

# **Annual Report 2010**

### **Corporate Profile**

Newron (SIX: NWRN) is a biopharmaceutical company focused on novel therapies for diseases of the Central Nervous System (CNS) and pain. It is headquartered in Bresso near Milan, Italy.

The Company currently has a late-stage product candidate, safinamide, in development, three further clinical-stage compounds and a promising pipeline of five earlier/preclinical compounds. Phase III trials of safinamide are currently ongoing for the treatment of Parkinson's disease (PD). As per the agreement signed with Newron in 2006, Merck Serono, a division of Merck KGaA, Darmstadt, Germany, has exclusive worldwide rights to develop, manufacture and commercialize the compound in PD, Alzheimer's disease, and other therapeutic applications.

Newron is evaluating the further clinical development of ralfinamide in psychiatric diseases and pain. Although the compound did not show efficacy in the treatment of Neuropathic Low Back Pain, an independent Board recommended its further investigation due to a good overall efficacy and safety profile.

Recently, Newron has been granted a licence from Merck KGaA to develop pruvanserin, a highly selective 5-HT2A receptor antagonist that has demonstrated efficacy in a phase II trial and sarizotan, a full agonist at the 5-HT1A receptor and a functional modulator at the D2, D3 and D4 receptors, that has an exciting pharmacological profile and has demonstrated efficacy in multiple animal models of psychiatric and neurological disorders. Newron will be conducting further testing and analyses of results to date before moving into phase II trials in new indications.

Newron's additional five projects are progressing at various stages of preclinical and clinical development, including NW-3509 for the treatment of schizophrenia, which is a project from Newron's ion channel research.

### **Key Corporate Events**

#### 2010

Top-line results of a long-term study of safinamide as add-on treatment to levodopa in advanced Parkinson's disease were announced by Newron and Merck Serono.

CHF 3.5 million (EUR 2.7 million) were raised through a private placement to Great Point Partners, LLC, a leading US institutional investor.

Positive outcome of meetings with the FDA and MHRA to determine the development of Newron's novel ion channel compound, NW-3509, as an add-on to antipsychotics in patients with schizophrenia, a major psychiatric disorder which is inadequately served, was reported.

Together with its partner, Merck Serono, Newron presented new results on safinamide at the 14th Annual Meeting of the Movement Disorder Society (MDS), in Buenos Aires.

The inconclusive results seen with ralfinamide in the SERENA phase IIb/III study were reviewed by an independent US Advisory Board, that recommended its evaluation in other pain conditions.

Restructuring/downsizing of operations has been executed by July 1.

### 2011

Scope of collaboration with Merck Serono broadened with two compounds being licensed to Newron for further evaluation ahead of new phase II studies.

Newron received EUR 3.7 million as part of a EUR 5 million grant for innovative R&D by the Italian government.

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### Shareholders' Letter







Luca Benatti

#### **Dear Shareholder**

Newron is focused on the development of our innovative CNS pipeline. Despite the setback with ralfinamide during 2010, we have much to look forward to in the coming year as our lead compound moves towards the final stages of clinical development.

On this front, we are working closely with our global partner Merck Serono to conclude the clinical development of safinamide, our adjunctive treatment for Parkinson's disease, which is in phase III trials. In November we announced the top-line results for the 18-month extension study of a previously completed and reported six-month Phase III study (study 016), which confirmed the safety profile of safinamide and its effect on motor function. Although the trial did not meet the primary efficacy endpoint measuring dyskinesia after 24 months of treatment, results of the exploratory analysis of the prespecified main secondary endpoints were consistent with the effects observed in study 016. The placebo-controlled two-year study 018 showed that safinamide improved motor fluctuations, parkinsonism, activities of daily living, depressive symptoms and quality of life without worsening dyskinesia. The longterm safety data provided by the extension study 018 are part of the clinical development programme of safinamide, together with completed studies 015, 016 and 017, as well as the ongoing MOTION and SETTLE studies. This clinical programme is designed to support an application for marketing authorization of safinamide as an add-on therapy of dopamine agonist therapy in patients with early Parkinson's disease and as an add-on to levodopa therapy in patients with advanced Parkinson's disease. New proof-of-concept studies sponsored and conducted by Merck Serono have been initiated to evaluate the efficacy of safinamide in improving cognition in PD and reducing levodopa-induced dyskinesia.

The Company was very disappointed by the unexpected results seen with ralfinamide in the SERENA phase IIb/III study in patients with Neuropathic Low Back Pain (NLBP). The results showed that the compound was safe and well tolerated, but it demonstrated no statistical significance in efficacy against placebo. This outcome is in contradiction to results that had previously been achieved in a phase II study in mixed neuropathic pain, including NLBP patients. Following recommendations from the Company's Scientific Advisory Board Newron is considering to further develop rafinamide in another indication, based on their view that its pharmacology is extremely exciting and predictive of efficacy in neuropathic pain conditions, especially those with a central component. We are currently evaluating a number of opportunities for ralfinamide and expect to progress a plan for its further development in a non-pain indication, as well.

In January 2010 we reported successful outcome of pre-IND and CTA meetings with the US FDA and the UK MHRA for our novel new chemical entity, NW-3509, which is intended to be developed as an adjunctive treatment for patients with schizophrenia experiencing inadequate benefit from their current antipsychotic treatment. The Regulatory Authorities accepted the pharmacological, toxicological and pharmaceutical information collected in our IND- enabling studies and the clinical development plan for phases I and II. We look forward to moving ahead with this potentially significant compound in an area of major unmet need.

Trident Pharmaceuticals, a 17% financial holding of Newron, has continued progress on completion of the necessary preclinical studies for HF1020, under development for inflammatory diseases, required for a CTA filing in the UK. Assuming acceptance of the CTA filing by the UK MHRA regulatory authority, Trident expects to start phase I safety testing in man during 2011.

In December we raised CHF 3.5m through a private placement to Great Point Partners, LLC. In February 2011, we received a payment of EUR 3.7m as part of a EUR 5m grant for innovative R&D. These sums, combined with new funds to be received from Merck Serono in early 2011, will enable us to further develop our pipeline and allow us to further review partnering and M&A opportunities. The Company is now funded well through most of 2012.

Although outside of the period covered by this report, it would be remiss not to mention the recent broadening of our collaboration with Merck Serono by which we have taken in two late-stage compounds. Even though these compounds did not complete development in the indications intended for them, the considerable data amassed so far makes them exciting programmes to pursue further. With the expertise of our team, we will be running studies and undertaking further analyses before moving in to phase II trials, if the evidence supports this.

We are committed to the successful development and commercialization of our pipeline. During the year we held active discussions with a number of potential partners and licensors and we continue to look for opportunities to create value in the business through partnering and M&A.

The Newron team has worked hard throughout a challenging year and we are grateful for the ongoing support of our investors as well as to our employees and partners. The Board and Management Team are committed to unlocking the value that lies within Newron; in our underlying technology, our CNS expertise and our pipeline. We look forward to demonstrating this to you in 2011.

Rolf Stahel

Chairman

Luca Benatti

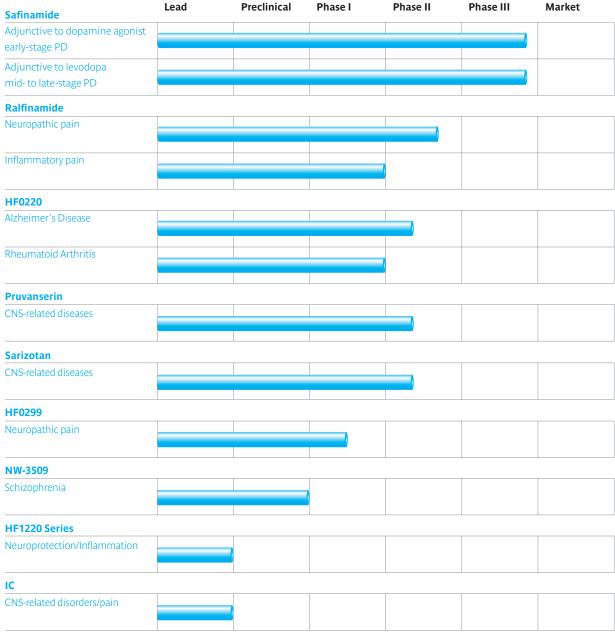
Chief Executive Officer



# **Company Information**

### **Drug Portfolio**

Newron has built a CNS-focused pipeline that embodies highly innovative compounds at a variety of development phases. Safinamide, partnered with Merck Serono, is in latestage Phase III trials; all other compounds are being developed by Newron and will progress in new partnerships with other companies at various stages.



IC = Ion Channel Programme

HF1020 in preclinical development for inflammatory disorders is part of Newron's equity holding in Trident

### Safinamide

"Managing motor fluctuations and reducing the time during which anti-Parkinson drugs are not working and symptoms return, the so-called 'OFF' times, are still unmet medical needs for patients with mid- to late-stage Parkinson's disease." "These long-term treatment results are encouraging because they confirm the safety profile of safinamide and its effect on motor function observed in the six month study in the advanced Parkinson's disease population. The effect of safinamide on dyskinesia will be further explored in an ongoing dedicated pilot study \*."

Dr. Bernhard Kirschbaum, Executive Vice-President for Global Research and Development, Merck Serono, February 3, 2009, commenting on the outcome of the first phase III pivotal trial of Safinamide in mid- to late-stage PD patients, and November 4, 2010, commenting on the 24 months' long term study top line results. \*\*

#### **Profile**

Safinamide stems from a novel chemical class called alpha amino-amide derivatives. It enhances brain dopamine by highly selective MAO-B inhibition, dopamine re-uptake inhibition and it antagonizes the stimulated release of glutamate. It is highly bioavailable with an amount of absorption unaffected by food, shows linear kinetics and a half-life of 21–24 h, making it well suited for once-a-day treatment.

Phase III trials with safinamide are currently ongoing for the treatment of Parkinson's disease (PD). As per the agreement signed with Newron in 2006, Merck Serono, a division of Merck KGaA, Darmstadt, Germany, has exclusive worldwide rights to develop, manufacture and commercialize the compound in PD, Alzheimer's disease, and other therapeutic applications.

If regulatory approvals are obtained, Newron and Merck Serono believe that safinamide, as an adjunctive treatment to dopamine agonists and levodopa, could bring an additional treatment option for PD patients.

Parkinson's disease treatment strategies: potential options with safinamide as add-on therapy

### **Current PD treatment paradigm**

**Dopamine agonist** 

Levodopa + adjunct

- Efficacy decreases over time, significant side effects
- Associated with dyskinesia and other major side effects

- safinamide

### Potential to enhance existing treatment paradigm

- Enhances dopamine agonist effects
- Improves "ON" time without worsening dyskinesia
- Reduces "OFF" time
- Delays levodopa use (MOTION Extension, Study 27938)

Safinamide could be the first add-on treatment for both dopamine agonists and levodopa

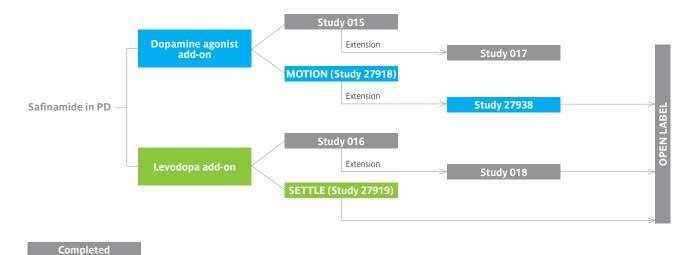
Parkinson's disease is a degenerative disorder of the Central Nervous System that often impairs the patient's motor skills and speech. Parkinson's disease belongs to a group of conditions called movement disorders. It is characterized by muscle rigidity, tremor, a slowing of physical movement (bradykinesia) and, in extreme cases, a loss of physical movement (akinesia). The primary symptoms are the results of decreased stimulation of the motor cortex by the basal ganglia, normally caused by the insufficient formation and action of dopamine, which is produced in the dopaminergic neurons of the brain. Secondary symptoms may include high-level cognitive dysfunction and subtle language problems. Parkinson's disease is both chronic and progressive. It is estimated that more than 3 million people in the industrialized countries suffer from Parkinson's disease. World sales of anti-Parkinson's drugs for the 12 months to Q3 2009 were at about USD 4.0bn.\*\*\*

### **Key achievements**

Safinamide is being developed in clinical phase III for two indications in PD: as an add-on to any dopamine agonist in early-stage PD patients, and as add-on to levodopa and other dopaminergic treatments in mid- to late-stage PD patients.

The development plan foresees two phase III trials each of 6 months' duration per indication, followed by an extension period of 12 or 18 months and longer for assessment of long-term safety. Although not required for regulatory submission, further assessments of efficacy are performed to demonstrate that the beneficial effects of treatment are preserved during long-term use. In addition, these studies will document the long-term safety of safinamide in combination with other dopaminergic treatments.

### **Safinamide Clinical Development Plan**



Phase II PoC

A phase II placebo-controlled study in early PD patients on dopamine agonists had already shown a statistically significant and clinically relevant superiority versus placebo at a daily dose of I mg/kg ( $\sim$ 85 mg) of safinamide on the primary endpoint of the responder rate ( $\geq$ 30% improvement UPRDS III from baseline).

### **Phase III Studies**

Add-on treatment to dopamine agonist therapy in patients with early-stage PD Studies 015/017

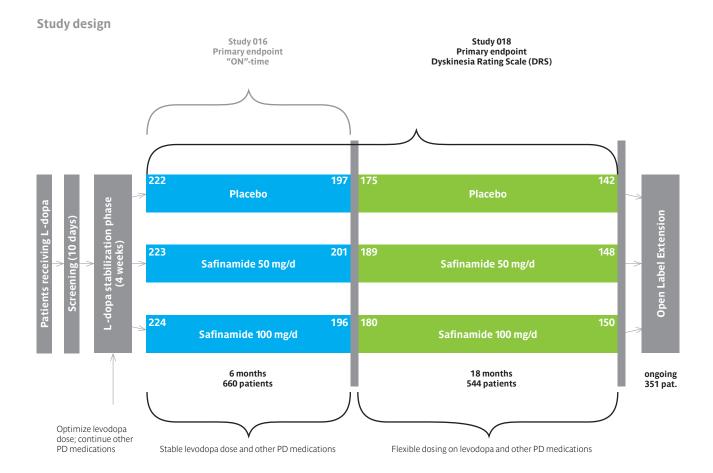
In 2007, Newron and Merck Serono had completed reporting on the first phase III trial of safinamide as add-on treatment to dopamine agonist therapy in patients with early-stage PD (study 015 and extension study 017) in 270 patients.

Safinamide at a dose of 50 to 100 mg/day added to patients who were still benefiting from dopamine agonist treatment showed:

At 6 months (all endpoints p<0.05)

- Clinically relevant improvement in motor symptoms (UPDRS III)
- Improvement in activities of daily living (UPDRS II) and quality of life instrument At 18 months:
- Side effects, ECG changes and vital signs abnormalities reported with similar frequency in patients receiving safinamide and in placebo group
- Improvement in motor symptoms (UPDRS III) and quality of life instrument in a post-hoc analysis
- Potential to reduce the number of patients experiencing interventions in a post-hoc analysis

Add-on treatment to dopamine agonist therapy in patients with mid- to late-stage PD Studies 016/018



### Study 016

Newron and Merck Serono reported in February 2009 that the first pivotal phase III trial of safinamide as add-on to levodopa in mid- to late-stage PD patients met its primary endpoint by increasing daily "ON" time in mid- to late-stage Parkinson's disease patients with motor fluctuations by 1.3 hours compared to 0.7 hours for patients in the placebo group. "ON" time represents periods when Parkinson's patients experience their best level of motor function.

