



Newron Pharmaceuticals S.p.A.

Media Conference – 2007 Results

Zurich, 27 March 2008

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Agenda



- R&D pipeline update
- Acquisition Hunter-Fleming
- Financial review and outlook
- Q&A

Dr. Luca Benatti, CEO

Dr. Luca Benatti, CEO

Stefan Weber, CFO

Overview



- Focus on global, growing CNS market, addressing diseases with significant unmet medical needs
- Late-stage validated clinical pipeline
- Proven drug discovery expertise
- Management with proven track record of bringing CNS drugs to market (Comtan™, Cabaser™, Exelon™, Clozaril™)
- Total funds raised: € 137M
- Listed on main segment of SWX Swiss Exchange (NWRN)
- Strong analyst coverage
- Pipeline expanded through acquisition of neuro-inflammation company Hunter Fleming

Recent Milestones



- **Commercial settlement with Purdue – option to Purdue patents** ✓
- **Positive ralfinamide Phase II data in neuropathic pain** ✓
- IND approved for ralfinamide in neuropathic pain ✓
- Start/completion of enrolment of ralfinamide Phase II study in post surgical (dental) pain ✓
- EU use patent for ralfinamide in migraine ✓
- **Positive safinamide 18 months Phase III data in PD** ✓
- **Start of safinamide Phase III MOTION trial (Merck Serono)** ✓
- **Extension of safinamide patent protection: EPO intention-to-grant letter** ✓
- **Start of development of NW-3509** ✓
- Opening of clinical development facility in Basel ✓
- Carlos de Sousa appointed as CBO ✓
- Dr. Hans-Joachim Lohrisch appointed non-executive member of BoD ✓
- **Acquisition of Hunter-Fleming** ✓

Newron's late-stage CNS pipeline – prior to HF acquisition



		Lead	Preclinical	Phase I	Phase II	Phase III
Safinamide ⁽¹⁾	Adjunctive to dopamine agonist <i>Early Stage Parkinson's disease</i>	[Progress bar spanning Lead, Preclinical, Phase I, Phase II, and Phase III]				
	Adjunctive to levodopa <i>Mid to late Stage Parkinson's disease</i>	[Progress bar spanning Lead, Preclinical, Phase I, Phase II, and Phase III]				
Ralfinamide	<i>Neuropathic pain</i>	[Progress bar spanning Lead, Preclinical, Phase I, and Phase II]				
	<i>Post surgical (dental) pain</i>	[Progress bar spanning Lead, Preclinical, Phase I, and Phase II]				
Others	NW-3509 <i>CNS-related disorders and pain</i>	[Progress bar spanning Lead and Preclinical]				
	Ion Channel Programs <i>CNS-related disorders and pain</i>	[Progress bar spanning Lead]				

(1) Newron is undertaking Phase III trials with safinamide for the treatment of PD on behalf of its partner Merck Serono



Safinamide

Safinamide



- Oral use, small molecule
- New chemical class
- High bioavailability
- CNS/plasma > 10 times
- Unique mechanism of action
 - Enhancement of dopaminergic function
 - Reduction of glutamatergic activity
- Once a day adjunctive therapy for any stage of PD
- Potential in cognitive disorders
- Currently in Phase III development for PD with partner Merck Serono

... with potential benefits in Parkinson's disease (target product profile)



Current PD paradigm

Early stage (mild)



Late stage

Dopamine agonist

- First-line treatment in early patients, efficacy decreases over time, significant side-effects

Levodopa + adjunct

- Associated with dyskinesia and other major side effects

Safinamide enhances existing treatment paradigm

Early stage (mild)



Late stage

Dopamine agonist

Dopamine agonist + safinamide

- Enhances dopamine agonist effects
- Delays levodopa use
- Improves cognition

Levodopa + (adjunct +) safinamide*

- Improves "on" time, reduces "off" time
- Improves dyskinesias
- Reduces levodopa dose
- Improves cognition

* as suggested by earlier studies and mechanism of action

**Delay the use of levodopa as long as possible;
once you use levodopa, dose as low as possible**

Add-on to dopamine agonists in early PD



- First Phase III trial confirms positive Phase II results
- Double-blind, placebo controlled, multinational trial (270 patients)
- Safinamide 50 to 100mg/day added to patients who are still benefiting from dopamine agonist treatment showed:

At 6 months

- Statistically significant, clinically relevant increase in efficacy (motor symptoms, UPDRS III, primary regulatory objective)
- Statistically significant benefit in activities of daily living (UPDRS II) and quality of life (EUROQOL)

At 18 months

- Excellent safety (primary regulatory objective)
- Improvement in motor symptoms (UPDRS III $p=0.019$) and quality of life (EUROQOL $p=0.046$)
- Potential to reduce the number of patients experiencing interventions

Safinamide also shows promising results in cognition...



- Tests carried out in selected centres for 6 months
- Cognitive effects seen as early as 12 weeks after starting safinamide treatment
- Addition of safinamide (50-100 mg/day) to stable dose of dopamine agonists resulted in statistically significant improvement of two major cognitive domains often impaired in early stage PD (executive functioning and working memory)
- Full data presented at the Movement Disorder Society's 11th International Congress – Istanbul, 7 June 2007
- Safinamide offers the opportunity to be explored in multiple cognitive disorders
- Huge market opportunity beyond cognition in PD
 - Age Associated Memory Impairment (AAMI, 13M in US)
 - Mild Cognitive Impairment (MCI, 10 -15% diagnosed with AD each year)
 - Alzheimer's disease (4.5M in US; 14M in 2030)

Regulatory requirements for approval as adjunctive treatment in PD



- 1 positive Phase III trial in early PD as add-on to dopamine agonist therapy
 - 6 months' efficacy on motor symptoms
- 1 positive Phase III trial in mid-to-late stage PD as add-on to levodopa (and other PD) treatment(s)
 - 6 months' efficacy on on-time
- 1,500 patients treated, of which:
 - Several 100 for at least 6 months and;
 - 100 for at least 1 year



Ralfinamide

An innovative therapeutic agent for neuropathic and inflammatory pain



- Oral use, small molecule, new chemical class
- Linear kinetics, excellent “drugability”
- Blocks ion channel subtypes
- Long-lasting anti-allodynic and anti-hyperalgesic effects in models of neuropathic pain
- No development of tolerance on chronic dosing
- No need for titration
- One of the largest pharmaceutical market: analgesics ~\$23bn

Phase II in neuropathic pain



- Multi-centre, randomised, D-B, placebo-controlled, flexible ascending dose (80-320mg/day) study
- Indication: Mixed Neuropathic Pain Syndromes
- Randomization: Unequal; ralfinamide vs placebo 2:1
- 272 patients
- Treatment duration: 8 weeks
- Countries: Austria, India, Italy, Poland, Czech-R, UK
- Primary efficacy measure: VAS score

