,173	(11,629)
Income tax	(5,551)	(24)
Net profit/(loss)	15,843	(16,224)
Profit/(loss) per share (EUR)	0.85	(0.91)



- Licence income reflects the signature of the EA Pharma/EISAI deal
- Royalties increased more than 2%
- Delta between Operating and Net loss mainly related to EIB interests and Newron ITA accrued income taxes
 - Newron ITA income taxes won't impact cash as will be paid using "fiscal receivables"

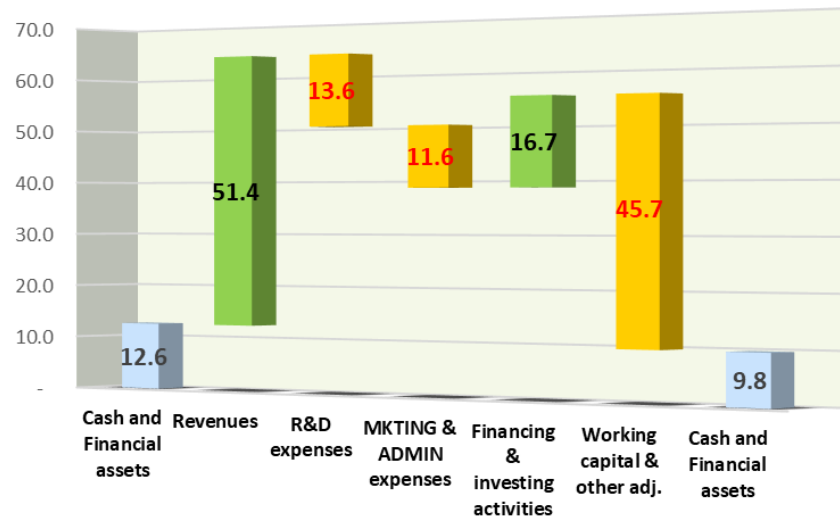
GROUP CONSOLIDATED FINANCIALS (IFRS) FY 2024 – BALANCE SHEET AND CASH FLOW STATEMENTS

EUR/000	2024	2023
Non-current assets	2,804	6,214
Current assets	51,278	7,053
Cash and other financial ass.	9,826	12,599
Total shareholders' equity	1,458	(29,908)
Non-current liabilities	38,944	26,848
Current liabilities	23,506	28,926

- Current assets are mainly composed by EA Pharma/EISAI receivable (EUR 44m)
- Cash and Other financial assets together with the cashed-in receivables will finance Newron' development activities way into 2026
- EIB loan (at amortized cost) is equal to 49m€: 13.4m€ have been reclassified among Current liabilities as they fall due in Nov 2025

Cash flow year 2024

Amounts in EUR/m



- Opening and year-end position, includes both Cash and Other current financial assets
- Working capital includes: i) increase in Current receivables; ii) increase in Payables partially compensated by decrease in Non-current receivables

ANNUAL GENERAL MEETING



DATE

April 23, 2025



TIME

10.00am CET



LOCATION

Newron- Via Meucci 3, Bresso (Italy)



AGENDA

ORDINARY

1. Approval of financial statements as at 31 December 2024
2. Appointment of Chris Martin as Chairman of Board of Directors until 2025 AGM
3. Appointment of audit Company for the period 2025-2027
4. Appointment of Statutory Auditors for the period 2025-2027

EXTRAORDINARY

1. Proposal to grant powers to Directors to increase Company's share capital for a max of 10%
2. Proposal to grant powers to Directors to increase Company's share capital for a max of 3% for option plan/s
3. Proposal to grant powers to Directors to increase Company's share capital for a max of 35% (uplisting to NASDAQ)
4. Proposal to create ADRs

All documents connected with the agenda as per applicable laws and regulations as well as the necessary information to register and attend the meeting will be made available on the Company's website (www.newron.com/investors/shareholders-meeting)

CONTACT DETAILS

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