Detailed results from the study were presented at the Movement Disorder Society's 13th International Congress in Paris in June 2009, the XVIII WFN World Congress On Parkinson's disease and Related Disorders in Miami in December 2009, and the Movement Disorder Society's 14th International Congress in Buenos Aires in June 2010.

#### In summary

Safinamide 50 and 100 mg/day as add-on to stable levodopa therapy in patients with mid-to late-stage PD improved motor symptom control; it significantly

- increased total daily "ON" time primary endpoint without increasing troublesome dyskinesia
- reduced daily "OFF" time and "OFF" time after first morning dose of levodopa (secondary endpoint)
- improved UPDRS-III motor scores (secondary endpoint)
- reduced UPDRS-IV complication of therapy scores (secondary endpoint)
- increased patient response rates (post-hoc analysis)

Safinamide effects on other clinical endpoints:

- safinamide 50 and 100 mg/day significantly improved severity and improvement scores on the Clinical Global Impression (CGI) scale
- statistically significant improvement in UPDRS-II scores (ADL) with safinamide 100 mg/day. The adverse event profile from phase II/early phase III studies supports further investigation of safety and efficacy of safinamide.

Newron's management was upbeat on the study 016 results, as in addition to increasing "ON" time and reducing total "OFF" time, as well as "OFF" time after a morning dose in patients with mid- to late-stage Parkinson's disease receiving optimized treatment with drugs including levodopa, dopamine agonists, COMT inhibitors, anticholinergics and amantadine, the results indicate a statistically significant improvement of motor function.

Previously reported results from phase II and phase III studies have shown improvement of motor symptoms in early Parkinson's disease patients on dopamine agonist monotherapy. Yet, additional results suggest that safinamide could have benefits beyond motor symptoms, motor fluctuations and activities of daily living. The increase in "ON" time without any increase in troublesome dyskinesia is critical for patients and physicians.

### Study 018

On November 4, 2010, Newron and Merck Serono reported the outcome of the long-term extension study of study 016, study 018, of safinamide as add-on treatment to levodopa in advanced Parkinson's disease.

The objective of this extension study was to assess the long-term (24 month) efficacy and safety of two doses of safinamide (50 mg and 100 mg once daily tablets) as add-on therapy to levodopa in patients with advanced Parkinson's disease.

While the primary efficacy endpoint of study 018 measuring dyskinesia after 24 months of treatment was not met, results of the exploratory analysis of the prespecified main secondary endpoint were consistent with the effect on motor function observed in study 016. Results from the study also further support the safety profile of safinamide.

The primary efficacy endpoint of study o18 was the mean change in the ratings of the Dyskinesia Rating Scale (DRS). After 24 months, non-statistically significant mean improvements of 0.19 and 0.28 in the DRS score were observed in patients who received safinamide 50 mg and 100 mg respectively, versus a worsening of 0.32 for the placebo group (respectively p=0.21 and p=0.15 versus placebo). Dyskinesia, which consists of involuntary twisting

movements of the face and body, is a major complication of levodopa therapy, resulting in a significant deterioration of patient quality of life. At baseline, 32% of patients showed troublesome dyskinesia.

Out of the 544 patients enrolled in the extension study, 81% of patients treated with safinamide completed the study (78% in the 50 mg dose group and 83% in the 100 mg dose group) compared to 81% in the placebo group. The incidences of dropouts, serious adverse events or clinically notable events among both groups treated with safinamide were comparable with those in the placebo group over 24 months and similar to the safety profile reported in study 016.

Prespecified secondary endpoints were analyzed in an exploratory fashion. The significant effect on "ON" time without troublesome or minor dyskinesia observed in study 016 (primary endpoint) was maintained at the end of the 24 month period for both safinamide doses (I.01 and I.18 hours for the 50 mg and 100 mg dose groups respectively versus 0.34 hours for the placebo group; p=0.0031 and p=0.0002 for the 50 mg and 100 mg dose groups respectively versus placebo).

Additional secondary and tertiary endpoints indicated a benefit (p<0.05) of the 100 mg/day dose on: activities of daily living (UPDRS II), motor symptoms (UPDRS III), complications of dopaminergic treatment (UPDRS IV), symptoms of depression (GRID HAMD) and quality of life (PDQ-39) at the 2-year endpoint.

### In summary

Safinamide 50 and 100 mg/day as add-on to stable levodopa therapy in patients with mid- to late-stage PD at the two-year endpoint showed

- non-significant improvement in the DRS vs. worsening for the placebo group (primary end-point)
- effect on "ON" time without troublesome or minor dyskinesia (secondary endpoint with p<0.05)

Other secondary endpoints with safinamide 100 mg/day as as add-on to stable levodopa therapy in patients with mid- to late-stage PD at the two-year endpoint showed improvement (p<0.05) on

- activities of daily living (UPDRS II)
- motor symptoms (UPDRS III)
- complications of dopaminergic treatment (UPDRS IV)

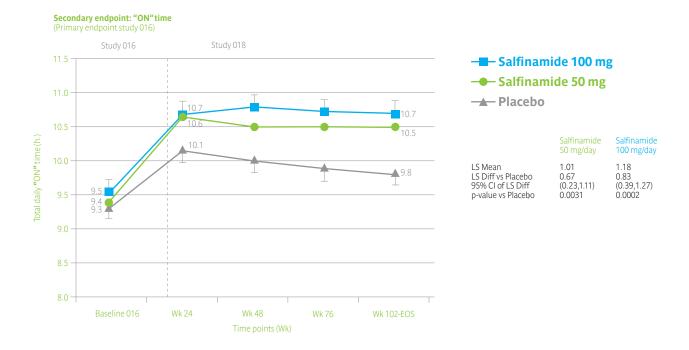
Furthermore, tertiary endpoints showed improvement (p<0.05) at the two-year endpoint on

- symptoms of depression (GRID HAMD)
- quality of life (PDQ-39)

Newron is excited about the outcome of the 24-months study, as results in such a rigorously controlled long-term double-blind study are particularly relevant as they address key questions in terms of long-term safety and maintenance of the effect on motor function of safinamide over time. These results may offer new hope to patients with Parkinson's disease as they need to take medications for long periods of time.

The results from both early and advanced Parkinson's disease patients underline safinamide's potential to be used as adjunctive therapy along the continuum of Parkinson's disease.

Study 018: Safinamide maintained clinical effect over two years



SETTLE study (SafinamidE Treatment as add-on To LEvodopa in idiopathic Parkinson's disease with motor fluctuations):

On May 7, 2009, Newron and Merck Serono reported the initiation of this study, that would evaluate the efficacy and safety of a dose range of safinamide (50–100 mg once daily) as add-on therapy to a stable dose of levodopa, in mid- to late-stage Parkinson's disease patients with motor fluctuations compared to placebo.

SETTLE is a six-month (24-week), randomized, double-blind, international phase III trial. The trial will involve more than 450 patients with mid- to late-stage idiopathic Parkinson's disease (more than five years of disease duration) treated with a stable dose of levodopa for at least four weeks who have motor fluctuations with more than 1.5 hours of "OFF" time during the day. Additionally, patients may be receiving concomitant treatment with stable doses of a dopamine agonist, a COMT inhibitor, an anticholinergic and/or amantadine. After a four-week levodopa dosage stabilization phase, study participants will be randomized in one of the two arms of the trial (1:1) to receive either safinamide or matching placebo tablets, as adjunctive treatment to levodopa therapy.

The primary endpoint of the trial is the change in daily "ON" time, as assessed by the recordings of diary cards maintained by patients after prior training, from baseline to week 24. Secondary endpoints include changes in measures of activities of daily living, global clinical status and health-related quality of life instrument.

The MOTION study (Safina Mide add-On To dopamine agonist for early Idiopathic Parkins ON's disease), another randomized, double-blind, international phase III trial for safinamide as add-on to dopamine agonist therapy, is currently ongoing. It has an associated 18-month double-blind extension trial.

The long-term safety data provided by the extension study 018 are part of the clinical development programme of safinamide, together with completed studies 015, 016 and 017, as well as the ongoing MOTION and SETTLE studies. This clinical programme is designed to support an application for marketing authorization of safinamide as an add-on therapy of dopamine agonist therapy in patients with early Parkinson's disease and as an add-on of levodopa therapy in patients with advanced Parkinson's disease.

\* For details please see: http://www.clinicaltrials.gov/ct2/show/NCT01113320?term=safinamide&rank=1

<sup>\*\*\*</sup> For full quote please see Newron press releases dd.
February 3, 2009: http://www.newron.com/uploads/SAfinamidePIIIresultsNewronENG3Feb.pdf
November 4, 2010: http://www.newron.com/uploads/NewronSafinamidestudy018PressReleaseEnglishFinal.pdf
\*\*\*IMS Knowledge Link, IMS Health Inc. 2010

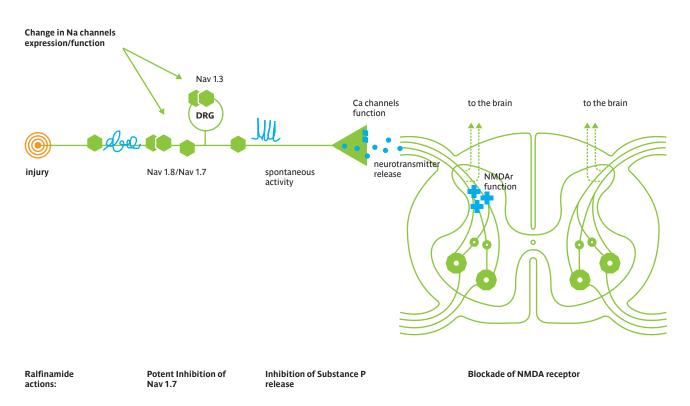
### Ralfinamide

Based on the view that ralfinamide's pharmacology is extremely exciting and predictive of potency, Newron is intending to develop the compound in appropriate neuropathic pain indications and/or as an antipsychotic.

#### **Profile**

Ralfinamide is a unique New Chemical Entity that is believed to mediate its potent analgesic effect through the inhibition of sodium channels, including Nav I.7, N-type calcium channels and NMDA receptors. In addition to its well-established analgesic effects in models of peripheral pain, ralfinamide has lately been shown to be efficacious in a preclinical model of central pain, thus indicating that its analgesic effects in chronic pain may be mediated through modulation of central pain mechanisms. This indicates a broad spectrum of analgesic activity involving both peripheral and central mechanisms.

Peripheral and central changes in neuropathic pain



Ralfinamide shows linear kinetics and excellent drugability characteristics. In models of neuropathic pain it has shown long-lasting allodynic and antihyperalgesic effects and was not associated with the development of tolerance when given chronically. Ralfinamide does not require titration and is administered twice a day.

### **Key achievements**

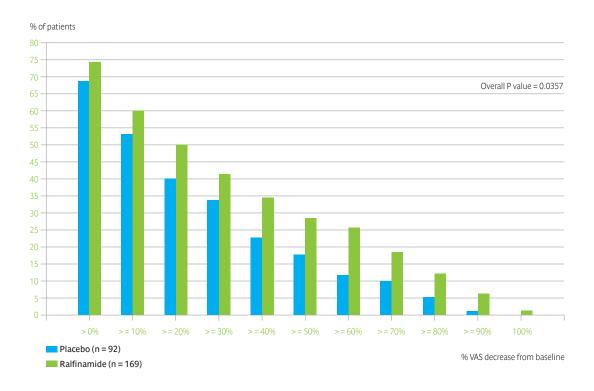
#### Phase II

In 2008, Newron presented the results from the detailed analyses of the phase II trial of ralfinamide in patients with neuropathic pain at the American Academy of Neurology 60th Annual Meeting in Chicago (for trial design and detailed results, see http://www.newron.com/uploads/NewronRalfinamidePhaseIIresultsAprili6.pdf).

The trial had been designed to include patients with numerous forms of Peripheral Neuropathic Pain (PNP) conditions to determine if the multiple mechanisms of action of ralfinamide would show a unique benefit in any specific neuropathic pain condition. In the overall study population ralfinamide was well tolerated and safe, with reported side effects comparable to placebo. More importantly, ralfinamide was statistically significantly superior compared to placebo on the mean change in the Visual Analog Scale (VAS) and Likert Scale – measures of the severity of pain as rated by the patient. Responder rates were significantly increased compared to placebo and patients experienced a significant improvement in the quality of sleep and their performance of daily activities.

Ralfinamide efficacy in overall study population in phase II PoC trial

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



A review of the trial population indicated that the largest group, 96 out of 272 patients included, was experiencing neuropathic pain due to Nerve Compression/Nerve Entrapment (NCET). In these patients, treatment with ralfinamide compared to placebo was demonstrated to be highly efficacious as judged by the reduction in the intensity of pain as measured by the VAS and LPS in analyses of mean change from baseline, as well as responder rates in all patients with NCET included in the trial (ITT population).

Upon further assessment of the results for the subpopulation and consultation with European and American health authorities, Newron decided to progress the ralfinamide development towards Neuropathic Low Back Pain and start a phase IIb/III study, SERENA, in such indication.

### Phase IIb/III - SERENA\* study

The negative results seen with ralfinamide in the SERENA study, announced in May 2010, were unexpected and extremely disappointing. The phase IIb/III study, which was initiated at the end of 2008, recruited 411 patients with Neuropathic Low Back Pain (NLBP). The top-line results, which continued to show that the compound was safe and well-tolerated, demonstrated no statistical significance in efficacy against placebo. This outcome is in contradiction to results that had previously been achieved in the phase II study in mixed neuropathic pain, including NLBP patients. All associated work on the SERENA trial and its extension have been halted.

### Effects of ralfinamide on central pain

In September 2009, Newron reported positive results from a preclinical study showing that ralfinamide has statistically significant analyseic benefits against spontaneous chronic pain in an experimental model of central pain. The study was conducted by Professor Ze'ev Seltzer, Canada Senior Research Chair in Genetics of Pain, University of Toronto, Canada, and was presented on September 10, 2009 at the Sixth International Congress of the European Federation of IASP Chapters (EFIC), Lisbon, Portugal.

The study showed that ralfinamide significantly suppressed spontaneous pain behaviour, expressed as self mutilation of the denervated hindpaw of a rodent, providing evidence that ralfinamide is also a centrally acting analgesic. These effects were recorded both when ralfinamide was administered orally twice daily for one week before the surgery and stopped thereafter ("preemptive analgesia" regimen), as well as when it was administered only for 42 days postoperatively ("palliative analgesia" regimen). Analgesic effects were still noted 21 days after stopping drug administration on day 42. In this model of central pain, ralfinamide uniquely showed significant superiority compared to placebo, while pregabalin, used as an active control, failed to show significant benefits compared to placebo.

Due to the CNS origin of pain in this rodent model, the analgesic effects of ralfinamide must have targeted mechanisms of neuropathic pain in the CNS. The CNS target of this compound is yet to be discovered, but chronic alterations in the function of neurons and glial cells in the CNS are a seminal part of the development and maintenance of neuropathic pain in rodent models and in many pain syndromes in humans, including Neuropathic Low Back Pain. Moreover, these new findings open the potential for new therapeutic perspectives for ralfinamide in central pain syndromes that are known to be refractory to current analgesics.

