Newron Pharmaceuticals S.p.A.

Media and analyst conference

Full year results 2009

Zurich

March 3, 2010

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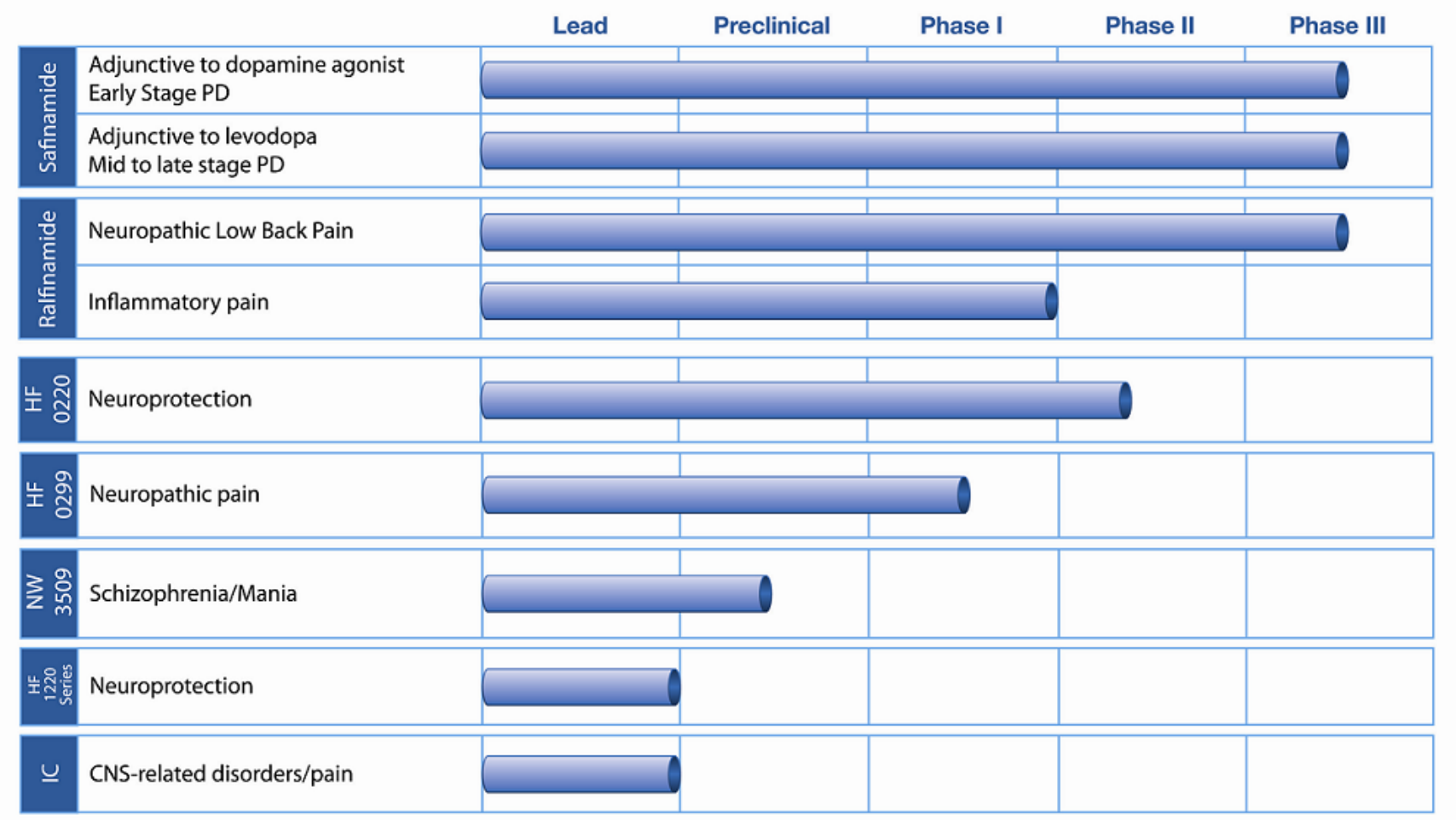
Agenda

• Start	11:00 am CET
• Welcome	Luca Benatti, CEO
• R&D pipeline update	Ravi Anand, CMO
• Financial review and outlook	Stefan Weber, CFO
• Q&A	Audience present/conference call participants
• End	12:00 CET
• Imbiss	

Overview

- Leading the field in the development of novel therapies for the treatment of CNS and pain: large markets with significant unmet medical needs
- Listed on main segment of SIX Swiss Exchange (NWRN), covered by 8 analysts, headquartered in Bresso (Mi, Italy)
- Broad and late stage validated pipeline addressing major therapeutic indications
- Management with strong track record of bringing CNS drugs to market (Comtan™, Cabaser™, Exelon™, Clozaril™)
- Cash reach end 2011 +
- Goal is to become a Fully Integrated Biopharmaceutical Company

Broad, innovative and diversified pipeline



- Newron is undertaking Phase III trials with safinamide for the treatment of PD on behalf of its partner Merck Serono
- IC = Ion Channel Program
- HF 1020 in preclinical development for asthma is part of Newron's equity holding in Trident
- HF 0420 rights were returned to the inventor, with potential future milestones and royalties due to Newron