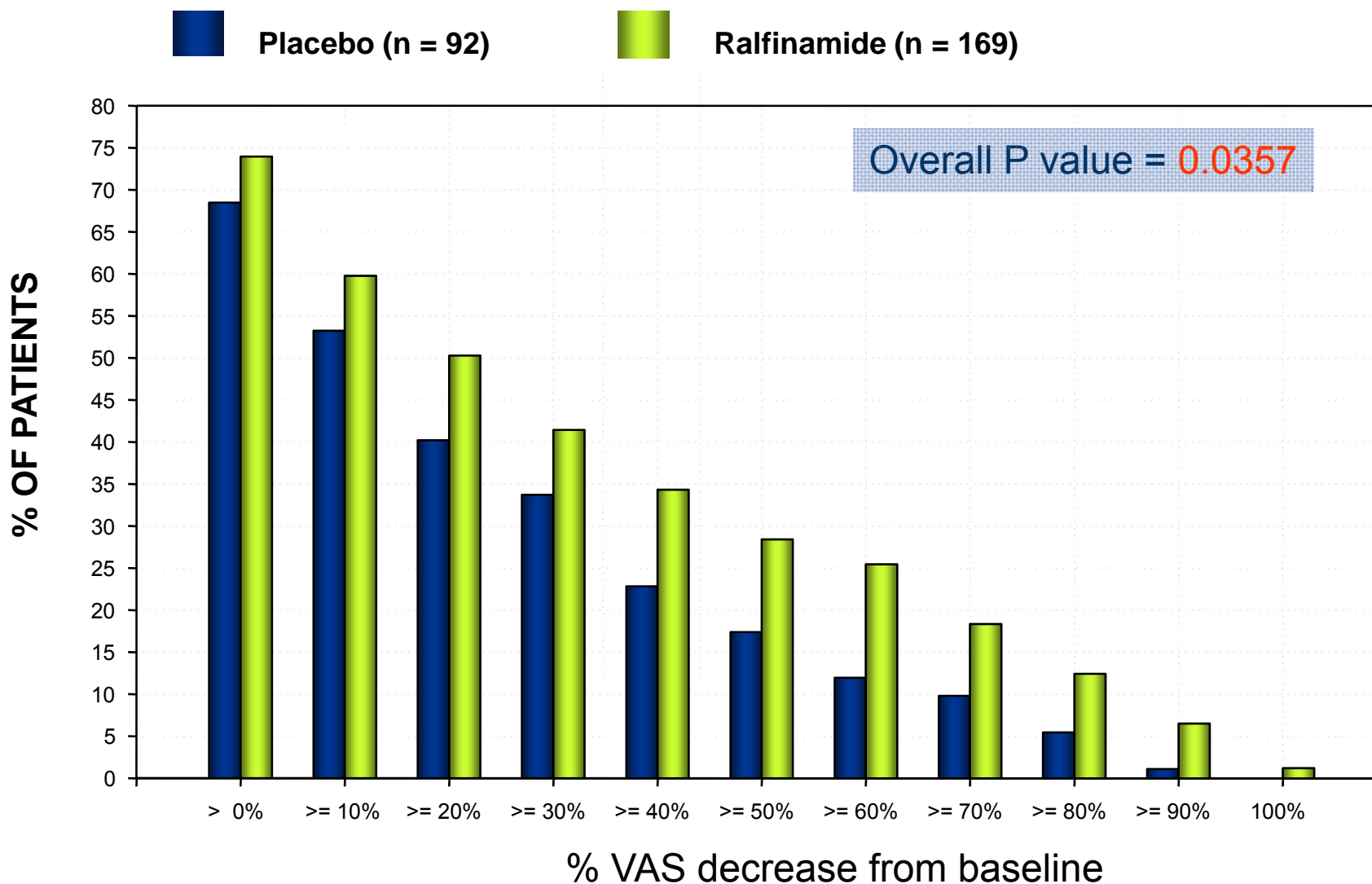
Phase II results in neuropathic pain – drug well tolerated, side effects comparable to placebo



- Ralfinamide was well tolerated with no evidence of any statistically significant or clinically relevant pattern of change compared to placebo
- Highest dose (320 mg/day BID) reached in 81.4 % of patients, with about 75 % of patients maintaining the dose

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 %

VAS (% reduction by treatment): significant increase in responder rates



Ralfinamide: summary and next steps



- Clear evidence of efficacy in mixed neuropathic pain (NP)
 - VAS
 - Quality of sleep
 - Daily Pain Diary
 - Daily Activities
- Very interesting results in NP subtypes
 - Data to be presented at AAN, Chicago, on April 15, 2008
- Post surgical (dental) pain study ongoing
 - Recruitment completed
 - Top line results by mid-April 2008
- Phase IIb/III in NP to be started in 2008



NW-3509 |

NW-3509



- Resulting from Newron's ion channel program
- Innovative compound from new chemical class
- Most advanced from a series of compounds
- Potent, highly specific sodium channel blocker, acting on Nav 1.3, 1.7, 1.8
- Fast onset of action, high availability in the brain
- Modulating neuronal hyperexcitability, involved in several CNS indications
- Due to its promising activity in in vivo models of mania, the compound will be developed in acute mania
 - Severe medical condition
 - High unmet medical need
 - Total market valued at \$6bn in 2007, CAGR 2006/07 = 16 %