<sup>\*</sup> SERENA: Safety and Efficacy of Ralfinamide in nEuropathic low back paiN pAtients

Since reporting the outcome of the SERENA trial, Newron's US Advisory Board met to undertake a thorough review of the preclinical and clinical data. The Board concluded that the development of ralfinamide in pain should continue based on the exciting pharmacology, the evidence of efficacy in the phase II study, and the excellent safety profile seen in the SERENA trial. The Board recommended that its efficacy be evaluated in neuropathic pain conditions, especially those with a central component. Therefore, the Company has decided to keep the long-term preclinical studies ongoing, which are required for a potential filing of the compound at a later point in time. Newron is currently evaluating the further development of ralfinamide in pain and psychiatric diseases.

### HF0220

HF0220 has potential to become the first in-class disease-modifying agent for neurodegenerative diseases.

#### **Profile**

HF0220 is a naturally occurring human steroid ( $7\beta$ -hydroxy-epiandrosterone), which has shown strong neuroprotective effects in several experimental models of neurotoxicity, both in vivo and in vitro.

### **Key achievements**

#### Phase II

In 2008, Newron announced the results of its phase II safety and tolerability study with HF0220 in patients with mild to moderate Alzheimer's disease (AD).

This 28-day, multinational, randomized, double-blind, placebo-controlled pilot study was performed in 42 patients in 10 centres in the UK, Sweden and India. HF0220 (n = 29) was administered at doses ranging from 1 to 220 mg per day versus placebo (n = 13). Patients were allowed to continue their current Alzheimer's disease medication.

The data from the titration period were overseen by an independent Data Safety Monitoring Board.

The safety analysis of the data demonstrated that HF0220 in the dose range indicated was very well tolerated and could not be differentiated from placebo.

The very high rate of completion of the study by patients, the absence of clinically relevant or statistically significant changes in safety measures, and the very low number of patients experiencing any adverse events, indicate that HF0220 can be safely administered to patients with Alzheimer's disease who often experience multiple concomitant illnesses and who are more susceptible to the side effects of their usual medications.

HF0220 has strong potential to reduce the secondary progressive damage associated with neurodegenerative conditions. In fact, HF0220 has demonstrated in the past to be neuroprotective at nanomolar concentrations in several in vitro and in vivo experimental models, against multiple challenges. Additional experiments have been performed to further support this potential.

### **Pharmacology**

In 2010, a significant amount of additional pharmacological work was performed, to evaluate the compound's potential in ameliorating cognitive deficits in various neurodegenerative diseases. In 2011, Newron plans to perform further studies to confirm the benefits in models of stroke/trauma-induced cognitive impairment predictive of possible efficacy in post-stroke patients with cognitive deficits and to evaluate the effects on neurogenesis. Should these works prove to be successful, a PoC trial could be started in 2012, conditional to sufficient funding or partnering of the compound.

### NW-3509

NW-3509, potentially the first selective sodium channel blocker being specifically developed for schizophrenia therapy – a novel approach for the treatment of psychiatric disorders and a major opportunity in the USD 23bn market of antipsychotic treatments.

"The addition of NW-3509 to conventional schizophrenia treatments might enhance their efficacy, provide additional benefits such as cognitive improvement, and potentially reduce serious side effects such as weight gain, sexual dysfunction, cognitive and emotional blunting, as well as extrapyramidal symptoms." Ravi Anand, Newron's CMO

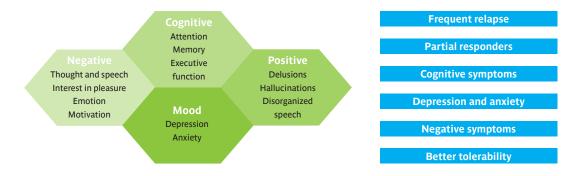
#### **Profile**

NW-3509 is an innovative compound from a new chemical class, stemming from Newron's ion channel programme. Its mechanism of action involves selective modulation of voltage-gated sodium channels (VGSC) that have been implicated in the pathogenesis of psychiatric and neurological disorders. It has been hypothesized that the occurrence of psychotic symptoms is associated with firing abnormalities in specific brain areas. VGSC modulators might stabilize such membrane hyperexcitability and normalize neuronal functions.

The compound therefore is completely unlike any other second generation antipsychotic under development for the treatment of schizophrenia, mostly conventional dopaminergic- and serotoninergic-blockade-targeted compounds, producing only limited benefits, yet accompanied by major side effects.

The compound is intended to be developed as an adjunctive treatment for patients with schizophrenia experiencing inadequate benefit from their current antipsychotic treatment and is nearing the completion of IND-enabling studies.

Schizophrenia is a devastating psychiatric disease where several major needs remain unmet by current medications, such as cognitive symptoms, refractory patients and co-morbidities such as anxiety and depression.



Preclinical studies in an animal model (PPI) that closely mimics the impairment of information processing present in patients have demonstrated that NW-3509 significantly improves this deficit, induced by pharmacological agents and stress. Notably, PPI deficits in schizophrenic patients correlate with core symptoms of psychoses, such as: thought disorder, distractibility, cognition. So far, only clozapine, the most clinically effective antipsychotic, shows complete reversal of PPI in patients. The combination of subthreshold doses of NW-3509 and risperidone achieves a complete normalization of PPI deficits, like clozapine, but with potentially less side effects than the usual/standard doses of existing antipsychotics.

Efficacy of NW-3509 per se has been demonstrated in other animal models of psychosis, aggression, mania and in experiments where cognition was impaired by drugs, or by natural means.

### **Key achievements**

In 2010, Newron reported the positive outcome from its Pre-IND and CTA meetings with the US FDA and the UK MHRA for NW-3509. The meetings with the regulatory authorities indicated their acceptance of the pharmacological, toxicological and pharmaceutical information collected in IND enabling studies to date, as well as the proposed clinical development plan for phases I and II. Newron has got close to finalize the IND application which is expected to be filed early in QII/2011, followed by the start of clinical development in man, conditional to sufficient funding or partnering of the compound.

### **Newron's Team**

Upon disclosure of the SERENA trial results in May 2010, Newron has reviewed and reprioritized its spending, to extend its cash reach.

While spending in the first half year of 2010 has been dominated by the completion of the SERENA study and the termination of the 40-week extension study of SERENA, the remainder of the year saw significantly decreased spending. Amongst the actions taken was a significant reduction in research and general & administrative expenses, including personnel.

Effective July 5, 2010, Newron has placed 16 employees in "Cassa Integrazione Guadagni", a government-supported programme under Italian law, which allows for employees to be kept in a contractual relationship, without any material cost to the Company. In addition, temporary employment agreements were not prolonged and employment agreements with several managers were terminated in mutual agreement. All in all, the cost of 21 employees was taken off the Company's books.

The number of fully paid employees by end of 2010 was 21, as compared to 50 by end of 2009. Another 12 employees are in "Cassa Integrazione Guadagni" as per December 31, 2010.

### **Funding**

On December 22, 2010, Newron announced a private placement of 660,395 newly issued shares to Great Point Partners, LLC, raising CHF 3.5m, to further capitalize the company.

By subscribing to the issuance, Great Point Partners' managed funds reached a 9.1% holding in Newron, post closing of the transaction. The subscription price of the new shares was set at CHF 5.25 per share, representing a 3.7 % discount to the closing price of Newron's shares on December 16, 2010 of CHF 5.45.

In addition to the private placement, Newron during the first quarter of 2010 exercised in a cautious and restrictive manner, utilizing the minimum exercise share price protection, the equity funding agreement that it entered into in 2008 with YA Global Investments, L.P. (YA Global). As per year-end 2010, a cumulated total of 127,233 shares were subscribed under the rules of the agreement by YA Global and funds of EUR 1.7m so generated by Newron.

On February 15, 2011, Newron announced that the Company has received a total payment of EUR 3.7m, as part of a EUR 5m grant for innovative R&D by the Italian government. About 40% of the grant is non-reimburseable. The rest bears interest of 0.5% per year and is required to be fully repaid within 10 years from the grant date.

### **Information for Investors**

### **Stock exchange information**

Symbol	NWRN
Listing	SIX
Nominal value	EUR 0.20
ISIN	IT0004147952
Swiss Security Number (Valor)	002791431

### **Share price data**

Share price data	FY 2010	FY 2009
Number of fully paid-in shares as at December 31	7,264,378	6,557,552
Year high (in CHF)	23.6	28.0
Year low (in CHF)	5.0	13.0
Year-end (in CHF)	5.7	18.7
Loss per share (in EUR)	3.11	3.86
Cash and cash equivalents, other short-term financial assets as at December 31 (in EUR 1,000)	8,087	24,294
Market capitalization as at December 31 (in CHF)	41,261,667	122,626,222

### Major shareholders\*

Goodman & Company
Great Point Partners
3i Group plc
NWB Investissments S.p.r.l.
TVM Life Science Ventures VI GmbH & Co. KG
Aviva Life & Pensions UK Ltd.
Capital Group Companies

<sup>\*</sup> With holdings of more than 3% (to the best of the Company's knowledge)

### Financial calendar

April 5, 2011	Year-end results 2010
April 27, 2011 (first call) April 28, 2011 (second call) April 29, 2011 (third call)	Annual General Meeting, Milan
September 9, 2011	Half-year results 2011

### Contact

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# **Corporate Governance**

Newron's Board of Directors (the "Board") and management are committed to high standards of corporate governance, including transparency and accountability towards its shareholders as well as equal treatment of all shareholders. This report explains how the leadership and the management of the Company are organized and provides background information on the Group's executive officers and bodies, effective December 31, 2010. The report is based on the SIX Swiss Exchange Directive on Information relating to Corporate Governance, in force since July 1, 2009. The Swiss Code of Best Practice for Corporate Governance, in force since July 1, 2002, has also been taken into account, in particular Appendix 1 regarding the recommendations for remuneration levels published in 2007.

# Group Structure and Shareholders

Newron Pharmaceuticals S.p.A. ("Newron" or the "Company") is a joint stock company (Società per Azioni or S.p.A.) organized under the laws of the Republic of Italy.

Since April 17, 2002, it has been registered with the Chamber of Commerce in Milan, Italy, under the name "Newron Pharmaceuticals S.p.A." and with its registered office and principal business office in Bresso (Milan), Italy.

The operations of the Company focus on the discovery and development of pharmaceutical products. Currently, the Company is not generating revenues from the sale of any commercial pharmaceutical product.

The operations of the Company are managed by the Chief Executive Officer (CEO) together with the other members of the management team: the Chief Financial Officer (CFO), the Chief Medical Officer (CMO), the Vice-President Preclinical Research and Development and the Vice-President Strategic Marketing and Head of Legal Affairs.

#### **Related entities**

Newron Suisse SA is a joint stock company (Société Anonyme/Aktiengesellschaft) organized under the laws of Switzerland. The company has been registered with the commercial register of the canton of Basel-Stadt, for an unlimited duration, under the name Newron Suisse SA, since September 13, 2007, and with registered office and principal business office in Basel, Switzerland. The company has a share capital of CHF 100,000, divided into 1,000 fully paid-in registered shares with a nominal value of CHF 100 each. All these shares are held by Newron Pharmaceuticals S.p.A. The operations of the company focus on the research and development, manufacturing and distribution of pharmaceutical products and services. The operations of the company are managed by Luca Benatti as General Manager (Geschäftsführer). Philippe A. Weber is the sole Board member (Verwaltungsrat) of the company.

Hunter-Fleming Ltd. is a limited company incorporated under the laws of England with its registered office and principal business office in Bristol, UK. The company has a share capital of GBP 222,044.64, divided into 22,204,464 ordinary shares of GBP 0.01 nominal value, each. All these shares are held by Newron Pharmaceuticals S.p.A. The operations of the company are managed by Luca Benatti and Stefan Weber as directors. The operations related to the development compounds of the company are taken care of by Newron Suisse SA and Newron Pharmaceuticals S.p.A.

During 2002, Newron contributed EUR 26,000 to the capital of Consorzio Italbiotec (formerly Roberto Lepetit). The Consortium is a non-profit partnership. Its main objective is to promote research and development in the medical and pharmaceutical field. It also undertakes research and other projects for the benefit of the partners, who have joint control, as well as other interested parties. The management has decided not to consolidate the Company's interest in the Consortium.

### **Segment reporting**

The Company is in a start-up stage and its activities are sufficiently homogeneous to preclude the identification of reportable business or geographical segments.

### **Listed company**

The shares of Newron Pharmaceuticals S.p.A., Via Ludovico Ariosto 21, Bresso (Milan), Italy, are listed according to the main standard of the SIX Swiss Exchange AG, Zurich, Switzerland.

Swiss Security Number	2 791 431
ISIN	IT0004 147 952
Common Code	027612440
Ticker Symbol	NWRN
Market capitalization on December 31, 2010	CHF 41,261,667 (based on 7,264,378 outstanding shares and a share price of CHF 5.68)

### Significant shareholders

In line with Swiss law, which is not applicable to Newron as an Italian entity, Newron's by-laws ask shareholders to comply with the Ownership Disclosure Laws as set forth in Article 20 of the Swiss Federal Act on Stock Exchanges and Securities Trading of March 24, 1995, as amended (the "SESTA"), as well as pertinent regulations, including Articles 9 ss. of the Ordinance of the Swiss Financial Market Supervisory Authority on Stock Exchanges and Securities Trading of October 25, 2008, as amended (the "SESTO-FINMA") (all such laws and regulations, the "Swiss Ownership Disclosure Laws"). Such Swiss Ownership Disclosure Laws provide, among other things, that persons who, directly, indirectly or in concert with third parties, acquire or dispose of shares or rights or obligations to acquire shares and thereby attain, exceed or fall below the thresholds of 3%, 5%, 10%, 15%, 20%, 25%, 33  $^{1}$ /3%, 50% or 66  $^{2}$ /3% of the voting rights (whether exercisable or not) of a company shall notify such company and the SIX Swiss Exchange of such transactions within four trading days. Following receipt of such notification, the Company is also obliged to publish the disclosure.

Newron's information about the exact holding position of individual shareholders is depending on and deriving from the reports filed with SIX Swiss Exchange and Newron by such shareholders.

To the best of Newron's knowledge, the following shareholders had holdings of more than 3% of the equity capital or voting rights of Newron as at December 31, 2010. The number of shares shown as well as the holding percentages are based on the last disclosure of shareholding received from the shareholder. Please be aware that since then, the information could have become outdated because of changes that did not trigger notifications:

Shareholder	Note	Holdi	Holding at Dec. 31, 2010		Holding at March 15, 2011	
		share	5	% of equity capital	shares	% of equity capital
Goodman & Company		L 7	08,150	9.7%	708,150	9.7%
Great Point Partners		<u> </u>	_	<3%	660,395	9.1%
3i Group plc		3 5	39,937	7.4%	539,937	7.4%
NWB Investissements S.p.r.l.*		1 4	10,900	5.7%	410,900	5.7%
TVM Life Science Ventures VI GmbH & Co. KG		1 2	274,062	3.8%	274,062	3.8%
Aviva Investors		5 2	235,000	3.2%	235,000	3.2%
Capital Group Companies		5 3	399,000	5.5%		<3%

Link to access individual significant shareholders' reports: http://www.six-swiss-exchange.com/shares/companies/major\_shareholders\_de.html

### **Cross-shareholdings**

As of December 31, 2010, there are no cross-shareholdings in excess of 5% of capital or voting rights with any other company.

