Newron Pharmaceuticals S.p.A.

Getting back on track

Full year results 2011

Conference call

Milan

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Back on track – mastering the 2011 challenges

- Status end October 2011:
  - MS terminates global safinamide collaboration and license agreement effective 04/2012
  - Biotie steps back from merger valuing Newron at €45m
  - Safinamide final phase III studies MOTION and SETTLE ongoing in the field
  - Cash in the bank < €10m; market cap down to CHF16m (12/2011)

Back on track – mastering the 2011 challenges / 2

- Achievements since:
  - Smooth take-over of global safinamide development program from MS (10/2011-06/2012)
  - Safinamide rights for Japan and key Asian rights licensed to Meiji Seika (02/2012)
  - Safinamide rights for rest of world licensed to Zambon Group as part of strategic collaboration agreement (05/2012)
  - Immediately due funds of €15m for equity, option premium and license downpayments
  - Additional commitment to cover internal Newron and external cost to finalize development activities and prepare for filing of safinamide in the US and the EU of €10m
  - NW-3509 IND/FDA approval of further clinical trials with ralfinamide

Back on track – current status

- Newron status end of May 2012:
  - Safinamide phase III development program completed
  - Preparations for regulatory filing in the US and EU ongoing for filing in 2013
  - Cash position and commitment of €26m, taking Newron post safinamide filing, into 2014
  - Change in management implemented
  - Market cap back up to CHF40m

Strategy

- Move safinamide into regulatory filing in the US and the EU with Zambon
- Support development of safinamide in Japan and Asia with Meiji Seika
- Focus development efforts and resources on value-creating steps:
  - NW 3509 Phase I/Ib PoC to outlicense; first add-on in schizophrenia
  - Sarizotan PoC in Rett syndrome (orphan disease)/ralfinamide in pain
- Partner or monetize other opportunities: HF0220
- Secure additional funding
- Use M&A to further strategy

Group Consolidated Financials 2011 (IFRS)

Financial Highlights 2011

- License income EUR0.3m (2010: EUR0.6m) - revenue recognition from MS downpayment
- Other income EUR4.0m (2010: EUR0.2m) – one time payment from MS under agreements to broaden collaboration
- Gross R&D expenses €6.2m (2010: €17.0m), incl. safinamide-related expenses as well as R&D covered by tax credits and grants excl. write-offs (2010: €3.8m)
- Net R&D expenses €3.8m (2010: €15.9m), net of MS reimbursement of safinamide of €2.0m (2010: €4.3m), tax credits and grants of €0.4m (2010: €0.6m)
- SG&A expenses €6.9m (2010: EUR6.5m)
- Net loss €6.4m (2010: EUR20.5m)
- Net cash used in operating activities €4.9m (2010: €19.1m)
- Cash position at year end 2010: €5.4m
- Cash-in post end of reporting period: €15m
- Cash and commitment at end of May 2012: €26m
- Cash reach: 2014, post safinamide regulatory filing

Consolidated Financial Statements 2011 (IFRS)

Consolidated Income statement

€ ('000)	2011	2010
License income	280	626
Other income	4,009	180
R&D expenses	(3,822)	(15,922)
Marketing and advertising expenses	(51)	(73)
General and administrative expenses	(6,898)	(6,451)
Operating Loss	**(6,482)**	**(21,640)**
Financial income, net	(45)	(33)
Income tax expense	(8)	1,128
Net loss	**(6,445)**	**(20,545)**
Loss per share in €	**(0.89)**	**(3,11)**

Consolidated Cash flow statement

€ ('000)	2011	2010
Net cash used in operating activities	(4,942)	(19,127)
Net cash flows from investing activities	65	1,621
Net cash flows from financing activities	2,157	2,904
Net decrease in cash and cash equivalents	**(2,720)**	**(14,602)**