Highlights

- Ralfinamide: first in-class for the treatment of NLBP
  - Enrollment completed in first NLBP pivotal trial
  - Datamonitor forecasts $1.5bln peak sale potential in NLBP
  - Partnership sought post pivotal results
    - Ex-US or global with US co-promotion
- Safinamide: moving into final stages of development
  - Efficacy validated by 2 positive Phase III trials
  - Partnered ww with MerckSerono
  - Regulatory filing not prior to 2011
- Highly promising earlier pipeline (NW-3509 and HF0220)
- Cash position at year end 2009: €24.3m, plus option to CHF28.3m under equity line

Safinamide
A unique proposition for Parkinson's disease

Safinamide: a novel intervention

- First once a day oral adjunctive therapy for all stages of PD (>$4bn)
- Unique mechanism of action
- Positive Phase II and III results both in early and advanced PD
  - MOTION and SETTLE studies ongoing
- Potential in cognitive disorders
- Partnered ww with Merck Serono
  - Development costs covered by partner
  - Up to $187.5m regulatory and sales related milestones plus significant royalties

Safinamide: add-on to DA in early PD

- No drug approved as add-on to DA
- DA are very effective in reducing motor symptoms in early stage PD
- DA efficacy begins to fade in 3-5 years
- When this occurs, the only choice for physicians is to add L-dopa
- Although highly effective, long-term use of L-dopa is associated with significant side effects: motor fluctuation and dyskinesia
- Unmet needs met with safinamide:
  - Prolong DA effects
  - Delay levodopa use (levodopa-induced motor complications)
- Safinamide as add-on to DA in early PD:
  - Excellent tolerability
  - Long term (18 months) improvement of motor symptoms
  - Reduce need for levodopa intervention
  - Improves cognition and quality of life
- Recent competitor's results further support our strategy:
  - Stalevo: Orion withdrew US application for extending Stalevo indication to early PD
  - Rasagiline: results of the ADAGIO trial not convincing for disease progression claim

Add-on to levodopa in advanced PD: reduce levodopa-induced side effects

Diary categories: no increase in 'ON' time with troublesome dyskinesia

Characteristic recorded	Safinamide 50 mg/day	Safinamide 100 mg/day
'ON' time without dyskinesia LS means difference vs placebo (hours) p-value	**0.5** **0.0367**	**0.7** **0.0070**
'ON' time with minor dyskinesia LS means difference vs placebo (hours) p-value	0.0 0.9196	-0.1 0.5881
'ON' time with troublesome dyskinesia LS means difference vs placebo (hours) p-value	0.1 0.5324	0.0 0.9931
'OFF' time LS means difference vs placebo (hours) p-value	**-0.6** **0.0022**	**-0.6** **0.0027**
Asleep time LS means difference vs placebo (hours) p-value	-0.1 0.5021	0.0 0.6727

LS means and p-values were calculated from an ANCOVA model based on the change from baseline to endpoint, with the baseline value as a covariate.

Study 016 - Efficacy endpoints

		Safinamide 50mg/day n= 223	Safinamide 100mg/day n= 224
		Treatment difference vs placebo	
ON Time		0.6	0.6
	p value	**0.0082**	**0.0048**
OFF Time		-0.6	-0.6
	p value	**0.0022**	**0.0027**
OFF Time after morning dose of L-Dopa		-0.6	-0.6
	p value	**0.0013**	**0.0009**
CGI-S		-0.2	-0.1
	p value	**0.0038**	**0.0219**
CGI-C		NA	NA
	p value	**0.0003**	**0.0097**
UPDRS III		-2.1	-2.8
	p value	**0.0075**	**0.0002**
UPDRS II		-0.6	-1.0
	p value	**NS**	**0.006**
UPDRS IV total		-0.4	-0.6
	p value	**0.0381**	**0.0004**
PDQ-39 total score		-8.0	-17.4
	p value	**NS**	**0.0267**
PDQ- 39 activities of daily living		-3.8	-2.8
	p value	**0.0183**	**NS**
PDQ- 39 emotional well being		-1.1	-3.5
	p value	**NS**	**0.009**
GRID-HAMD		-0.3	-0.7
	p value	**NS**	**0.0179**

Study 016 - Response Rates

	Placebo (n=222)	Safinamide 50 mg/day (n=223)		Safinamide 100 mg/day (n=224)	
	Responders, n (%)	**Responders, n (%)**	**p-value vs placebo**	**Responders, n (%)**	**p-value vs placebo [A]**
Increase in ON time,[b] n (%)	88 (39.6)	106 (47.5)	0.0641	125 (55.8)	<0.0001
Improvement in ON and OFF time,[c] n (%)	87 (39.2)	99 (44.4)	0.2069	117 (52.2)	0.0008
UPDRS III, ≥30% improvement from baseline n (%)	70 (31.5)	84 (37.7)	0.0698	92 (41.1)	0.0095
Overall response rate,[d] n (%)	42 (18.9)	60 (26.9)	0.0177	66 (29.5)	0.0016

[A] Response rate was analyzed using a Cochran-Mantel-Haenszel test with center as the stratification factor comparing safinamide versus placebo at endpoint