As per disclosure of shareholding published Feb. 3, 2010
 As per disclosure of shareholding published Jan. 13, 2011, shares in transit as per Dec. 31, 2010
 As per disclosure of shareholding published Jan. 30, 2010

<sup>&</sup>lt;sup>4</sup> No disclosure in 2010

<sup>&</sup>lt;sup>5</sup> As per disclosure of shareholding published Feb. 3, 2010

<sup>&</sup>lt;sup>6</sup> As per disclosure of shareholding published Jan. 18, 2011

<sup>\*</sup> Indirectly controlled by Apax France VI

### **Capital Structure**

Amount in euro	December 31, 2010	December 31, 2009	December 31, 2008
Number of ordinary shares with par value of EUR 0.20	7,264,378	6,557,552	6,020,508
Share capital	1,452,875.60	1,311,510.40	1,204,101.60
Number of authorized shares with par value of EUR 0.20 (up to)	850,000	850,000	983,141
Authorized share capital (up to)	170,000.00	170,000.00	196,628.20
Number of conditional shares with par value of EUR 0.20 (up to)	526,005	572,436	976,339
Conditional share capital (up to)	105,201.00	114,487.20	195,267.80

As of December 31, 2010, Newron's outstanding share capital was EUR 1,452,875.60, consisting of 7,264,378 ordinary shares with a nominal value of EUR 0.20 each. All shares are fully paid-in.

As per the same date, Newron in addition had an authorized share capital of EUR 170,000, represented by 850,000 shares with a nominal value of EUR 0.20 per share.

These 850,000 shares related to the purchase of 100% of the shares of Hunter-Fleming Ltd. Under the agreement, milestone payments of no more than EUR 17m in new Newron shares could become due to former Hunter-Fleming Ltd. shareholders. The milestones are strictly linked to development and commercialization success mostly of HF0220, the lead compound. So far, none of the milestones have been achieved. Should any milestones be achieved prior to year-end 2012 (with a potential extension to year-end 2013), the amount due in EUR will be split by the market price of the Company's shares at the time, but no less than CHF 34.40, and the resulting number of shares transferred to the former shareholders of Hunter-Fleming.

The authorized capital is valid for a period of five years from the date of the creation by the Company's shareholders' meeting on April 24, 2008.

As per December 31, 2010, Newron had a conditional capital of EUR 105,201.00, represented by 526,005 shares with a nominal value of EUR 0.20 per share.

Of these, 526,005 shares related to the purpose of implementing stock-based incentive compensation plans for employees and directors of the Company and subsidiaries. As for the term of validity and the terms and conditions of the issuance of these equity securities, please see "Stock-based remuneration", page 37.

### **Changes in capital**

On April 24, 2008, the extraordinary shareholders' meeting resolved, among other things, to a) increase the Company's share capital up to a maximum amount of EUR 80,000.00, corresponding to a maximum amount of 400,000 of Newron's ordinary shares, with par value of EUR 0.20 per share, which may be issued and allotted in one or more instalments in exchange for shares in Hunter-Fleming Ltd., to the exclusion, as permitted under Italian Civil Code Article 2441, Paragraph 4, of any pre-emptive right by the Company's current shareholders to subscribe to the share capital increase. Of this capital increase, only 185,742 shares were required and used in the closing of the acquisition of the totality of the share capital of Hunter-Fleming Ltd. By July 31, 2008, the shares not subscribed turned null and void. b) increase the Company's share capital up to a maximum amount of EUR 3,000.00, corresponding to a maximum amount of 15,000 of Newron's ordinary shares, with par value of EUR 0.20 per share, which could be issued and allotted in one or more instalments, to the exclusion, as permitted under Italian Civil Code Article 2441, Paragraph 8, of any pre-emptive right by the Company's current shareholders to subscribe to the share capital increase, to be offered in the subscription to the employees of the Company and to the employees of the Company's subsidiaries. Of this capital increase, no shares were required and used in the closing of the acquisition of the totality of the share capital of Hunter-Fleming Ltd. By August 31, 2008, the shares turned null and void.

c) granting of powers to the Board of the Company, as permitted under Article 2443 of the Italian Civil Code to increase the Company's share capital up to a maximum amount of EUR 170,000.00, corresponding to a maximum amount of 850,000 of Newron's ordinary shares, with par value of EUR 0.20 per share, which may be issued and allotted in one or more instalments at varying subscription prices, to the exclusion, as permitted under Italian Civil Code Article 2441, Paragraph 5, of any pre-emptive right by the Company's current shareholders to subscribe to the share capital increase. The duration of such grant is for five years upon granting date.

d) granting of powers to the Board of the Company, as permitted under Article 2443 of the Italian Civil Code to increase the share capital up to 10% of the Company's share capital, to the exclusion of any pre-emptive right by the Company's current shareholders to subscribe to such share capital increase, as permitted under Italian Civil Code Article 2441, Paragraph 4, second sentence and under Article 6 of the Company's by-laws, as eventually amended. The duration of such grant is for five years upon granting date.

In exercise of the powers granted to the Board in the extraordinary shareholders' meeting as of April 24, 2008, the Board has by decision as of December 3, 2008, reserved 450,334 ordinary shares for the execution of the Standby Equity Distribution Agreement with YA Global Investments, L.P. During 2009, a total of 97,044 shares had been newly issued and delivered to YA Global Investments, L.P., under the agreement, of which 16,242 shares were used to cover the commitment fee under the agreement and 80,802 shares were newly issued in return for about CHF 1.7m proceeds that were received from YA Global Investments, L.P.

As per decision of the Board as of November 27, 2009, the Board has revoked the not yet issued 306,859 shares reserved for the execution of the Standby Equity Distribution Agreement with YA Global Investments, L.P. As per the same date, the Board has decided to increase the Company's share capital, excluding any pre-emptive rights by the Company's current shareholders to subscribe to such share capital increase, by an amount of EUR 88,000.00, corresponding to 440,000 new Newron ordinary shares with a par value of EUR 0.20 per

share. These shares have been subscribed in a private placement announced by the Company as of November 20, 2009, by two groups of leading international institutional investors.

On April 2, 2010, the extraordinary shareholders' meeting resolved, among other things, to a) increase the Company's share capital with option right by the Company's current shareholders pursuant to Article 2441 of the Italian Civil Code, in one or more tranches, up to a maximum par value of EUR 375,844.00, corresponding to a maximum amount of 1,879,220 Newron ordinary shares, of which a maximum of 230,781 new ordinary shares to be offered to employees of the Company or its subsidiaries with exclusion of the option right pursuant to Article 2441, paragraph 8, of the Italian Civil Code

b) revoke, for the non executed part, the December 3,2008 Board resolution – as amended by the November 27,2009 Board resolution – and increase the Company's share capital up to 10% of the Company's share capital as permitted by Article 2441, paragraph 4, second sentence of the Italian Civil Code.

As per decision of the Board as of December 16, 2010, the Board has decided to increase the Company's share capital, excluding any pre-emptive rights by the Company's current shareholders to subscribe to such capital increase, by an amount of EUR 132,079.00, corresponding to 660,395 new Newron ordinary shares with a par value of EUR 0.20 per share. These shares have been subscribed in a private placement announced by the Company as of December 22, 2010, by a leading international institutional investor.

### **Shares and participation certificates**

As of December 31, 2010, Newron's outstanding share capital was EUR 1,452,875.60, consisting of 7,264,378 ordinary shares with a nominal value of EUR 0.20 each. All shares are fully paid in. Each share is entitled to one vote at the shareholders' meeting. All shares are entitled to full dividend rights. In the event of a capital increase through the issuance of new shares, the existing shareholders have subscription rights in proportion to their existing shareholding, unless the shareholders' meeting restricts or excludes such rights for important reasons, in particular in connection with the acquisition of investments or employee participation. Newron has not issued any (non-voting) participation certificates.

### **Dividend-right certificates**

Newron has not issued dividend-right certificates (Genussscheine).

### **Transfer of shares**

The transfer of shares is effected by corresponding entry in securities accounts which record the transfer of financial instruments opened with authorized financial intermediaries and in accordance with the applicable law. Upon registration of the transfer and upon request of the shareholder, the financial intermediaries shall inform the Company of the transfer of shares, and the Company shall update the Libro Soci (Shareholders' Ledger) in accordance with Italian law. A shareholder may ask for his registration at any time. No restrictions apply to the transferability of Newron shares.

### **Convertible bonds**

Newron has no convertible bonds outstanding.

### Stock-based remuneration (stock options, stock appreciation rights)

### 2003 plan

On July 22, 2003, the shareholders' meeting authorized the Board to increase the share capital of the Company by up to EUR 27,734.00 by issuing up to 138,670 shares (after giving effect to subsequent changes in the nominal value of the shares), solely for the purpose of implementing stock-based incentive compensation plans for employees, managers, directors, collaborators of the Company or subsidiaries. Stock options may be granted without charge and the exercise price for such options, inclusive of share premium, is determined by the Board in light of the "normal value" of the shares, as determined in accordance with Italian tax law applicable at the time of issuance. However, the exercise price may not be lower than EUR 19.60 per share (of which EUR 19.40 represents a share premium) or the amount of total shareholders' equity per share, considering as well the market trend of the shares during the previous six months. The Board is authorized to determine the beneficiaries and the terms of any stock option plan. Newly issued shares pursuant to this stock option plan are not subject to pre-emptive rights of existing shareholders pursuant to Article 2441 of the Italian Civil Code.

In accordance with the above authorizations, in October 2003 the Board adopted a stock option plan pursuant to which, as of December 31, 2010, options to purchase 106,805 shares have been granted to certain employees and directors of the Company, including certain of the Company managers.

Of these 106,805 options

- 84,805 options have expired by December 31, 2010 and have been converted into 63,603 new options in line with the 2009 plan (for details see "2009 plan", page 38);
- 22,000 options are exercisable at the price of EUR 35.03, of which EUR 34.83 represent a share premium. These options are fully vested and will expire by December 31, 2011.

### 2004 plan

On May 31, 2004, the shareholders' meeting authorized the Board to further increase the share capital of the Company by up to EUR 27,040 by issuing up to 135,200 shares (after giving effect to subsequent changes in the nominal value of the shares) solely for the purpose of implementing stock-based incentive compensation plans for employees and directors of the Company and subsidiaries. In accordance with this authorization, in May 2004 the Board adopted a stock option plan pursuant to which, as of September 30, 2006, a member of the Board has been granted options to purchase 135,200 shares at the exercise price of EUR 20.00 per share, of which EUR 19.80 represent a share premium. These options have expired by April 30, 2009, and have been converted into 101,400 new options under the 2009 plan (for details, see "2009 plan", page 38).

### **2007** plan

On April 23, 2007, the shareholders' meeting resolved to increase the share capital for payment by up to EUR 56,800, in one or several steps, and to issue up to 284,000 shares of a nominal value of EUR 0.20 per share, for subscription prior to December 31, 2012. The shares are to serve one or several new stock-based remuneration schemes for employees and other qualifying persons, at the discretion of the Board. In accordance with this authorization, in June 2007 the Board adopted a stock remuneration plan pursuant to which, as of December 31, 2010, options to purchase 105,000 shares had been granted to certain employees, consultants and members of the Board, of which 3,750 options have been returned to the Company due

to the entitled employees leaving the Company, in 2010. Therefore, at December 31, 2010, a total of 101,250 options have been granted to employees, consultants and members of the Board.

Of these 101,250 options

- 44,250 options are exercisable at the price of EUR 36.83 per share, of which EUR 36.63 represent a share premium. All these options are fully vested and will expire by June 18, 2012;
- 4,500 options are exercisable at the price of EUR 17.81 per share, of which EUR 17.61 represent a share premium. These options will vest on July 18, 2011, and will expire by December 31, 2012;
- 46,500 options are exercisable at the price of EUR 13.43 per share, of which EUR 13.23 represent a share premium. These options will vest on January 22, 2012, and will expire by December 31, 2012;
- 6,000 options are exercisable at the price of EUR II.66 per share, of which EUR II.46 represent a share premium. These options will vest on December 19, 2011, and will expire by December 31, 2012.

At the discretion of the Board, the stock-based remuneration can alternatively be allocated via stock appreciation rights with the same vesting period and the same exercise price as for the stock options. Pursuant to the stock appreciation rights programme, stock appreciation rights to purchase 122,000 shares had been granted to certain employees, consultants and members of the Board, of which 8,250 stock appreciation rights have been returned to the Company due to the entitled employees leaving the Company, in 2010. Therefore, at December 31, 2010, a total of 113,750 stock appreciation rights have been granted to employees, consultants and members of the Board.

Of these 113,750 stock appreciation rights,

- 109,250 rights are exercisable at the price of EUR 36.83 per share. These rights are fully vested and will expire by June 18, 2012;
- 4,500 rights are exercisable at the price of EUR 17.81 per share. These rights will vest on July 18, 2011 and will expire by December 31, 2012.

### 2009 plan

By decisions of the Board dated March 10, 2009, and April 16, 2009, a new programme was established. The new plan takes into consideration the material changes in the tax treatment of stock remuneration programmes under Italian law and the financial markets' adverse development in the last two years.

As a consequence, all holders of stock options or stock appreciation rights under the 2003, 2004 and 2007 plans from the day of the Board decision onwards and prior to the date of the expiration date under the 2003, 2004 and 2007 plans at their discretion can opt to convert four of the stock options or stock appreciation rights they have been assigned under such plans into three new stock options under the 2009 plan. These three new stock options come with a renewed 3 years' vesting period and will expire uniformly as at December 31, 2012. Their exercise price will be the market price at the date of assignment. The conversion of the stock options or stock appreciation rights under the 2003, 2004 and 2007 plans will, to the extent that the holders of the stock options or stock appreciation rights have not opted for the conversion prior to the date of expiration under the 2003, 2004 and 2007 plans, be automatically converted to new stock options under the 2009 plan by the date of expiration of the stock options or stock appreciation rights under the 2003, 2004 and 2007 plans.

By December 31, 2010, no holders of stock options or stock appreciation rights under the 2003, 2004 and 2007 plans have exercised such option to convert their instruments into new stock options under the 2009 plan.

By December 31, 2010, options to acquire a total of 220,005 shares, of which 84,805 options under the 2003 plan and 135,200 options under the 2004 plan, had expired and were automatically converted into options to aquire a total of 165,003 shares under the 2009 plan.

Of these 165,003 options

- 13,751 options have been returned to the Company due to the entitled employees leaving the Company, in 2010;
- 151,252 options are exercisable at the price of EUR 11.50 per share, of which EUR 11.30 represent a share premium. These options will vest on April 15, 2012, and will expire by December 31, 2012.

By decision of the Board dated April 16, 2009, options to acquire a total number of 9,752 shares under the 2009 plan have been granted to certain employees. All these options will vest on April 15, 2012. The exercise price will be EUR 11.50 per share, of which EUR 11.30 represent a share premium. The options will expire by December 31, 2012.

The total volume of granted stock options under the above programmes is 284,254 options to acquire one share, each, at nominal value of EUR 0.20, each. This is an equivalent of 3.9 % of the total number of fully paid-in ordinary shares of the Company. In addition, 113,750 stock appreciation rights to acquire one share, each, have been granted, an equivalent of 1.6 % of the fully paid-in ordinary shares of the Company.

The total number of rights granted to employees, members of the Board and consultants thus adds up to 5.5% of the fully paid-in ordinary shares of the Company.

## **Board of Directors**

### **Members of the Board of Directors**

The Company's by-laws establish that the Board shall consist of a minimum of seven (7) and a maximum of eleven (II) members. As per December 3I, 20I0, the Board was comprised of eight (8) directors. All of these directors were elected on April 24, 2008, for a three-year term expiring on the date of the shareholders' meeting scheduled to approve Newron's financial statements for the year ending December 3I, 20IO. All Newron Board members are due for re-election at the same time. Board members can be re-elected for an unlimited number of terms. In case of replacements of Board members, the replacing new members take over the mandate for the left period of the leaving member. The shareholders' meeting elects the new members by individual vote.