Acquisition of Hunter-Fleming

Hunter-Fleming overview



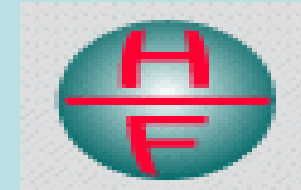
- Private UK biopharmaceutical company
- An outstanding opportunity in the fields of neurodegeneration and inflammation
- Three compounds in clinical development, one discovery program and an equity holding in Trident (preclinical compound)
- Founded in 1999 by Dr. James Murray, Dr. John Fox (former senior executives from Shire) and Professor Ernst Wulfert (former Research Director at Fournier & UCB)
- Virtual research facilities
- £20m raised since inception

Transaction rationale: Accelerating Newron's growth



- **Safinamide**
 - In Phase III for early and late stage PD
 - Partnership with Merck Serono
- **Ralfinamide** in Phase II for neuropathic and inflammatory pain
- **NW3509** in preclinical development for CNS and pain indications

- **Building a leading CNS company**
- **Significantly increases Newron's upside potential**
- **Broadened clinical pipeline = improved risk return profile**
- **Expanded CNS/ neuro-inflammation expertise**



- **HF0220**
 - In Phase II for AD
 - Phase II in RA to be initiated in 2008
- **HF0420** in Phase I for anti-cancer therapy induced neuropathy
- **HF 0299** in Phase I for neuropathic pain
- **HF1220** series, neuroprotection program

Neuro-inflammation added to existing CNS expertise



- **Strong link between neuro-degeneration and chronic inflammation**
- Brain damage in chronic CNS disorders is associated with the release of inflammatory mediators
- Etanercept, a widely used treatment for RA, showed sustained improvement of cognitive function in AD
- **HF0220 potentially a “first-in-class disease-modifying agent”** for chronic neurodegenerative diseases and for RA with a unique mechanism of action

Hunter-Fleming lead compound: HF0220



- Naturally occurring human steroid (7 β -hydroxy-epiandrosterone)
- Devoid of AEs associated with this class of molecules
- Modulator of prostaglandin pathway
 - Believed to act as a catalyst to drive 15d-PGJ2 production (anti-inflammatory)
- Shown to:
 - reduce amyloid level in AD transgenic mice
 - be protective in stroke models
 - be protective in murine CIA models

Hunter-Fleming lead compound: HF0220



- Patented, new mechanism of action offers new paradigm for treatment of neuro-degenerative and inflammatory diseases
- **A first-in-class therapeutic with powerful cytoprotective and regenerative effects**
- **Ongoing phase II safety and tolerability** study with exploration of biological markers in patients with Alzheimer's disease
 - DSMB recommended continuation of Phase II
- Phase II study in RA to be initiated in late 2008

HF0420



-
- Prevention of anti-cancer therapy induced neuropathy, in Phase I
 - A low molecular weight oligosaccharide for neuronal repair and protection
 - Extensive use of anti-cancer compounds offers significant market opportunity
 - Side effects of anti-cancer therapy limits the dose levels tolerated in patients
 - Additional potential for an orphan indication in paediatric patients
 - Series of use patents

Additional HF compounds



HF0299

- Naturally occurring human steroid
- In Phase I, with **potential in the treatment of neuropathic pain**
- Series of use patents

HF1220

- Second generation neuroprotective compound series
- Discovery stage
- New composition of matter patent

HF1020 – Trident SPV (Special purpose vehicle)

- **In pre-clinical development for asthma**, Phase I expected to commence 2008
- Funded by Advent International, Omega Fund et al.
- Hunter-Fleming owns non-dilutable 17 % of shares
- No further financing required from Hunter-Fleming
- Exit via trade sale of SPV

HF Acquisition highlights



- Outstanding opportunity to enter neuro-inflammation field
- Fully in-line with Newron's growth strategy to become a leading CNS company
- Three new compounds in clinical development and one discovery program
- Opportunity for early, significant development milestones upon investment of minimal funds
- CNS expertise expanded into neuro-inflammation
- Low upfront payment and limited success based milestones