[B] ≥30-minute increase in ON time from baseline without increase in troublesome dyskinesia, based on analysis of daily diaries

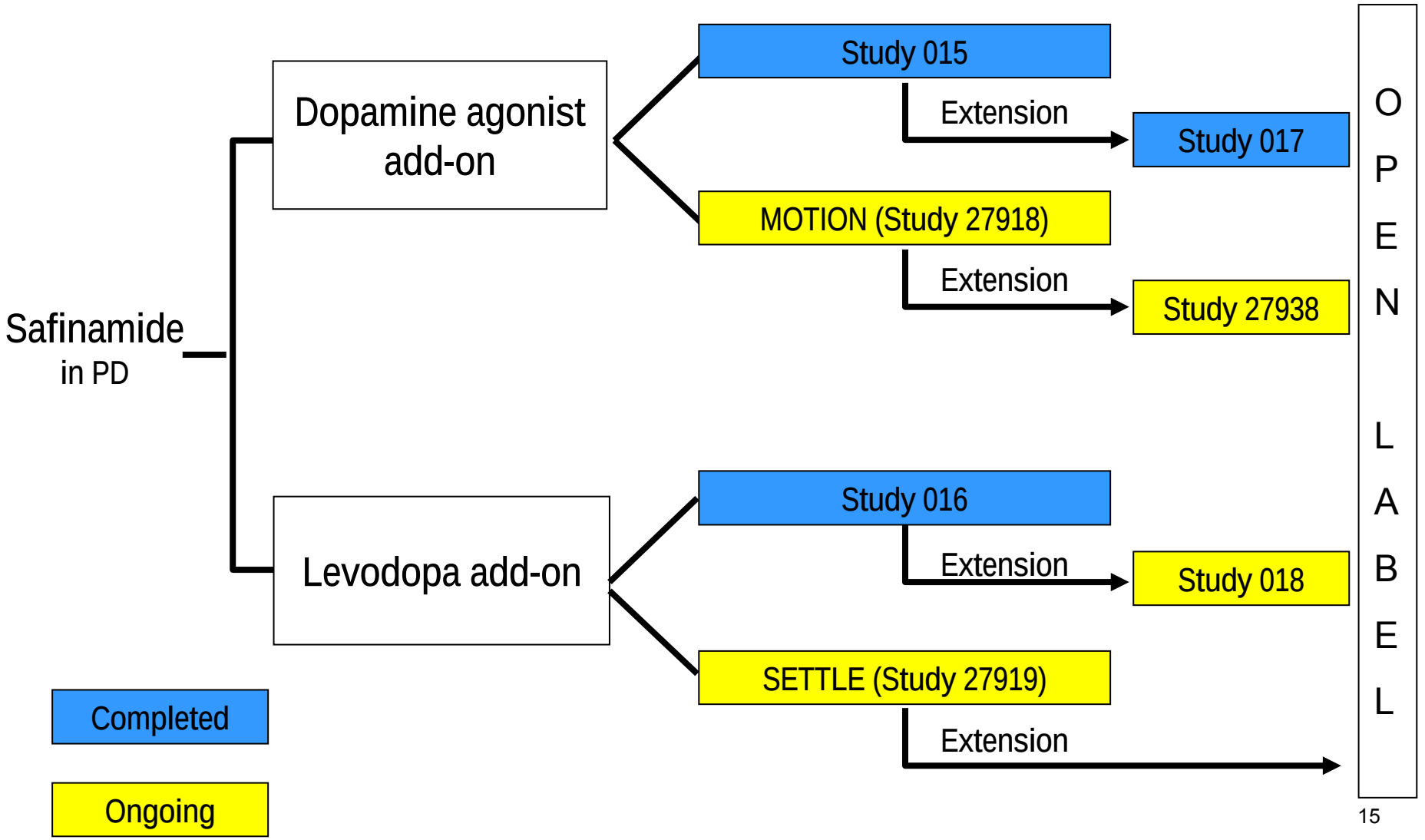
[C] ≥30-minute increase in ON time without increase in troublesome dyskinesia and ≥30-minute decrease in OFF time from baseline, based on analysis of daily diaries

[D] Patients exhibiting ≥30-minute increase in ON time, ≥30-minute decrease in OFF time AND ≥30% improvement in UPDRS III scores

Safinamide: add-on to L-Dopa in advanced PD

- Levodopa-induced motor complications
  - Wearing off / on-off response
  - Dyskinesia
- Unmet need
  - All adjunctive therapy to levodopa improve on-off response but on the same time worsen dyskinesia
  - Depression is a significant co-morbidity in advanced PD
- Safinamide as add-on to levodopa in advanced PD improves:
  - Motor symptoms (ON/OFF response) without increasing troublesome dyskinesia
  - UPDRS part II/III (motor symptoms and quality of life)
  - UPDRS part IV (motor complications)
  - Depressive symptoms