The following table sets forth certain information about the Company's directors:

Name	Position	Member since	Relevant external positions
Rolf Stahel	Chairman, non- executive director	2004	Former CEO of Shire Pharmaceuticals Group plc; non-executive BoD chairman of Connexios Life Sciences Pvt Ltd, Cosmo Pharmaceuticals S.p.A. and EUSA Pharma Inc.; executive BoD chairman of Chesyl Pharma Ltd; member of the Advisory Board of Imperial Business School, Imperial College London
Luca Benatti	Managing Director, CEO, executive director	1998	Former Head of the Molecular Neurobiology Department at Pharmacia & Upjohn S.p.A.
Francesco Parenti	Non-executive director	1999	Former Chief Scientific Officer of Vicuron Pharmaceuticals; partner and director in Livolsi & Partners
Renée Aguiar- Lucander	Non-executive director	2006	Partner of Omega Funds, non-executive chairman of Egalet Ltd, BoD member of ImpactRx Inc, Sophion Bioscience A/S and NsGene A/S
Hans-Joachim Lohrisch	Non-executive director	2008	Former CEO of Altana Pharma and member of the Board of Management of ALTANA AG; BoD member of Ennar Pharma, Harvester Capital and during 2010 Inview Technology
Patrick Langlois	Non-executive director	2008	Former CFO and Vice-Chairman of the Management Board of Aventis; General Partner of PJL Conseils; BoD member of Shire Pharmaceuticals Inc., Scynexis, Nanobiotix and Exonhit Therapeutics
Ragnar Linder	Non-executive director	2008	Former Managing Director of Amgen in Scandinavia; CEO of Pygargus AB; BoD member of Umecrine Mood AB and Umecrine Cognition AB
Hanns Moehler	Non-executive director	2008	Vice-Director of Swiss National Center of Neuro- science Research, member of the Swiss Academy of Medical Sciences and the European Academy of Sciences; Professor em. University of Zurich and Swiss Federal Institute of Technology (ETH) Zurich

None of the non-executive members of the Board as per December 31, 2010, was a member of Newron's management in the three financial years preceding the current year. None of the Board members had significant business connections with the Company or its subsidiaries, unless mentioned below or in section "Compensation, Shareholdings and Loans" (page 51). None of the Board members exercises official functions or holds political posts.



Rolf Stahel has been the Chairman of the Board since 2004. Mr. Stahel, a Swiss national, has a degree in Business Studies from Kantonsschule Lucerne, Switzerland, and has attended the Advanced Management Programme at Harvard Business School. From March 1994 to March 2003, Mr. Stahel was the Chief Executive Officer of Shire Pharmaceuticals Group plc (now Shire plc). He was also a Main Board Director and Chairman of

the Executive Committee of Shire Pharmaceuticals. From 1967 to 1994, he worked for The Wellcome Foundation (later Wellcome plc) in Switzerland, Italy, Thailand, Singapore and the United Kingdom. From 1990 to 1994, Mr. Stahel was Wellcome's Director of Group Marketing, based in London and Beckenham, with responsibility for group strategy, R&D portfolio evaluation, marketing of existing and new products and business development. In this position, Mr. Stahel reported to the Chief Executive Officer of Wellcome. From 1979 to 1990, he was a Regional Director of Wellcome, based in Singapore, with responsibility for 18 Pacific Rim countries. In addition to his position at Newron, Mr. Stahel is also the non-executive Chairman of the Boards of Connexios Life Sciences Pvt Ltd, Cosmo Pharmaceuticals S.p.A. and EUSA Pharma Inc. Mr. Stahel is also the Executive Chairman of Chesyl Pharma Ltd. This company supports the services provided by Mr. Stahel. Mr. Stahel was the recipient of the Chief Executive Officer of the Year Award for the global pharmaceutical industry, awarded by Informa, in 2001, and the "Most Significant Contribution to UK Life Sciences", awarded by TechMark, Mediscience, sponsored by Evolution Beeson Gregory in association with the London Stock Exchange and the BIA (UK Biotech Association), in 2003. Rolf Stahel joined on November 1, 2007, the Advisory Board of Imperial College's Business School, London. He was awarded the UK BioIndustry Association's (BIA) Lifetime Achievement Award for 2009. Permanent management and consultancy functions for important Swiss and foreign interest groups besides those mentioned: none.



**Luca Benatti**, the Company's Managing Director and Chief Executive Officer since 1998, founded Newron in 1998 along with Dr. Ruggero Fariello and Dr. Patricia Salvati. He has more than 15 years of scientific experience in molecular biology and neurobiology. Dr. Benatti has a degree in molecular biology from Milan University. He started his career as a scientist for Farmitalia Carlo Erba, where he held several positions in its

biotechnology department. Following a postdoctoral training at the Oxford University, Dr. Benatti was the head of the Molecular Neurobiology Department at Pharmacia & Upjohn S.p.A., holding that position until he resigned to found Newron in 1998. He holds several patents and has authored publications in peer-reviewed journals. Luca Benatti is a member of Emerging Enterprise Board of EuropaBio, of the Italian Association of Biotechnology and since 2004 jury member of the European Biotechnica Award. He is Italian by nationality. Permanent management and consultancy functions for important Swiss and foreign interest groups besides those mentioned: none.



Francesco Parenti, a director since 1999, holds a PhD in biological sciences from the University of Milan and has conducted postdoctoral research at Yale University. He is currently a partner and director of Livolsi and Partners, a merchant bank. Previously, he was the Chief Scientific Officer of Vicuron Pharmaceuticals, Inc. (formerly, President and Chief Scientific Officer of Biosearch Italia prior to its merger with Versicor in 2003 which created

Vicuron). A biologist with over 30 years of experience in the pharmaceutical industry, Dr. Parenti has served as Vice-President of Hoechst Marion Roussel, President (Europe, Middle East and Africa) for Marion Merrell Dow and General Manager of Dow Lepetit Italy and has overseen the creation of the Antinfective Research Center at the Merrell Dow Research Institute. He has also served on the board of directors of several biotechnology companies. Dr. Parenti is inventor or coinventor of about thirty patents. He is Italian.

Permanent management and consultancy functions for important Swiss and foreign interest groups: none.



Renée Aguiar-Lucander has been a director since November 2006. Since February 2009, she has been a partner in Omega Funds, a secondary fund focused on healthcare. Within Omega, she heads up the London office and is responsible for both private and quoted healthcare portfolio companies. As such Ms. Aguiar-Lucander serves on the Board of selected, privately held Omega investments. Between 2005 and 2009, she was a

partner in the venture capital team of 3i Group plc, a leading private equity and venture capital firm with around USD 10 billion of assets under management, where she was a senior member of the European portfolio management team with a focus on healthcare assets. From 2000 to 2003 she was a Managing Director in corporate finance with Lehman Brothers, focusing primarily on the technology, media and communications sectors, following which she worked as an advisor for private equity funds prior to joining 3i Group in January of 2005. Prior to joining Lehman Brothers in 1999, Ms. Aguiar-Lucander worked for Deutsche Bank and Alex. Brown & Sons, both in the United States and in Europe, focusing on M&A and private/public capital-raising for growth companies. Ms. Aguiar-Lucander has a bachelor's degree in finance from Stockholm School of Economics and a master's degree in business administration from INSEAD. In addition to her position at Newron, Mrs. Aguiar-Lucander is non-executive chairman of Egalet Ltd and Board member of ImpactRx Inc, Sophion Bioscience A/S and NsGene A/S. She is of Swedish nationality.

Permanent management and consultancy functions for important Swiss and foreign interest groups: none.



Hans-Joachim Lohrisch has been a director since January 2008. He was CEO of Altana Pharma AG from 1999 to 2006 and a member of the Board of Management of ALTANA AG, a DAX 30 company, from 1999 to 2006. In the course of the spin-out and take-over of Altana Pharma by Nycomed, he joined the Board of Nycomed SA, a position that he resigned from end of January 2008. Prior to Altana, Mr. Lohrisch was at Merck KGaA for 21

years. Between others his experience and responsibilities embraced: R&D project management, licensing and M&A, General Manager Pharma Portugal, Head of International Strategic Marketing, Country Manager Pharma Germany, CEO Merck Generics Group (London) and Division Head of Pharma Ethicals with worldwide business responsibility. Mr. Lohrisch served as a member of the Pharma Executive Committee from 1993 to 1999. His career in the pharmaceutical industry spans a total of 30 years. He holds a doctorate in organic chemistry from Bonn University and graduated from INSEAD's AMP programme. Hans-Joachim Lohrisch is a Board member of Ennar Pharma and Harvester Capital and during 2010 served on the Board of Inview Technology. He is German.

Permanent management and consultancy functions for important Swiss and foreign interest groups: none.



Patrick Langlois, a director since April 2008, was the CFO and Vice-Chairman of the Management Board of Aventis from 2002 to 2005 and served for 30 years in various senior financial functions in Rhône-Poulenc and Aventis Group in France and the USA. Prior to that, he was with Banque Louis-Dreyfus. He is presently General Partner of PJL Conseils, a consulting firm in healthcare. He holds a doctorate in economics from University

of Rennes (France). Patrick Langlois is a Board Member of Shire Pharmaceuticals Inc (UK), Scynexis (USA), Nanobiotix (France) and Exonhit Therapeutics (France). He is French. Permanent management and consultancy functions for important Swiss and foreign interest groups: none.



Ragnar Linder, a director since April 2008, was the Managing Director of Amgen in Scandinavia from 2001 to 2004. Prior to that, he was with the Sanofi-Aventis Group from 1980 to 2001 in senior positions in Europe and the USA. His final position was director New CNS products in the Global Marketing and Medical Group of Aventis. He is now the CEO and member of the Board of Pygargus AB, a CRO acting in the Scandinavian

region, and serves in the Boards of Umecrine Mood AB and Umecrine Cognition AB. He brings to Newron's Board sales and marketing experience of more than 25 years in international pharmaceutical industry. He has a master degree in science from Royal Institute of Technology, Stockholm. Ragnar Linder is Swedish.

Permanent management and consultancy functions for important Swiss and foreign interest groups: none.



Hanns Moehler, a director since April 2008, is Vice-Director of the Swiss National Center of Neuroscience Research, of which he was the first director from 2000 to 2004. He held a professorship in the Department of Applied Biosciences, ETH Zurich, and in the Medical Faculty of the University of Zurich, where he was director of the Institute of Pharmacology from 1988 to 2005. Prior to his academic positions, Hanns Moehler served as

a Vice-Director in the Research Department of Hoffmann-La Roche, Basel, Switzerland. Prof. Moehler's research is devoted to the therapeutic neuroscience of brain disorders. He is a member of the Swiss Academy of Medical Sciences and the European Academy of Sciences. Hanns Moehler is German and Swiss.

Permanent management and consultancy functions for important Swiss and foreign interest groups: none.

### **Responsibilities and organization**

Pursuant to the Company's by-laws, the Board has complete power over the administration of the Company's business and it has the power to take actions deemed advisable for the pursuit of the Company's corporate purposes. Within the limits prescribed by Italian law, the Board may delegate its general powers to an executive committee and/or any managing director. The Board has delegated certain of its powers, excluding, amongst others, the conduct of material litigation, material non-budgeted expenditure, material agreements, entering into joint ventures, M&A, licensing, material lending agreements, variation in share option schemes, approval of the annual budget and actions on the intellectual property exceeding ordinary administration to the Company's Managing Director, Luca Benatti, whose functions include coordination and supervision of the Company's business. Although the Company's by-laws specifically permit the Board to appoint an executive committee, this right has not been exercised by the Board. The Board also determines the duration of the term of the Company's Managing Director. The Chairman of the Board, any Deputy Chairman as well as any Managing Director are the legal representatives of the Company. The Board and any Managing Director may delegate the power to carry out certain acts within the scope of their respective authority.

Pursuant to the Italian Civil Code, Newron is also required to appoint a supervisory body referred to as the Board of Statutory Auditors (see "Board of Statutory Auditors").

The Company's directors are elected at the Company's annual ordinary meeting of shareholders for a term of three financial years. The Company's directors may be re-elected for an unlimited number of consecutive terms. If the shareholders fail to elect a Chairman at the shareholders' meeting, the members of the Board elect, from amongst themselves, the Chairman, and one or more Deputy Chairmen and/or Managing Directors.

Under Italian law, directors may be removed from office at any time by a shareholder's resolution. However, if removed without just cause, such director may have a claim for damages against Newron. The Company's directors may resign at any time by written notice to the Board of Statutory Auditors. Further to such removal or resignation, the Board may appoint substitute directors, subject to the approval of the Company's Board of Statutory Auditors, who will serve until the next general meeting of shareholders.

### **Meetings**

Meetings of the Board may be called by the Company's Chairman or any Deputy Chairman, Managing Director or two directors by notice setting forth the matters to be discussed at the meeting, to be sent at least five days (or in cases of urgency, at least one day) before the date of the meeting. The minimum quorum required for Board meetings is a majority of the Company's directors in office. Board meetings are chaired by the Company's Chairman or, if the Chairman is absent or otherwise unable to act, by any Deputy Chairman or the Company's Managing Director. Resolutions are adopted by a majority vote of the directors present at the meeting.

In 2010, a total of seventeen meetings of the full Board were called, of which six were held physically and eleven via phone. In addition, the nomination and compensation subcommittee convened for three times and the audit subcommittee for two times. While the physical meetings are called on a bi-monthly basis and usually take a business day, the phone Board meetings are called upon requirement and usually take between one and three hours. The subcommittee meetings usually take between half an hour and three hours. The subcommittees have a predetermined annual agenda to ensure that important reviews take place at the appropriate time throughout the year and they undergo a periodic self-review to ensure continued effectiveness.

Members of senior management are regularly attending the Board and subcommittee meetings to report on areas of the business within their responsibility, to present proposals for decision and to participate, if requested by the Board, to the discussion prior to a vote being taken by the Board.

### Information and control instruments

The members of the Board receive on a monthly to bi-monthly basis a comprehensive management report designed to provide them with an update on business activities in general and relevant developments with regard to clinical trials and preclinical activities, the collaboration with licensing partners, as well as on legal, business development and financial matters. The reports are subject to discussion during the Board meetings, which senior management regularly attends. With regard to the subcommittees as described below, the CEO is the main contact to the members of the nomination and compensation committee, while the CFO takes this function towards the members of the audit committee. Yet, decisions might be taken by the members of the Board as well as each subcommittee without the attendance of senior management, but following presentation of facts and discussion with senior management.

Members of the Board and the subcommittees usually do not participate in meetings of senior management.

Management provides the Board annually with a consolidated financial budget for the next business year for the parent company and the subsidiaries, and regularly, senior management presents to the Board strategic considerations for review, discussion and decision.

The Board and the subcommittees closely follow the progress on the major activities, as presented by management. Analysis of deviations are to be provided and explained in writing on a monthly to bi-monthly basis, required action will be closely monitored via update phone calls. Each member of the Board may demand information on any business of Newron's affairs and may inspect all books, business files and corporate documents.

On a quarterly basis, the Board of Statutory Auditors is updated as well, as required by Italian law (see below). The permanent observation and control of the Company's risks is a management objective. For identified risks, mainly clinical development and financial risks, a risk assessment is performed. Appropriate actions (including for example the performance of additional preclinical or clinical studies, fundraising activities etc.) are defined and executed to minimize the risk. Management and Board of the Company during the Board meetings review the identified risks, discuss and decide on the measures and reassess the situation after an adequate period of time.

### **Subcommittees**

The Board has formed an audit committee and a nomination and compensation committee to support its work. The overall responsibility of the Board is not limited by these committees. The role of such committees is to exercise review and control and to report the findings to the full Board and to express certain recommendations to the full Board, while decisions are finally taken by the full Board, with the exception described below for the nomination and compensation committee.