Consolidated Statement of Financial Position

€ ('000)	31/12/2011	31/12/2010
Non-current assets	5,937	6,026
Current assets	7,629	13,106
Total assets	**13,566**	**19,132**
Deferred tax liability/income, borrowings - non-current	3,520	1,718
Employee severance indemnity/cash settled share-based liabilities	634	588
Deferred income	121	400
Current liabilities	2,706	4,235
Total shareholders' equity	6,585	12,191
Total equity and liabilities	**13,566**	**19,132**

Corporate Snapshot

- SIX Swiss Exchange Code: NWRN
- Number of fully paid in shares: 7,990,813
- Market cap: CHF40m (May 2012)
- Major Shareholders:
  - Zambon Group 9.1 %
  - Great Point Partners 8.3 %
  - 3i Group 6.8 %
  - Founders 4.2 %
  - TVM 3.4 %
  - Orbimed 3.0 %
  - Aviva 2.9 %
- Analysts:
  - Bank Vontobel
  - Helvea
  - Jefferies

Safinamide in PD

- >$4bn market with no significant therapies introduced in recent years
- First once a day oral adjunctive therapy for all stages of PD
- Unique mechanism of action
  - Enhancement of dopaminergic function
  - Reduction of glutamatergic activity
- Efficacy and safety achieved in early and advanced PD
  - Early PD: studies 09, 015 and MOTION
  - Advanced PD: studies 016 and SETTLE
- Partnered with
  - Meiji Seika (Japan and key Asian territories)
  - Zambon (rest of world)
    - Significant milestones and double digit royalties
    - Internal and external cost to filing covered by partner

Safinamide in PD – Differentiation (Phase II and III clinical studies outcome)

- **First add-on treatment to any dopamine agonist in early PD**
  - Maintenance of long term benefits on motor symptoms
  - Reduction in use of levodopa/interventions by 50 %
- **First add-on to levodopa in advanced PD showing long term (24 months) maintenance of effect**
  - No increase in troublesome dyskinesia
  - Improvement of dyskinesia
  - Only add-on to levodopa showing benefit in motor fluctuations, motor symptoms, activities of daily living, depression, quality of life
- **Potential for cognitive improvement**

Ralfinamide

- Oral use, small molecule, new chemical class
- Ion channel blocker and NMDA modulator originated from in-house ION channel program
- Efficacy demonstrated in multiple models of neuropathic, visceral and central pain and mania
- No titration required in patients (very well tolerated)
- Mechanism of action, strong pharmacology, positive Phase II in NP patients, excellent safety (>600 patients)
- US pain expert panel recommended continued development in pain indications
- FDA approved trials in non-responding patients with severe NP of specific causes
- Exciting pharmacological results support ralfinamide development in non pain indications

Saritozan and Pruvanserin

- Licensed from Merck KGaA in March 2011
- Buy-back option for Merck upon PoC
- If Merck exercises buy-back option, Newron has co-development option

Characteristics

- Highly selective compounds for specific serotonin or dopamine receptors
- Modulating the activity of such neurotransmitters in the brain
- Both compounds exhibit pharmacological properties and have clinical data that support further evaluation and development

Next steps

- Additional preclinical experiments
- PoC studies in diseases of the CNS

NW-3509

- Innovative compound from Newron's ion channel program
- Addressing unmet needs in schizophrenia
- Large market opportunity (anti-psychotic market >$23bn)
- Rapid onset of action; high availability in the brain
- Positive pre IND and CTA meetings on planned development as add-on to antipsychotics for patients with psychosis
- IND granted in late 2011
- Next step: Phase I study

HF0220

- HF0220 is the 7-ß-hydroxyl derivative of epiandrosterone (EPIA)
- It showed potent anti-inflammatory effect in experimental models of RA as well as strong neuroprotective and pro-cognitive properties
- TRIOLEX, a similar but much less potent compound from Harbor BioSciences is currently undergoing Phase II trial in obese type 2 diabetes mellitus patients
- Phase II safety of HF0220 in AD patients showed high tolerability of the drug
- Next step: PoC study

Key Priorities

- Safinamide regulatory filing and milestone payments
- NW-3509 Phase I start
- HF1020 Phase I (Trident SPV) results
- Ralfinamide POC trial start
- M&A