Safinamide Clinical Development Plan



Ralfinamide

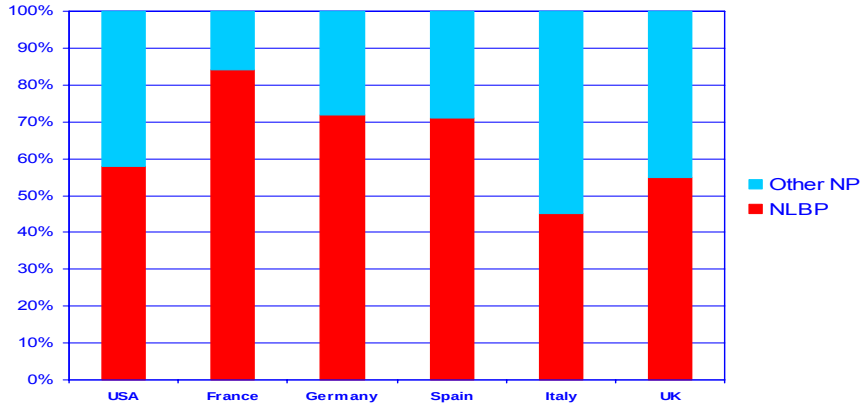
First in-class compound for the treatment of NLBP

Ralfinamide

- Oral use, small molecule, new chemical class
- Novel mechanism, innovative compound
- Demonstrated efficacy in placebo-controlled trial in patients with peripheral neuropathic pain
- No development of tolerance on chronic dosing
- No need for titration, very well tolerated
- First in-class agent for the treatment of NLBP, large market, no approved medications
- Undergoing pivotal SERENA trial in 411 patients with NLBP

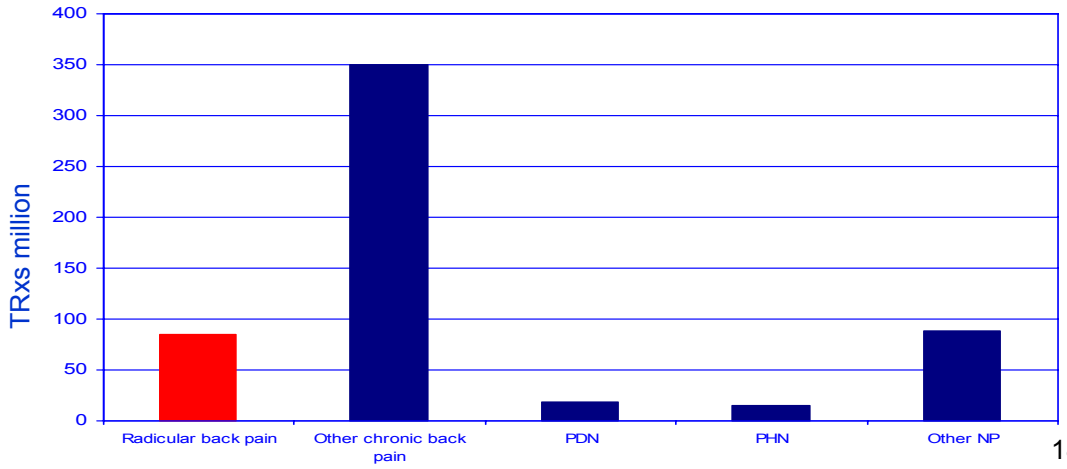
Neuropathic Low Back Pain

- Area of High Unmet Medical Need
- No approved medications
- ~7.5% of total population suffer from NLBP
- Over 55 million patients in US, EU and Japan



NLBP represents 45-84% of all diagnoses made for NP

NLBP has the highest rate of treated prescriptions within neuropathic pain



Datamonitor on ralfinamide

- According to Datamonitor's report "Forecast Insight: Neuropathic Pain" published in December 2009, ralfinamide possesses the greatest potential of all late-stage neuropathic pipeline agents examined
- The Datamonitor report forecasts sales for ralfinamide in NLBP of over $1.5 billion by 2018

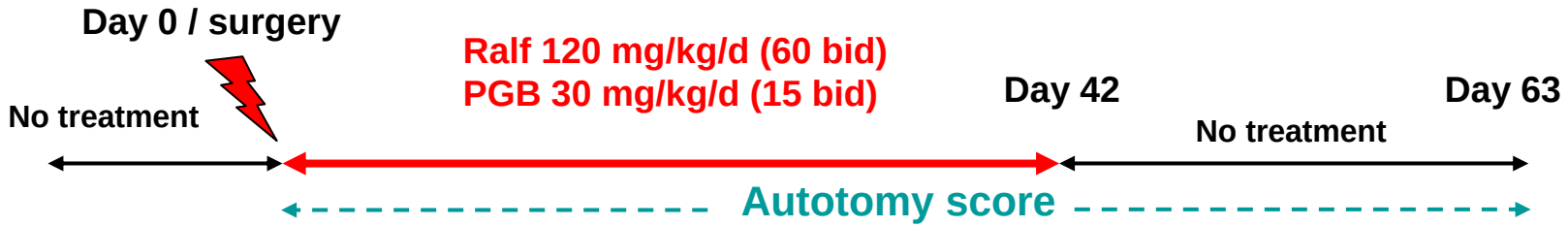
Reference:

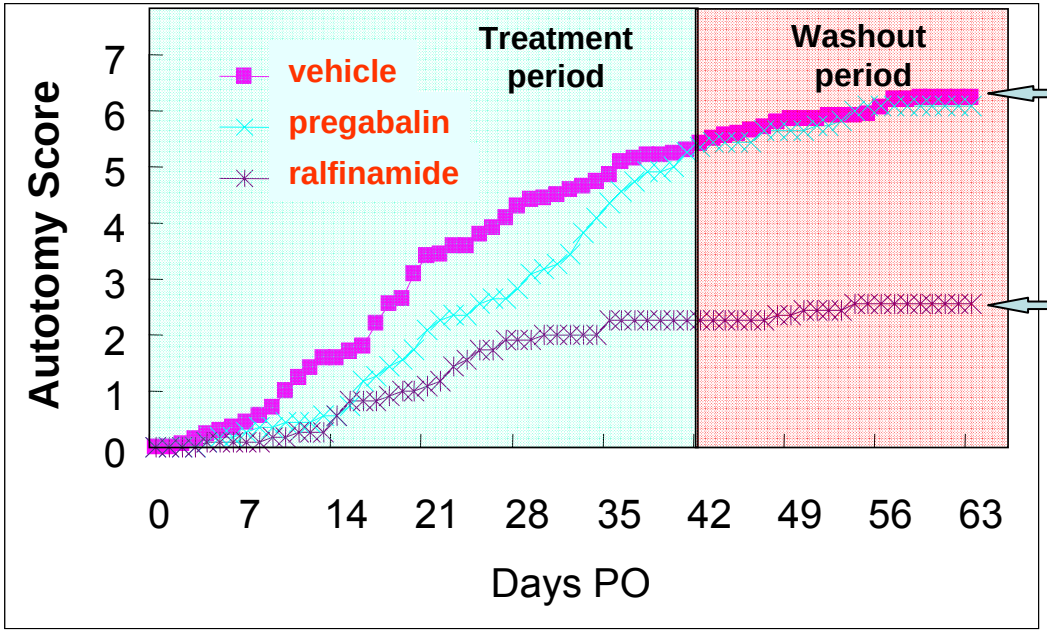
Forecast Insight: Neuropathic Pain

Brighter future for pipeline drugs while current brands downgraded

DMHC2567, Publication Date: 4 December 2009

Ralfinamide and not pregabalin produces long lasting analgesic effect in a model of central pain





vehicle and **pregabalin** treated animals

ralfinamide

- delays autotomy onset
- suppresses autotomy scores
- retains analgesia after cessation of drug administration

Ralfinamide: demonstrated safety and efficacy in patients with neuropathic pain

- Double blind, placebo controlled escalating dose (80-320mg/day) in patients with neuropathic pain: NLBP, DPN, PHN, carpal tunnel etc.
- Ralfinamide was well tolerated with no evidence of any statistically significant or clinically relevant pattern of change compared to placebo

Side effects:	ralfinamide	placebo
— Headache	15.3%	17.9%
— Dizziness	5.1%	13.7%
— Nausea	6.8%	10.5%
— Dyspepsia	5.1%	8.4%
— Diarrhea	4.5%	6.3%
— Dry mouth	5.7%	2.1%

Ralfinamide: demonstrated safety and efficacy in patients with neuropathic pain

Endpoints		Ralfinamide (n=126)	Placebo (n=74)
VAS	Change Vs Baseline (±SD)	-20.1 (25.74)	-10.4 (20.62)
	Treatment Difference* (95% CI)	-8.1 (-14.9, -1.4)	
	p-value	0.0187	
Likert (Pain)	Change Vs Baseline (±SD)	-1.8 (2.22)	-0.84 (1.96)
	TreatmentDifference* (95% CI)	-0.93 (-1.5, -0.3)	
	p-value	0.0026	
Daily Diary Sleep	Change Vs Baseline (±SD)	-1.5 (2.14)	-0.44 (2.13)
	TreatmentDifference* (95% CI)	-0.95 (-1.5, -0.37)	
	p-value	0.0014	
VAS	Responder rate 50%	40 (31.7)	12 (16.2)
	p-value	0.016	
Likert	Responder rate 50%	34 (27.4)	11 (14.7)
	p-value	0.037	

* Difference in LS Mean

Strong effect in patients with NCET
Likert pain (patients with 2 or more point improvement)

Responder rate LOCF	Nerve Compression/Entrapment	
Treatment	**Ralfinamide**	**Placebo**
N	**57**	**39**
Proportion of Responders n (%)	**31 (54.4)**	**11 (28.2)**
Odds Ratio (95% CI for Odds Ratio)	**3.03 (1.27, 7.25)**	
P-value (A)	**0.012 ***	

***p=<0.05**

NCET: Nerve Compression and Entrapment

N: Number of patients. n: Patients with data available. %: Percentage based on N. Not Est: Not estimable due to insufficient patient numbers. Responder: Patient with a 2 or more point improvement in Mean Daily Pain Score on the Likert Scale.
(A) Treatments compared using a Cochran-Mantel-Haenszel test.