The audit committee currently consists of Patrick Langlois (Chairman), Renée Aguiar-Lucander and Hans-Joachim Lohrisch, each of whom is a non-executive and independent member of the Board. The audit committee meets at the option of its members on the same date as the Company's scheduled Board meetings and at such other times as its chairperson deems it appropriate. The main tasks of the audit committee are to verify the scope of the audit, the audit programme and the procedures, the audit reports, the annual budgets and issuing recommendations to the Board regarding the acceptance of the Company's annual budgets and accounts and to review annually the Company's system of internal control. The committee's chairperson reports formally to the Board on its proceedings after each meeting on all matters within its duties and responsibilities.

The nomination and compensation committee consists of Rolf Stahel (Chairman) and Francesco Parenti, each of whom is a non-executive and independent member of the Board. The main task of the nomination and compensation committee is to issue recommendations to the Board regarding (i) the appointment and resignation of directors and senior managers, (ii) the Company's system of compensation (including equity and cash incentive programmes), and (iii) the overall compensation packages of the members of the Board and the Company's senior managers; on the following tasks, the subcommittee has the power to decide on its own: details of the remuneration and terms and conditions of service of the Company's executive members of the Board and senior management, of share option or pension schemes; further tasks are described in "Compensation, Shareholdings and Loans" (page 51). This committee meets at the option of its members on the same date as the Company's scheduled Board meetings and at such other times as its chairperson deems it appropriate. The committee's chairperson reports formally to the Board on its proceedings after each meeting on all matters within its duties and responsibilities.

### **Board of Statutory Auditors**

Pursuant to Italian Law, in addition to electing the Board, the Company's ordinary shareholders' meeting also elects a board of statutory auditors, which is required to meet at least once each quarter. Members of the Company's Board of Statutory Auditors are elected for a three-year term with a voting list (voto di lista) system.

The Company's current Board of Statutory Auditors has been elected on April 2,2010, for a three-year term expiring upon the approval of the Company's financial statements for the year ending December 31,2012. It is composed of three permanent statutory auditors, plus two alternate statutory auditors who would automatically replace a permanent statutory auditor who resigns or otherwise becomes unable to perform his duties. At least one member of the Board of Statutory Auditors and one alternate member must be registered with the national register of auditors (Registro dei Revisori Contabili). The other members, if not registered with the national register of auditors, must be registered in specific professional registers or must be chosen among certain university professors. All members of the Company's Board of Statutory Auditors are registered with the national register of auditors.

The Company's Board of Statutory Auditors is responsible for reviewing the Company's affairs and financial reporting and condition. It is required to review the Company's activities in order to determine compliance with the by-laws and applicable Italian law, as well as report specific matters to the shareholders and to the court. The Board of Statutory Auditors, among other things, ensures (i) that the Company be managed in a sound manner and (ii) that the Company's internal auditing, accounting and administrative procedures be adequate. The review of the Company's books and records performed by its Board of Statutory Auditors does not constitute an audit in accordance with Italian auditing standards.

Members of the Company's Board of Statutory Auditors must receive notice of, and are required to attend, meetings of the Board, shareholders' meetings and meetings of any executive committee of the Board.

The following table sets forth certain information about the current members of the Company's Board of Statutory Auditors, who have been appointed by the shareholders' meeting of April 2, 2010.

Name	Position	Member since
Richard P. Murphy	Chairman of the Board of Statutory Auditors	2002
Giorgio R. Fumagalli	Permanent auditor	2007
Lucio G. Ricci	Permanent auditor	2002
Luca G. Caretta	Alternate auditor	2007
Chiara Peja	Alternate auditor	2010

Each of the members of the Company's Board of Statutory Auditors also serves as statutory auditors for several other Italian and pharmaceutical companies.

## Senior Management

### Members of the senior management

Name	Position at the Company		
Luca Benatti Chief Executive Officer, Managing Dire			
Ravi Anand	Chief Medical Officer		
Stefan Weber	Chief Financial Officer		
Marco Caremi	Vice-President Strategic Marketing and Head of Legal Affairs		
Patricia Salvati	Vice-President Preclinical Research and Development		

For a biography of Luca Benatti, Newron's CEO, see "Board of Directors" above.

None of the members of the senior management is a member of governing and supervisory bodies of important Swiss or foreign organizations, institutions and foundations outside of Newron. None of the members of the senior management holds permanent management or consultancy functions for important Swiss or foreign interest groups, and none of them has official functions or holds political posts besides those mentioned. None of them has previously covered functions for Newron or one of Newron's subsidiaries besides those mentioned below



Ravi Anand, a Swiss resident, has been the Company's Chief Medical Officer since May 2005. He received his university education in New Delhi, India, and his medical training in the specialties of psychiatry and neurology in the United States. For over 20 years, Dr. Anand has worked in international drug development and registration departments of major pharmaceutical companies, including F. Hoffmann-La Roche (Switzer-

land), Sandoz/Novartis (United States) and Organon (Netherlands). From 1993 to 1997, he was the Medical Director of CNS, Clinical Research at Sandoz Research Institute. From 1997 to 2001, he served as the international Head of CNS Medical Affairs at Novartis. From 2001 to 2003, he served as the global Head of CNS Clinical Research at Organon. Since 2003, Dr. Anand has been acting as a consultant for Newron and other clients.

During his tenure in the pharmaceutical industry, Dr. Anand has worked in all phases (I through III) of drug development as well as in medical commercialization (phase IV). Overall, he has been responsible for the conduct of clinical trials in over 30 countries. He has been involved in over 30 investigational new drug applications, and over 7 international new drug applications. He has published extensively, including over 50 papers and 200 abstracts, posters and presentations.



**Stefan Weber** has been the Company's Chief Financial Officer since April 2005. He holds a master's degree in business management from Fernuniversität Hagen (Diplom-Kaufmann). He has more than 20 years of industry experience in finance and serves as the Chief Financial Officer of public and private biotechnology companies since 2000. From 1987 to 1999, he worked for the Lohmann group, a worldwide producer of

pharmaceutical, medical, technical and consumer products. His final position was Head of Finance of the Lohmann group. After joining Girindus, a fine chemistry process development and scale-up provider in 1999, he was appointed Chief Financial Officer in 2000. From 2001 to 2005, he was the Chief Financial Officer of Biofrontera, a company active in drug discovery and development. Stefan Weber has been responsible for executing numerous substantial financing transactions, including debt, equity and mezzanine financing as well as national and European grants. He has executed IPOs to the stock exchanges in Frankfurt and Zurich and managed investor relations. He furthermore has been involved in a number of M&A transactions, disinvestments and strategic restructurings. Stefan Weber is German.



Marco Caremi is Vice-President Strategic Marketing and Head of Legal Affairs since 2007. He has been in Vice-President positions with the Company since September 2002. He holds a university degree in natural science from the University of Milan and has successfully completed the Advanced Development Programme at the London Business School. Mr. Caremi has almost 30 years of experience in the pharmaceutical in-

dustry. From 1998 to 2002, he was the Director of Business Development at Schwarz Pharma S.p.A. where he had responsibility for researching and evaluating all in- and out-licensing deals, analysing companies for potential acquisitions and developing strategic plans for forthcoming market opportunities. From 1996 to 1998, he was the Business Development Manager at Schering-Plough S.p.A. From 1990 to 1996, he held several marketing and sales positions at Schering-Plough S.p.A. Before that time, he was a sales representative, sales specialist and sales district coordinator at Polifarma S.p.A. Marco Caremi is Italian.



Patricia Salvati is Vice-President Preclinical Research and Development since February 2008. She has been in Vice-President positions with the Company since 1999. She co-founded Newron in 1998 along with Dr. Benatti and Dr. Fariello. She is a pharmacologist with over 25 years of experience in research and development in the pharmaceutical industry. After receiving a doctoral degree in biological sciences from the University of

Bologna with honours, she underwent postdoctoral training in pharmacology at the University of Pavia, followed by additional training at the University College (London, United Kingdom); Prostaglandin Unit of the Wellcome Research Laboratory (Beckenham, Kent, United Kingdom); New York Medical College (Valhalla, New York, United States); the Biophysics Institute of Aarhus University (Denmark) and Shimane University (Izumo, Japan). Having gained extensive experience in gastrointestinal pharmacology and cardiovascular research, she devoted her research to neuropharmacology beginning in 1993. She holds over 60 patents and is the author of over 90 publications. Dr. Salvati has extensive experience in leading drug development projects in the industry. In 1978, she joined Farmitalia Carlo Erba where she became the Head of Cardiovascular Pharmacology in 1986 and then the director of Cardiovascular Research in 1990. After the merger with Pharmacia & Upjohn, she was appointed the Head of CNS Pharmacology and Project Leader of the antiepileptic project in 1995 and held that position until she co-founded Newron in 1998. Patricia Salvati is Italian.

### **Management contracts**

The Company does not have management contracts with third parties.

# Compensation, Shareholdings and Loans

In line with Italian law, the maximum total annual compensation for the members of the Board is proposed to the shareholders' meeting by the Company's management and Board and approved by decision of the shareholders' meeting. The proposal for such maximum total annual compensation was last elaborated by the nomination and compensation committee of the Company's Board in 2008, prior to the election of the current Board members by the shareholders during the shareholders' meeting. Since then, the maximum total remuneration for the members of the Newron Board is thousand EUR 220. The allocation of all or a part of the maximum total remuneration to the individual members is up to the decision by the Board. As per decision of the Company's Board, the compensation of the members of the Board since the 2008 shareholders' meeting consists of a fixed annual remuneration of currently thousand EUR 20 per capita and an additional remuneration for members of Board subcommittees of currently thousand EUR 5 per capita. The chairman's remuneration is thousand EUR 50. It is the current policy not to pay a variable remuneration nor to issue additional stock options/stock appreciation rights to non-executive members of the Board. For the fiscal year ended December 31, 2010, Luca Benatti and Renée Aguiar-Lucander have each fully waived their compensation as directors. The other members of the Board have waived 10 % of their fixed annual remuneration for a period of 12 months, from July 1, 2010, on, to support the Company in the period of restructuring.

When proposing the maximum total annual compensation for the members of the Board in 2008, the nomination and compensation committee of the Board was supported by a leading human resources consulting firm. The aim was to allow the Company to win internationally experienced senior executive managers from a variety of disciplines (R&D, marketing, finance, general management) in the pharmaceutical industry with the competence to execute the duties of the Board as described on page44, especially the management of the Company, to the extent it is not delegated to the senior management, and the control of management in the mid- and long term interest of the shareholders, as measured by the development of the market capitalization of the Company. The nomination and compensation committee is aware that the successful recruitment of qualified Board members as well as senior managers will depend on an overall remuneration that is competitive to companies of the same industry and comparable market capitalization. The nomination and compensation committee has qualified the following companies that are active in drug discovery and development as peers for such purposes: Santhera Pharmaceuticals, Liestal, CH; Cosmo Pharmaceuticals, Lainate, I; Evolva, Reinach, CH; MondoBiotech, Stans, CH and Paion AG, Aachen, D.

The compensation of the members of the senior management is set and reviewed annually by the nomination and compensation committee of the Board, in accordance with Newron's compensation policies. The review is based on experience of the members of the committee, publicly available information as well as advice from leading human resources consulting firms with regards to remuneration packages required to attract internationally experienced senior executive managers from the biopharmaceutical industry, including information available on peer companies, as mentioned in the previous paragraph. The nomination and remuneration committee is required to inform the Board of the decisions taken. The compensation consists of base salary, bonus and stock-based remuneration (stock options and stock appreciation rights, for more details see pages 53 and 54). The bonus for senior management is 30% of the base salary, half of this based on Company and half on individual performance objectives. In addition, Newron offers to senior management company cars, the mandatory Italian social security payments and certain life insurance coverage.

The nomination and compensation committee of the Board decides on an annual basis on the level of achievement of the Company performance objectives, which are related to the key value drivers of the company like development progress, licensing and M&A transactions, financing measures and budgetary discipline, and agreed upon at the beginning of each year. The achievement on individual performance objectives is determined by the nomination and remuneration committee of the Board compared to individual targets agreed at the beginning of each year. The nomination and remuneration committee is required to inform the Board of the decisions taken.

For 2010, the Company's senior management has not been rewarded any bonus, neither for Company nor individual achievements, by decision of the nomination and compensation committee, in reflection of the negative outcome of the SERENA phase IIb/III study, the reduced shareholder value as reflected in the share price reduction upon such event and in support of the financial situation during the restructuring phase of the Company. Furthermore, the Company's senior management has voluntarily waived 10 % of its base salary for a period of 12 months, from July 1, 2010, on, to support the Company in the period of restructuring.

The total gross compensation of the members of the Board in 2010 is outlined below:

(In thousand euro)	Cash com- pensation	Stock options**	Stock appre- ciation rights**	Total 2010	Total 2009
Rolf Stahel, non-executive Chairman	47	221	0	268	207
Luca Benatti, executive member*	304	87	(86)	305	707
Francesco Parenti, non-executive member	24	0	0	24	25
Renée Aguiar-Lucander, non-executive member	0	0	0	0	0
Hans-Joachim Lohrisch, non-executive member	24	0	0	24	25
Patrick Langlois, non-executive member	24	0	0	24	25
Ragnar Linder, non-executive member	19	0	0	19	20
Hanns Moehler, non-executive member	19	0	0	19	20
Total	461	308	(86)	683	1,029

<sup>\*</sup> Remuneration in his function as CEO

Chesyl Pharma Ltd., company-supporting services provided by Rolf Stahel, had a consulting agreement with Newron pursuant to which the Company provided business and strategic advice to Newron. In 2010, the remuneration amounted to a total of thousand EUR 58 (2009: thousand EUR 79). This remuneration is not included in the above table.

For the fiscal year ended December 31, 2010, the aggregate compensation (consisting of statutory auditors' fees) paid by Newron to the Company's Board of Statutory Auditors was thousand EUR 57 (2009: thousand EUR 48).

The total gross compensation and the highest individual compensation of the members of the senior management in 2010 are outlined below.

(In thousand euro)	Base salary	Bonus	Stock options	Stock appre- ciation rights	Total 2010	Total 2009
Luca Benatti, CEO	304	0	87	(86)	305	707
Total senior management	2,265*	0	217	(151)	2,331	2,672

<sup>\*</sup> This amount includes thousand EUR 834 of one-time redundancy payments for the termination of two managers' employment agreements.

<sup>\*\*</sup> Evaluation under IFRS rules, not necessarily reflecting personal income

### Payments to former management and directors

There were no compensation payments to former members of the Board, nor of senior management, neither were options issued to these persons.

### **Share allotment**

In the year ended December 31, 2010, no shares have been allotted to any members of the Board nor the senior management or parties closely linked to them.

The holdings of shares, stock options and stock appreciation rights in Newron of members of the Board, senior management and parties closely linked to them as of December 31, 2010, are outlined below:

	Shares*	Stock options	<ul><li>of which vested</li></ul>	Stock appre- ciation rights	<ul><li>of which vested</li></ul>
Rolf Stahel, non-executive Chairman of BoD	-	118,391	39,464	-	
Luca Benatti, CEO, executive member of BoD	167,305	40,000	20,000	60,000	60,000
Francesco Parenti, non-executive member of BoD	8,195	-	-	-	_
Renée Aguiar-Lucander, non-executive member of BoD	-	-	-	-	-
Hans-Joachim Lohrisch, non-executive member of BoD	-	-	-	-	-
Patrick Langlois, non-executive member of BoD	-	-	-	-	
Ragnar Linder, non-executive member of BoD	-	-	-	-	-
Hanns Moehler, non-executive member of BoD	-	-	-	-	_
Ravi Anand, CMO	6,040	33,875	22,625		
Stefan Weber, CFO	4,501	28,985	12,995	22,500	22,500
Marco Caremi, VP Strategic Marketing and Head of Legal Affairs	-	15,501	6,834	7,500	7,500
Patricia Salvati, VP Preclinical Research and Development	163,610	7,500	2,500	7,500	7,500

<sup>\*</sup> As far as the Company is aware.