Financial Review

Financial Highlights 2007



- License income up to EUR 4.0m from EUR 1.2m
- R&D expenses EUR 8.2m – net of costs related to the clinical development of safinamide (reimbursed by Merck Serono)
- G&A expenses: EUR 2.4m one-time effects of ending Purdue litigation, downpayment for Purdue patents and M&A process
- Financial income increased to EUR 2.6m
- Net loss significantly lowered to EUR 11.1m
- Cash and cash equivalents EUR 63.2m

Strong cash position – R&D relief by Merck Serono

Financial Statements 2007 (IFRS)



Consolidated Income statement

EUR ('000)	2007	2006
License income	4,024	1,191
R&D expenses	(8,197)	(11,488)
Grants	70	219
Marketing and advertising expenses	(131)	(55)
General and administrative expenses	(9,447)*	(6,619)
Operating Loss	(13,681)	(16,752)
Financial income, net	2,593	351
Income tax expense	(1)	0
Net loss	(11,089)	(16,401)
Loss per share in €	(1.90)	(4.33)

Consolidated Cash flow statement

EUR ('000)	2007	2006
Net cash used in operating activities	(13,866)	(9,630)
Net cash flows from investing activities	2,243	249
Net cash flows from financing activities	15	66,700
Net increase in cash and cash equivalents	(11,608)	57,319

Incl. €2.4m one-time effect for Purdue and M&A

Consolidated Balance sheet

EUR ('000)	31/12/2007	31/12/2006
Non-current assets	852	1,025
Current assets	69,516	85,132
Total assets	70,368	86,157
Borrowings - non-current	561	833
Deferred income - non-current	1,973	4,327
Employee severance indemnity/cash settled share-based liabilities	661	350
Current liabilities	9,773	12,789
Total shareholders' equity	57,400	67,858
Total equity and liabilities	70,368	86,157

HF: right deal, right price



- Stock purchase agreement signed 9 February, 2008
 - Providing for the acquisition of 100% of HF issued share capital
 - Conditional to confirmation by appraiser and Newron shareholders' approval (April 2008)
 - Newron pays EUR 8m upfront, minus net debt, for the fully diluted share capital of Hunter-Fleming, in newly issued Newron shares
 - Newron to pay success-based milestone payments relating to further progression of the HF programs, to a maximum of EUR 17m, over a period of 5 years (potential extension to 6 years), in newly issued Newron shares, upon:
 - Approval of an IND for HF0220 (AD excluded)
 - Out-licensing of HF0220
 - Phase II proof of concept for HF0220
 - Trade sale of the Trident SPV

Financial outlook



- Strong cash position of EUR 63.2m by year-end 2007
- R&D expenses significantly higher related to the clinical focus on Ralfinamide and other compounds
- Cash burn guidance 2008 EUR 18m (ex. Hunter-Fleming)
- Operative cash burn 2008 increased with acquisition of Hunter-Fleming by approx EUR 7m in event of development of all programs
- Newron's cash position fully supports ongoing operations into 2010 (and beyond, in event of successful completion of ongoing programs/activities)

Newron share information



- Number of shares (as per Dec. 31, 2007/current):
 - Non-diluted: 5,834,766
 - Fully diluted (SOP): 6,137,451
- Market capitalisation 20/3/2008:
 - Non-diluted: 216.5m CHF
 - Fully diluted: 227.7m CHF
- Listing and trading symbol: SWX, NWRN
- Analysts:
 - Karl Bradshaw, Morgan Stanley
 - Peter Welford, Lehman Brothers
 - Odile Rundquist, Bank Vontobel
 - Martin Voegtli, Sal. Oppenheim
 - John Reeve, Blue Oak
 - Florian Gaiser, Kepler Equities
 - Olav Zilian, Helvea
 - Bob Pooler, Bank am Bellevue

Anticipated upcoming milestones



- Ralfinamide Phase II data in post surgical (dental) pain
- Presentation of ralfinamide Phase II data in NP subtypes at AAN (Chicago – April 15, 2008)
- Start of ralfinamide Phase IIb/III study in neuropathic pain
- Safinamide Phase III data in add-on study to L-dopa
- Start of Phase I of HF1020 in Trident SPV
- Start of Phase II trial with HF0220 in RA
- Completion of Phase II safety and tolerability study with HF0220 in AD



Q&A