SERENA Pivotal Study in NLBP: Design

- Double-blind placebo controlled, parallel-group, multinational trial
- Treatments:
  - Placebo and 2 doses of ralfinamide (**160mg and 320 mg daily**)
  - Both doses at comparable exposure of effective ralfinamide doses in animal models of neuropathic pain
- Randomisation: Equally to all three groups
- Study Duration: **12 weeks**
  - Patients who complete 12 weeks of treatment will be eligible to enter a double-blind 40 week extension
  - Patients will continue on the same dose of study medication they were receiving at the end of the 12 week treatment period
- Number of Patients: **411**

SERENA Pivotal Study in NLBP: Diagnostic Criteria

- **At least moderate (>40mm) pain** as judged by patients' self ratings on the VAS
- Present for at least 3 months but not longer than 3 years
- Diagnostic criteria as specified in the Int. Ass. for the Study of Pain (IASP) Classification of Chronic Pain
- **Pain is due to a lesion of the PNS**
- Neuropathic nature of the low back pain is confirmed by
  - **A score >18 on the Pain Detect Questionnaire**
  - **Cutaneous and sensory testing** confirms the involvement of dermatomes corresponding to L1-S1
- Test of muscle power, flexion, and reflexes support the diagnosis
- Imaging will be performed where necessary to confirm the diagnosis

SERENA Pivotal Study in NLBP: Status

- First patient randomized on March 31 2009
- EMEA approved:
  - Plans for the NLBP indications
  - Study design
  - Diagnostic criteria
  - Outcome measures
  - Statistical analysis
- EMEA agreement confirms the earlier consensus by a number of Health Authorities in North America and Europe
- Completion of enrolment reported Jan 12, 2010
- Top line results May 2010

Ralfinamide in NLBP

- NLPB is a large market (55 million patients, US, EU, Japan)
- Area of high unmet patient need
- No approved medications
- Favorable access and pricing
- Physicians agree most Chronic Back Pain (CBP) has a neuropathic component
- Ralfinamide may become the first approved drug for NLBP
- Blockbuster potential

NW-3509

A novel approach for the treatment of psychiatric disorders

NW-3509

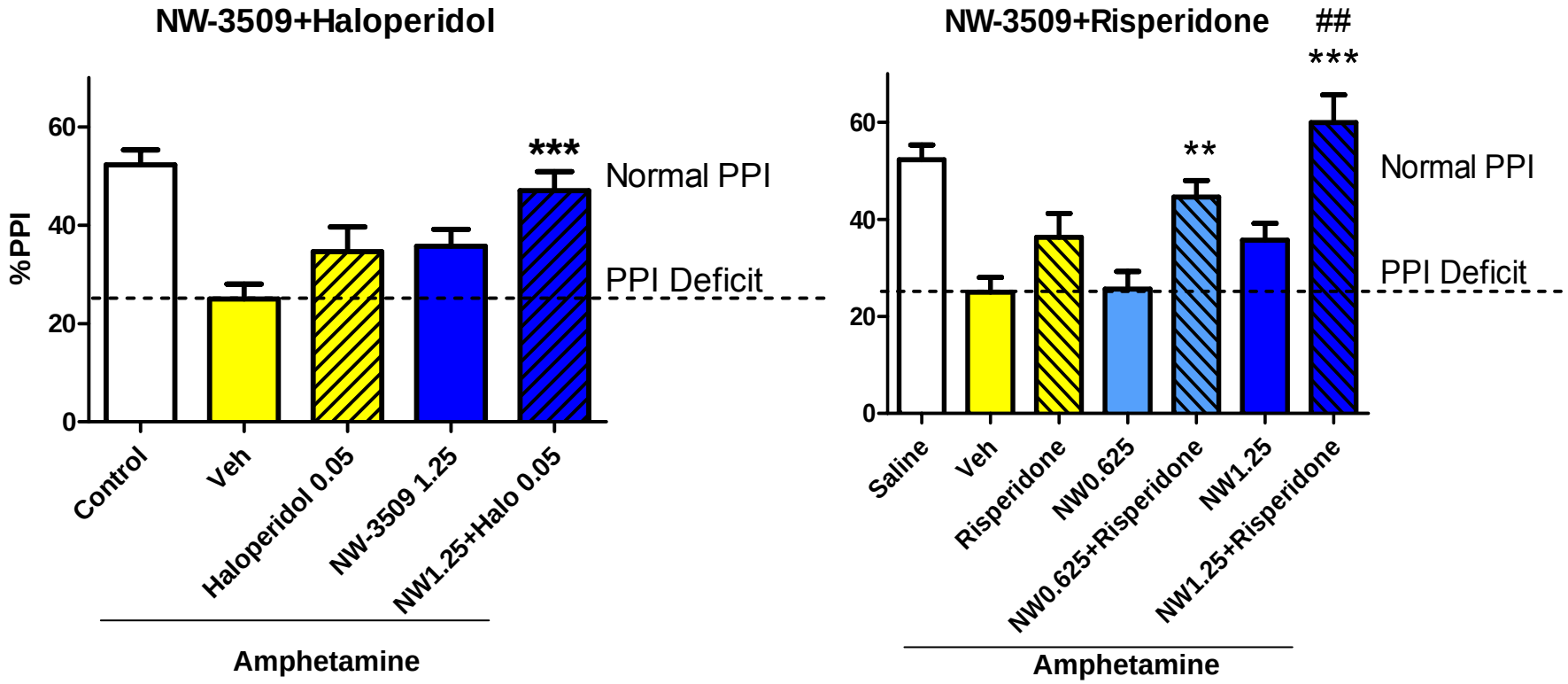
- Innovative compound from Newron's ion channel program: addressing unmet needs in schizophrenia
- Large market opportunity (anti-psychotic market >$23bn)
- High potency, selective inhibitor of key mechanisms involved in several psychiatric conditions
- Rapid onset of action; high availability in the brain
- Positive pre IND and CTA meetings with FDA and MHRA on planned development as **add-on to antipsychotics for patients with psychosis and mania**
- Undergoing IND – enabling studies
- Phase I development to be started in 2H2010