The weighted average exercise price of the stock options is EUR 17.31.

The weighted average exercise price of the stock appreciation rights is EUR 36.83.

The exercise ratio in all cases is I share for I stock option and I share for I stock appreciation right.

### **Additional fees and remunerations**

Besides the consulting agreement described above, no additional fees and remunerations have been billed to Newron by any member of the Board or of the senior management or parties closely linked to them for additional services performed during 2010.

### **Loans to governing boards**

No loans or credits were granted during 2010 to members of the Board, senior management or closely linked parties.

## Shareholders' Participation

### **Ordinary meetings**

Ordinary shareholders' meetings must be convened at least once a year within 120 days after the end of the fiscal year (180 days in particular circumstances) for the approval of the financial statements. At ordinary meetings, if necessary, shareholders may also be called to appoint directors and statutory auditors, determine their remuneration, vote on whether the Company should take action against any directors or statutory auditors, and vote on any business matter submitted by the directors.

The quorum required for an ordinary shareholders' meeting of Newron on first call is the presence of shareholders representing at least 50% of the Company's share capital. On the second and third calls, there is no quorum requirement. In all such cases, resolutions are approved by the shareholders representing the majority of the shares present or represented at the meeting.

### **Extraordinary meetings**

Extraordinary meetings of shareholders may be called to vote on proposed amendments to the by-laws, appointment, substitution and powers of liquidators and other resolutions provided by law.

The quorum required at an extraordinary shareholders' meeting of Newron on the first, second and third calls is the presence of shareholders representing more than 50%,  $33^{1/3}$ % and 20% of Newron's share capital, respectively. At extraordinary meetings, resolutions must be approved by at least two-thirds of the share capital represented at such meetings (save for specific matters which require special majorities).

### **Notice of meetings**

Notice of all shareholders' meetings of listed companies must be published in the Gazzetta Ufficiale, the Italian official gazette, or in at least one of the daily newspapers set forth in the by-laws, at least 15 days prior to the date set for the meeting. Pursuant to relevant provisions of the Company's by-laws, such notice will be published in the Italian daily newspaper MF Milano Finanza or, in the case that MF Milano Finanza is no longer published for any reason, in the Italian daily newspaper Corriere della Sera, or, in the case that Corriere della Sera is no longer published for any reason, in the official gazette of the Republic of Italy (Gazzetta Ufficiale). Pursuant to the Company's by-laws, such notice will also be published in the German language, Swiss daily newspaper Neue Zürcher Zeitung, or, in the case that Neue Zürcher Zeitung is no longer published for any reason, in the German language, Swiss daily newspaper Tages-Anzeiger, and the French language, Swiss daily newspaper, Le Temps or, in the case that Le Temps is no longer published for any reason, in French language, Swiss daily newspaper L'Agefi.

Notice for any meeting may specify a date for the second call and, if set forth in the by-laws, the third call of the same meeting in the event that a quorum is not obtained at the first meeting or the meeting lapses. If no date for a second call of the shareholders' meeting is specified, and quorum is not reached on the first call, then a new notice must be given calling for a new meeting, which must be held within 30 days from the previously called meeting. In this instance, notice must be published at least eight days prior to the date set for the new meeting.

In addition, pursuant to Article 2366 of the Italian Civil Code, a meeting will be deemed duly convened if shareholders representing 100% of the Company's share capital, together with the majority of directors and the majority of members of the Board of Statutory Auditors, are present at the meeting. Persons attending may object to discussions of matters on which they have not been sufficiently informed.

Shareholders' meetings (I) must be called promptly upon the request by holders of at least 5% of the share capital; (2) may be called by the Board whenever it deems appropriate; or (3) may be called by the Board of Statutory Auditors or the president of the court having jurisdiction (*Presidente del Tribunale*), in the cases provided by law.

### **Attendance and voting rights**

To attend any shareholders' meeting, a Newron shareholder must, at least one business day prior to the date fixed for the meeting, instruct the relevant intermediary to communicate his relevant shareholding and voting rights to the Company (see http://newron.com/shareholdersmeeting.html).

Shareholders may appoint proxies by written means according to Article 2372 of the Italian Civil Code.

Italian law does not foresee explicit rules for shareholders to ask for inclusion of certain topics to the agenda if the shares of a company are not listed on an Italian market. Yet, shareholders representing in the aggregate 5% of the share capital of the Company could request the directors to call a shareholders' meeting, implying their right to propose topics to the agenda.

### Minority shareholders' rights

The by-laws of the Company do not contain any limitations on the voting rights in respect of shares held by any shareholder. Resolutions adopted at a shareholders' meeting are binding on all shareholders.

Yet, under Italian law, any shareholder owning voting shares representing at least 0.1% of the stock of a listed company may, within specific terms, challenge any resolution of the shareholders in respect of which it has abstained from voting or cast a dissenting vote on the basis that the resolution was not adopted in conformity with applicable law or the by-laws; directors and statutory auditors may also challenge shareholders resolutions on that basis.

Each shareholder may submit a complaint to the Board of Statutory Auditors regarding facts that such shareholder deems to be censurable, and the Board of Statutory Auditors must take any such complaint into account in its report to the meeting of the shareholders.

If shareholders collectively representing 2% of the Company's share capital submit a complaint, the Board of Statutory Auditors must promptly undertake an investigation and present its findings and any recommendations to a meeting of the shareholders (which must be convened by the Board of Statutory Auditors immediately if there appear to be grounds for the complaint and there is an urgent need to take action).

Shareholders representing in the aggregate at least 5% of the Company's share capital have the right to report major irregularities in the management of the Company to the relevant court. In addition, shareholders representing at least 2.5% of the Company's share capital may bring legal action against the directors of the Company. The Company may waive or settle the suit provided that (i) such waiver or settlement is approved by the ordinary shareholders' meeting and (ii) holders of more than 5% of the Company's share capital do not vote against such waiver or settlement. The Company will reimburse the legal costs of such action in the event that the claim of such shareholders is successful and: (i) the court does not award such costs against the relevant directors, statutory auditors or general managers; or (ii) such costs cannot be recovered from such directors, statutory auditors or general managers.

In addition, under Italian law, a single shareholder may bring an action against members of a company's board of directors in respect of damages directly suffered for negligence or wilful misconduct.

## Change of Control and Defence Measures

In line with Swiss law, which is not applicable to Newron as an Italian entity, Newron's shareholders (and any direct or indirect holder, acquirer, or seller of shares) are required by the Company's by-laws to comply with the provisions as set forth in Article 22 ss. SESTA, including Article 32 of the SESTA, and pertinent regulations, including articles 24 ss. SESTO-FINMA and the Ordinance of the Takeover Board on Public Takeover Offers of August 21, 2008, as amended ("TOO") (all such laws and regulations, the "Swiss Tender Offer Laws"). The Swiss Tender Offer Laws provide, among other things, that if a person acquires shares of a company, whether directly or indirectly or acting in concert with third parties, which, when added to the shares already held by such person, exceed the threshold of 33  $^{1}$ /3% of the voting rights (whether exercisable or not) of such company, that person must make an offer to acquire all of the listed shares of that company.

Pursuant to the Company's by-laws, any shareholder who does not comply with the Swiss Tender Offer Laws will be prohibited from voting any shares until he either (i) launches the public offer required by the Swiss Tender Offer Laws, or (ii) disposes of an amount of shares such that he owns less than  $33^{\rm I}/_3\%$  of the voting share capital, unless the Board decides otherwise on the basis of applicable law. Any shareholder who does not comply with the Swiss Tender Offer Laws may also be subject to claims by the Company, other shareholders and/or other third parties for any damages they incur as a result of its non-compliance with the Swiss Tender Offer Laws.

Should the Company as per the assessment by the Board experience an extraordinary transaction of severe impact on its corporate structure, the stock options and stock appreciation rights as evidenced in section "Stock-based remuneration" (page 37) which have not vested by that point in time will automatically vest upon such assessment and decision by the Board.

No other applicable agreements or schemes that benefit members of the Board and senior management do include change of control clauses.

## **Auditors**

Upon proposal by the management and Board of the Company, on April 2, 2010, the shareholders' meeting has reappointed Reconta Ernst & Young S.p.A. as the Company's independent auditors in relation to the audit of the Company's financial statements for the three years ending December 31, 2012. The recommendation by the Company's management and Board, who had asked alternative audit companies to provide offers for a 3-year period (as foreseen by Italian law) of collaboration was based on the high quality of the audit team proposed by E&Y, its audit experience in the pharmaceutical industry, the capability to support international projects and the financial terms offered for the work expected to be done for Newron.

The auditor in charge since the first appointment of Reconta Ernst & Young in 2007 is Paolo Zocchi.

Reconta Ernst & Young will receive an expected fee of thousand EUR 138 (2009: thousand EUR 159) for the audit of the Company's Italian GAAP Financial Statements, the financial statements of the subsidiaries under the local GAAP standards, and the Group's consolidated IFRS Financial Statements.

In addition to the fees described above, aggregate fees of thousand EUR 34 (2009: thousand EUR 39) occurred from work done by Reconta Ernst & Young and international Ernst & Young S.p.A. offices during the year ending December 31, 2010, for an opinion related to a capital increase (thousand EUR 30) as well as tax services (thousand EUR 4).

### Supervisory and control instruments pertaining to the audit

The Board has installed an audit committee, whose task it is to discuss with the auditors the audit scope, audit and review procedures, significant reporting matters and fees and to assess the auditors' performance. The chairperson of the subcommittee, Patrick Langlois, is responsible for the information of the full Board about the results of the meetings and the recommendations of the subcommittee.

### The duties of the audit committee are

- to consider the appointment of the external auditor, the audit fee, the independence and objectivity of the auditors and any questions of retirement, resignation or dismissal;
- to review the nature and scope of the audit, discuss the audit with the external auditor before it commences, and ensure coordination where more than one audit firm is involved;
- to review the annual financial statements before submission to the Board, focusing particularly on (i) any changes in accounting policies and practices, (ii) major judgmental areas, (iii) significant adjustments resulting from the audit, (iv) the going concern assumption, (v) compliance with accounting standards, (vi) compliance with legal requirements, and (vii) the Chairman's statement and statement of operations to be made in the Company's annual report;

- to review the results of the audit and its cost-effectiveness and in particular: (i) to discuss problems and reservations arising from the interim and final audits and any matters the auditors may wish to discuss (in the absence of management where necessary), (ii) to review the external auditor's management letter and management's response, (iii) to consider any significant ventures, investments or operations which are not subject to external audit;
- to review the annual budgets of the Company;
- to review annually the Company's systems of internal control (including financial, operational and compliance controls and risk management) prior to review by the Board and from time to time to make recommendations to ensure the maintenance of a sound system of internal control to safeguard shareholders' investment and the Company's assets.

In 2010, the audit committee has held two meetings with Reconta Ernst & Young S.p.A., during which the members were presented the planned audit scope, timelines, budget and results of the work performed by Ernst & Young S.p.A. in auditing the IFRS Consolidated Financial Statements for the year 2010, the Italian GAAP Financial Statements for Newron Pharmaceuticals for the year 2010 and reviewing the Interim Consolidated Financial Statements for the six months ended June 30, 2010, as well as the other services provided by Ernst & Young S.p.A. The members of the audit committee do regularly give their input to such presentations and might ask for changes or a special focus of the audit/review work, thereby controlling audit focus, performance and cost.

During these meetings Reconta Ernst & Young S.p.A. reports any material findings of their audit and review procedures to the members of the committee as well as the CEO/CFO of the Company. In a separate part, to which members of the management of the Company do not attend, the members of the committee interrogate Reconta Ernst & Young S.p.A. for any potential weaknesses in the Company's systems of internal control. The essence of the results of these meetings is reported by the Chairman of the audit subcommittee to the members of the full Board.

The committee on an annual basis evaluates the performance of Ernst & Young S.p.A. and decides on its recommendation to the Board whether Ernst & Young S.p.A. should be proposed to the shareholders' meeting for re-election, when due.

Criteria applied include technical and operational competence, independent and objective view, sufficient and competent resources employed, focus on areas of importance to Newron, willingness to challenge, ability to provide appropriate and pragmatic recommendations and effective communication as well as open dialogue and coordination, with the committee and management.

## **Information Policy**

Newron undertakes significant efforts to keep its shareholders informed, as otherwise achievements cannot be considered properly by capital markets and the interested public, thus leaving shareholders with suboptimal stock price performance.

We regularly update the corporate web page (www.newron.com), provide the regular (annual report, half-year report) and extraordinary reports (directors' dealings, status of authorized capital, ad hoc news and publications) to the SIX Swiss Exchange and the general public, routinely visit conferences to present the Company to opinion leaders and multiplicators of public opinion and talk to analysts and the press. All interested parties have the possibility to directly receive from Newron free and timely notification of potentially pricesensitive facts via our website pull service, http://www.newron.com/Register4Updates.asp. It is our aim to reach out to all potentially interested addressees in the field and once attracted to Newron, keep them up to the news. In order to keep satisfaction at high levels, we do commit to give a true and fair view to the news. Newron's PR and IR representatives are at your disposal.

### Important dates for 2011

Annual General Meeting of Shareholders: April 27, 2011 (first call), or April 28, 2011 (second call), or April 29, 2011 (third call), in the Company's offices in Bresso (Mi), Italy Publication of half-year results: September 9, 2011

### Media

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### Non-applicability/negative disclosure

It is expressly noted that any information not contained or mentioned herein is non-applicable or its omission is to be construed as a negative declaration (as provided in the SIX Swiss Exchange Corporate Governance Directive and the Commentary thereto).