NW-3509 has the potential to address unmet medical needs in schizophrenia

- **Cognitive symptoms**
  - NW-3509 is active in models of short and long-term memory impairment. Most antipsychotic have detrimental effect on cognition
- **Incomplete responders**
  - NW-3509 is active in models of information processing, elicited by different mechanisms, both natural and pharmacological
- **Co-morbidities**
  - NW-3509 is active in models of anxiety and depression, suggesting to be able to address important co-morbidities in schizophrenia

NW-3509 augments the effect of typical and atypical antipsychotics in amphetamine-induced PPI deficits in rats

Combination of sub-threshold oral doses of NW-3509 and haloperidol (0.05mg/kg ip) or with risperidone (0.05mg/kg ip) completely reverses amphetamine-induced disruption of PPI.
Minimal effective doses: **0.62-1.25 mg/kg *po***



Amphetamine was given at 2.5 mg/kg ip, NW-3509 (NW) was administered orally 5 min before PPI session and haloperidol (Halo) was administered ip 30 min before PPI session. No effect of NW-3509 alone or in combination was shown on startle response *per se*. N=6-18 rats per group. Statistics: Tukey's multiple comparison test

***p<0.001 vs Vehicle, ##p<0.01 vs risperidone

HF0220

Potential first-in-class neuroprotective agent

HF0220

- HF0220 is the 7-ß-hydroxyl derivative of epiandrosterone (EPIA)
- EPIA and the related dehydroxy-EPIA (DHEA), are naturally occurring neuroprotectant steroids whose formation is increased in response to oxidative stress. Their activities are mainly due to their 7-hydroxyl derivatives
- Hydroxylation to 7-α is mediated by CYP7b and further conversion to 7ß-hydroxyl derivatives by 11β-HSD1
- This conversion is impaired in pathological conditions, such as AD
- The administration of HF0220 may overcome this deficit in neurodegenerative diseases
- HF0220 showed strong neuroprotective effect in experimental models
- Phase II safety in AD patients showed high tolerability of the drug
- POC study initiation subject to funding/partnership

Financials

Financial Highlights 2009

- License income EUR0.9m (2008: EUR2.6m) - revenue recognition from MS downpayment
- Other income EUR1.6m (2008: EUR1.3m) - grants, tax credits I, UK for years prior to 2009
- Gross R&D expenses €22.9m (2008: €22.4m), incl. safinamide-related expenses as well as R&D covered by tax credits and grants, excl. write-offs (€2.9m)
- Net R&D expenses €18.5m (2008: €12.9m), net of MS reimbursement of safinamide of €5.3m (2008: €9.5m), tax credits and grants of €2.1m (2008: €0)
- SG&A expenses €8.6m (2008: EUR9.4m)
- Financial income €0.2m (2008: EUR2.0m)
- Net loss €23.5m (2008: EUR16.4m)
- Net cash used in operating activities €23.1m (2008: €19.9m)
- Cash position at year end 2009: €24.3m, plus option to CHF28.3m under equity line
- Cash reach guidance – end of 2011+

Solid cash position – R&D relief by Merck Serono
Consolidated Financial Statements 2009 (IFRS)

Consolidated Income statement

€ ('000)	2009	2008
License income	946	2,635
Other income	1,596	1,298
R&D expenses	(18,544)	(12,881)
Marketing and advertising expenses	(86)	(115)
General and administrative expenses	(8,468)	(9,256)
Operating Loss	**(24,556)**	**(18,319)**
Financial income, net	205	1,963
Income tax expense	870	(8)
Net loss	**(23,481)**	**(16,364)**
Loss per share in €	**(3.86)**	**(2.74)**

Consolidated Cash flow statement

€ ('000)	2009	2008
Net cash used in operating activities	(23,056)	(19,932)
Net cash flows from investing activities	(1,444)	(1,615)
Net cash flows from financing activities	5,922	(343)
Net decrease in cash and cash equivalents	**(18,578)**	**(21,890)**

Consolidated Statement of Financial Position

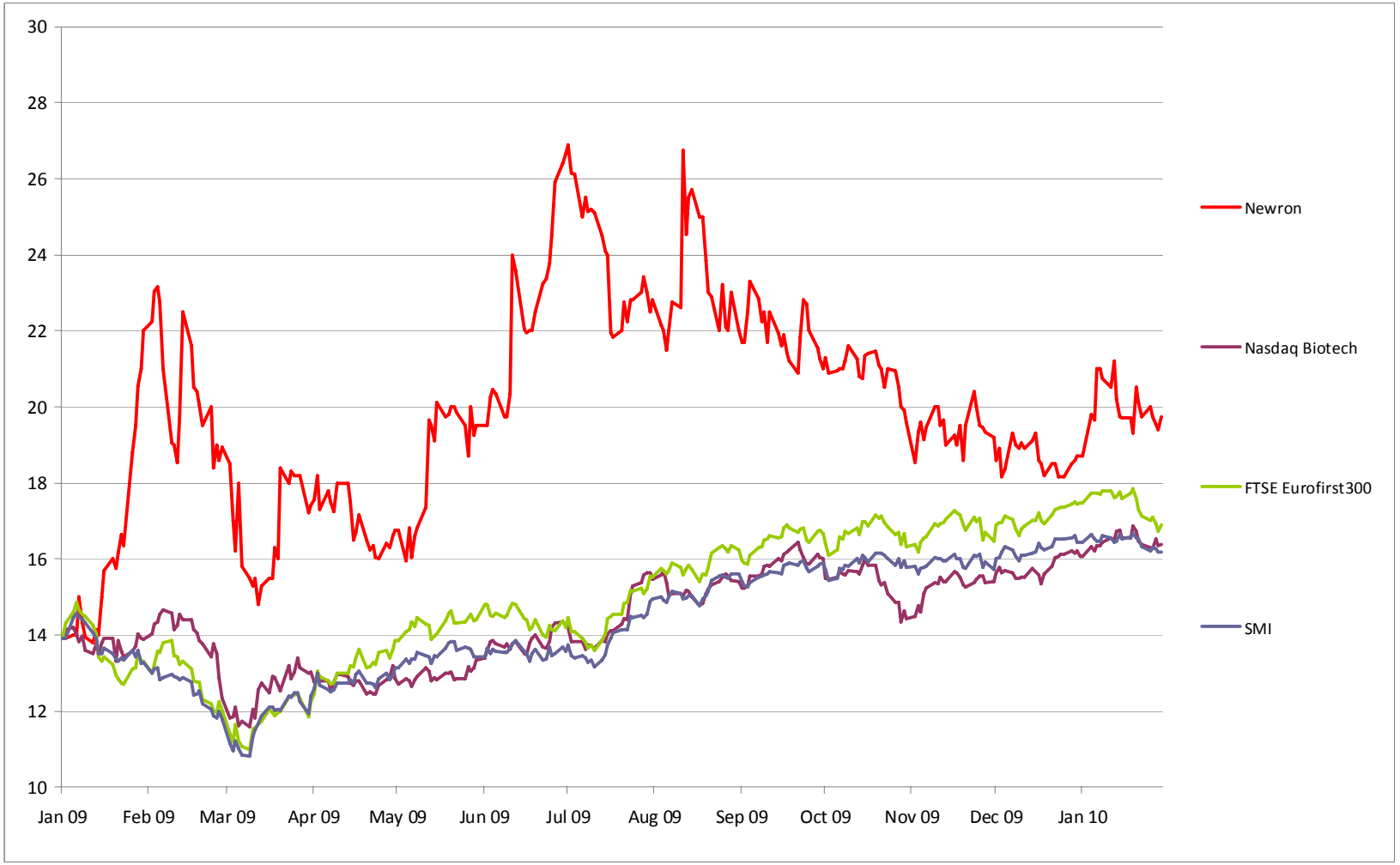
€ ('000)	31/12/2009	31/12/2008
Non-current assets	9,940	13,303
Current assets	31,738	47,237
Total assets	**41,678**	**60,540**
Deferred tax liability/income, borrowings - non-current	2,939	4,038
Employee severance indemnity/cash settled share-based liabilities	801	684
Deferred income	946	1,973
Current liabilities	7,709	8,034
Total shareholders' equity	29,283	45,811
Total equity and liabilities	**41,678**	**60,540**

Corporate Snapshot

- SIX Swiss Exchange Code: NWRN
- Number of fully paid in shares: 6,584,946
- Market cap: CHF125m
- Major Shareholders:
  - Goodman & Co 10.8 %
  - 3i Group 8.2 %
  - TRowe Price 7.7 %
  - NWB (Apax) 6.3 %
  - Capital Group 6.1 %
  - Founders 5.0 %
  - TVM 4.2 %
  - Aviva 3.6 %
- Analysts:

  Bank Bellevue, Bank Vontobel, Helvea, Jefferies, Kepler Equities, Morgan Stanley, Piper Jaffray, Sal. Oppenheim

Share price development



Anticipated key newsflow

- SERENA pivotal study results of ralfinamide in NLBP
- Ralfinamide partnership
  - US co-promotion rights or ex-US
- Safinamide:
  - Long term data (2 years) in advanced PD
  - Completion of MOTION and SETTLE trials
  - Regulatory filing for approval in the US and Europe
  - Significant milestones payments from MerckSerono
- NW-3509 start of Phase I
- Start of Phase II POC for HF0220

Summary highlights

- Leading the field in the development of novel therapies for the treatment of CNS and pain
- Broad and late stage validated pipeline addressing major therapeutic indications
- Safinamide: moving into final stages of development
  - Efficacy validated by 2 positive Phase III trials
- Ralfinamide: first in-class for the treatment of NLBP
  - Significant upside potential
- Highly promising earlier pipeline (NW-3509 and HF0220)
- Goal is to become a Fully Integrated Biopharmaceutical Company