## IFRS Consolidated Financial Statements

## **Consolidated Statement of Income**

(In thousand euro, except per share information)		For the year ended D	ecember 31
	Note	2010	2009
Licence income	5	626	946
Other income	6	180	1,596
Revenue		806	2,542
Research and development expenses	7/8	(15,922)	(18,544)
Marketing and advertising expenses		(73)	(86)
General and administrative expenses	7/9	(6,451)	(8,468)
Operating result		(21,640)	(24,556)
Financial result, net	10	(33)	205
Result before tax		(21,673)	(24,351)
Income tax expense	11	1,128	870
Net loss		(20,545)	(23,481)
Loss per share			
Basic and diluted	12	(3.11)	(3.86)
Weighted average number of shares (thousands)			
		6,614	6,085

# Consolidated Statement of Comprehensive Income

(In thousand euro)	For the year ended D	ecember 31
	2010	2009
Net loss for the period	(20,545)	(23,481)
Currency translation differences	22	(20)
Other comprehensive income /(loss), net of tax	22	(20)
Total comprehensive loss for the period	(20,523)	(23,501)

# Consolidated Statement of Financial Position

(In thousand euro)		As of December 31		
	Note	2010	2009	
Assets				
Non-current assets				
Property, plant and equipment	13	128	241	
Intangible assets	14	5,188	8,979	
Available-for-sale investments	15	584	584	
Non-current receivables	16	126	136	
		6,026	9,940	
Current assets				
Inventories		396	380	
Receivables and prepayments		4,623	7,064	
Other short-term financial assets		0	1,605	
Cash and cash equivalents	18	8,087	22,689	
		13,106	31,738	
Total assets		19,132	41,678	
Shareholders' equity				
Share capital	19	1,453	1,312	
Share premium and other reserves	20	36,551	52,399	
Share option reserve	21	3,310	3,065	
Retained earnings		(29,074)	(27,422)	
Translation differences		(49)	(71)	
Total shareholders' equity		12,191	29,283	
Liabilities				
Non-current liabilities				
Deferred income		0	81	
Deferred tax liability	22	1,718	2,858	
Employee cash-settled share-based liabilities	23	1	181	
Employee severance indemnity	24	587	620	
		2,306	3,740	
Current liabilities				
Deferred income	25	400	946	
Short-term borrowings	26	0	281	
Trade and other payables	27	4,235	7,428	
		4,635	8,655	
Total liabilities		6,941	12,395	
Shareholders' equity and liabilities			41,678	

# Consolidated Statement of Changes in Equity

(In thousand euro)	Note	Share capital	Share premium	Share option reserve	Foreign currency translation reserve	Retained earnings	Total
Balance at January 1, 2009		1,204	60,948	2,441	(51)	(18,731)	45,811
Total comprehensive loss for the period					(20)	(23,481)	(23,501)
Previous year loss allocation			(14,790)			14,790	0
Other share-based payment			(202)				(202)
Issue of shares		108	6,443				6,551
Share option scheme				624			624
Balance at December 31, 2009		1,312	52,399	3,065	(71)	(27,422)	29,283
Total comprehensive loss for the period					22	(20,545)	(20,523)
Previous year loss allocation			(18,893)			18,893	0
Issue of shares	19/20	141	3,210				3,351
Issuing cost			(166)				(166)
Share option scheme	21			245			245
Balance at December 31, 2010		1,453	36,551	3,310	(49)	(29,074)	12,191

# Consolidated Statement of Cash Flow

(In thousand euro)		For the year ended December 31	
	Note	2010	2009
Loss before tax		(21,673)	(24,351)
Adjustments for			
Depreciation and amortization	13/14	149	524
Impairment of in-process R&D	14	3,800	2,989
Interest income	10	(26)	(225)
Grants and other non-monetary income		(1,303)	(4,131)
Share option expenses		65	721
Employee severance indemnity expense	24	238	270
Changes in working capital			
Inventories		(16)	277
Current receivables and prepayments and deferred cost (excluding grants receivable)		2,896	1,793
Trade and other payables and deferred income (excluding advances of grants)		(3,193)	(926)
Cash used in operations		(19,063)	(23,059)
Cash flows from operating activities			
Cash used in operations		(19,063)	(23,059)
Government grants received		197	139
Pension fund paid	24	(271)	(250)
Change in non-current receivables		10	114
Net cash used in operating activities		(19,127)	(23,056)
Cash flows from investing activities			
Purchase of financial assets		0	(1,605)
Disposal of financial assets		1,602	0
Purchase of property, plant and equipment	13	(7)	(64)
Interest received	10	26	225
Net cash flows from/(used in) investing activities		1,621	(1,444)
Cash flows from financing activities			
Net proceeds from borrowings	26	(281)	(629)
Proceed from issue of shares	18/19	3,351	6,551
New shares issuing costs		(166)	0
Net cash flows from financing activities		2,904	5,922
Net increase/(decrease) in cash and cash equivalents		(14,602)	(18,578)
Cash and cash equivalents at January 1		22,689	41,267
Cash and cash equivalents at the end of the year		8,087	22,689

## Notes to the Consolidated **Financial Statements**

(In thousand euro unless otherwise stated)

### 1 General information

Newron Group (the Group) is composed of the following entities:

- Newron Pharmaceuticals S.p.A. (the Company), a clinical stage biopharmaceutical company focused on the discovery and development of drugs for the treatment of Central Nervous System (CNS) disorders and pain - the parent company;
- Newron Suisse SA, a clinical development fully owned subsidiary based in Basel (Switzerland) established during 2007;
- Hunter-Fleming Limited, a private biopharmaceutical company based in Bristol (United Kingdom) and focused on neurodegenerative and inflammatory disorders, which has been acquired in 2008.

The Company is incorporated and domiciled in Milan, Italy. The address of its registered office is via Ludovico Ariosto 21, Bresso MI 20091, Italy. The Company is listed on the main segment of the SIX Swiss Exchange, Zurich, Switzerland, under the trade name NWRN.

These consolidated financial statements have been approved for issuance by the Board of Directors on March 24, 2011.

### 2 Summary of significant accounting policies

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

### A Basis of preparation

The consolidated financial statements are based on the financial statements of the individual Group companies prepared for the same reporting period using consistent accounting policies. The financial statements have been prepared under the historical cost convention, as modified by financial assets and liabilities at fair value as described in the notes.

The presentation currency is euro. All figures included in these financial statements and notes to the financial statements are rounded to the nearest euro thousand except as otherwise stated.

Since its inception, the Group has incurred significant costs for the funding of its research and development activities without generating revenues to sustain them. Group's liquidity requirements arise primarily from the need to fund its ongoing research and development activities and, although the results of research are substantially positive, it is not certain that the research and development activities will lead to the introduction of new products to the market. Historically, Newron has primarily used capital contributions from shareholders, and limited government grants and loans, to finance the cash needs of its continuing development activities.

Considering the Group's current cash position and the level of spending according to management's plan and budgets, the directors believe the Group will be able to meet all of its obligations at least for a further 12 months as they fall due and, hence, the consolidated financial statements have been prepared on a going-concern basis.

The preparation of consolidated financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to make judgements in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed in note 4.

#### **B** Consolidation

Subsidiaries in which the Company has direct or indirect controlling interest are consolidated. Control is defined as the power to govern the financial and operating policies of an enterprise so as to obtain benefits from its activities. Control is normally evidenced when the Company owns, either directly or indirectly, more than 50% of the voting rights or potential voting rights of a company's share capital that are currently exercisable.

The consolidated financial statements of Newron Group include the accounts of Newron Pharmaceuticals S.p.A., Newron Suisse SA and Hunter-Fleming Ltd.

The consolidation commences from the date on which the subsidiary has been incorporated or established.

The purchase method is used to account for the acquisition of subsidiaries by the Company. The cost of an acquisition is measured at the fair value of the assets given, equity instruments issued and liabilities incurred or assumed at the date of exchange. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair value at the acquisition date, irrespective of the extent of any minority interest. The excess of the cost of acquisition over the fair value of the Group's share of the identifiable net assets acquired is recorded as goodwill. If the cost of acquisition is less than the fair value of the net assets of the subsidiary acquired, the difference is recognized directly in the income statement.

Intercompany balances and transaction between group companies are eliminated.

### C Change in accounting policies

The accounting policies used in the preparation of the consolidated financial statements are consistent with those applied in the previous year, except for the adoption of new or revised standards, amendments to standards and interpretation as noted below:

IFRS 2 Share-based Payment – 'Group Cash-settled Share-based Payment Transactions'. The standard has been amended to clarify the accounting for group cash-settled share-based payment transactions. This amendment also supersedes IFRIC 8 and IFRIC II. The adoption of this amendment did not have any impact on the financial position or performance of the Group.

IFRS 3 Business Combinations (Revised) and IAS 27 Consolidated and Separate Financial Statements (Revised). The Group adopted the revised standards from January 1, 2010. IFRS 3 (Revised) introduces significant changes in the accounting for business combinations occurring after this date. Changes affect the valuation of non-controlling interest, the accounting for transaction costs, the initial recognition and subsequent measurement of a contingent consideration and business combinations achieved in stages. These changes will impact the amount of goodwill recognized, the reported results in the period that an acquisition occurs and future reported results. IAS 27 (Revised) requires that a change in the ownership interest of a subsidiary (without loss of control) is accounted for as a transaction with owners in their capacity as owners. Therefore, such transactions will no longer give rise to goodwill, nor will it give rise to a gain or loss. Furthermore, the amended standard changes the accounting for losses incurred by the subsidiary as well as the loss of control of a subsidiary. The changes by IFRS 3 (Revised) and IAS 27 (Revised) will affect future acquisitions or loss of control of subsidiaries and transactions with non-controlling interests. The change in accounting policy was applied prospectively and had no impact on the financial position or performance of the Group.

- IAS 39 Financial Instruments: Recognition and Measurement Eligible Hedged Items.

  The amendment addresses the designation of a one-sided risk in a hedged item, and the designation of inflation as a hedged risk or portion in particular situations. The amendment had no effect on the financial position nor performance of the Group.
- IFRIC 17 Distribution of Non-cash Assets to Owners.

  This interpretation provides guidance on accounting for arrangements whereby an entity distributes non-cash assets to shareholders either as a distribution of reserves or as dividends. The interpretation had no effect on the financial position nor performance of the Group.

In 2010 the Group has implemented various amendments to existing standards and interpretations, which have no material impact on the Group's overall results and financial position.

New standards, amendments and interpretations issued but not effective for the financial year beginning January 1, 2010 and not early adopted:

- IAS 24 (Revised), Related Party Disclosures (effective from January I, 2011).
- IFRS 7 (Amendment), Disclosures; Transfers of Financial Assets (effective from July 1, 2011).
- IFRS 9 (Revised/Amendment), Financial Instruments; Recognition and Measurement (effective from January 1, 2013).
- IFRIC14 (Amendment), IAS 19 The Limit on a Defined Benefit Assets, funding Requirements and their Interaction (effective from January 1, 2011).
- IFRIC19 Extinguishing Financial Liabilities with Equity Instruments (effective from July 1, 2010).

The Group is currently assessing the potential impacts of these new and revised standards and interpretations that will be effective from January I, 20II and beyond, and which the Group has not early adopted. The Group does not anticipate that these will have a material impact on the Group's overall results and financial position.

### **D** Segment reporting

The Company operates in a single business segment, which is research and development of pharmaceutical drugs. Geographically the research and development activities are performed in Italy, Switzerland and the United Kingdom. The Company does not consider the geographies to be separate segments.

### **E** Related-party transactions

No significant transactions with related parties have been performed during the year.

### F Foreign currency translation

### (I) Measurement currency

Items included in the financial statements of the Company are measured using the currency of the primary economic environment in which the entity operates ("the functional currency"). The financial statements are presented in euro, which is the Company's functional and presentation currency.

### (2) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement. There are no translation differences on non-monetary items.

### (3) Group companies

The exchange rates used preparing the present document are detailed in the following table:

	Income statements in euro (average rates)		Balance sheet (rates as of)	s in euro
	2010	2009	Year-end 2010	Year-end 2009
CHF1	0.72448	0.66224	0.79974	0.67404
GBP 1	1.16577	1.12241	1.16171	1.12600

The financial statements of companies with functional currency other than euro are translated into euro for purposes of consolidation using year-end rates for balance sheet items and the average rate for the year

for the income statement items. Components of equity are translated at the dates of the relevant transaction. The resulting translation differences are recognized in the other comprehensive income.

# G Property, plant and equipment

Property, plant and equipment are stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items. Repairs and maintenance are charged to the income statement during the financial period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate the cost or residual value of the asset over the estimated useful life, as follows:

Leasehold improvements: remaining life of the lease contract

Laboratory equipment and instruments: 2.5 years Office equipment and other assets: 5–9 years

The residual values and useful lives of assets are reviewed, and adjusted if appropriate, at each balance sheet date. The carrying amount of an asset is written down immediately to its recoverable amount if the asset's carrying amount is greater than its recoverable amount.

Capital investment grants relating to the purchase of property, plant and equipment are deducted from the cost of the related assets. The grant is recognized as income over the life of the depreciable asset by way of a reduced depreciation charge.

### **H** Operating leases

Leases where a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) are charged to the income statement on a straight-line basis over the period of the lease.

# I Research and development

As stated by IAS 38, costs incurred on development projects (relating to testing of new or improved small-molecule drugs) are recognized as intangible assets when it is probable that the project will be a success considering its commercial and technical feasibility, the availability of adequate funding resources and the ability to measure its costs reliably.

Development costs which do not meet these criteria are recognized as an expense. Since inception, all research and development costs have been treated as expenses as commercial and technical feasibility continues to be assessed.

# J Intangible assets

Computer software and licences

Acquired computer software and licences are capitalized on the basis of the costs incurred to acquire and bring to use the specific software. These costs are amortized over the asset's estimated useful life of five years.

### **Brands**

Costs incurred in depositing the Group's name and logo and obtaining their exclusive use worldwide are classified as brands and are shown at historical cost. Brands have a definite useful life and are carried at cost less accumulated amortization. Amortization is calculated using the straight-line method to allocate the costs over the asset's estimated useful life of three years.

In-process research and development

In-process research and development ("IPR&D") projects acquired in a business combination are capitalized as intangible assets if the project meets the definition of an asset and its fair value can be measured reliably. Expenditure incurred on each project after acquisition is accounted for in accordance with the policy stated for internally incurred research and development costs. Before the achievement of the corresponding market authorization IPR&D are tested annually for impairment. When selling approval has been obtained, the projects are reclassified to developed technologies with the subsequent commencement of the amortization process.

### K Impairment of non-current assets

Assets that are subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use.

### **L** Investments

The Group classifies its investments in the following categories: financial assets at fair value through profit or loss, loans and receivables, held-to-maturity investments, and available-for-sale financial assets. The classification depends on the purpose for which the investments were acquired. Management determines the classification of its investments at initial recognition and reevaluates this designation at each reporting date.

In December 2006, the Board of Directors approved an investment policy, which foresees that "All investments in financial instruments by the Company shall be for capital preservation purposes, aimed at safeguarding its capital, reserves and liquidity until the funds are used in the Company's primary business". It is also stated that "Any investment in derivative financial instruments shall need to be previously authorized by the Company's Board of Directors".

### **M** Inventories

Inventories are stated at the lower of cost and net realizable value. Net realizable value is the estimated market price less applicable variable selling expenses. Inventories consist of drug substances used for testing and experiments.

### N Trade and other receivables

Trade and other receivables are recognized initially at fair value. A provision for impairment of trade and other receivables is established when there is objective evidence that the Group will not be able to collect all the amounts due according to the original terms of receivables. The amount of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows,

discounted at the effective interest rate. The amount of the provision is recognized in the income statement.

# O Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks and other short-term highly liquid investments with original maturities of three months or less.

# P Share capital

Ordinary shares and preferred shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction from the proceeds.

# **Q** Borrowings

Borrowings are recognized initially at fair value.
Borrowings are subsequently stated at amortized cost; any difference between the proceeds and the redemption value is recognized in the income statement over the period of the borrowings using the effective interest method.

### R Current and deferred income taxes

The income tax charge is based on profit for the year and includes deferred taxes. Deferred taxes are calculated using the liability method. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Deferred tax assets and liabilities are measured using the tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled based on enacted or substantially enacted tax rates as of the balance-sheet date.

Deferred tax assets and liabilities are not discounted and are classified as noncurrent assets (liabilities) in the balance sheet. They are offset against each other if they relate to the same taxable entity and tax authority.

### **S** Employee benefits

Employee severance indemnity
(Trattamento di Fine Rapporto, T.F.R.)
In accordance with Italian legislation, an employee benefit is accrued for service to date and is payable

immediately when the employee leaves the Company virtually for any reason. Accordingly, the benefit payable will depend on the employee's years of service and compensation.

According to IAS 19, the liability in respect of the severance indemnity is the present value of the defined benefit at the balance sheet date. The defined benefit obligation is calculated on a regular basis in accordance with the advice of independent actuaries using the projected unit credit method.

The present value of the defined benefit obligation is determined by the estimated future cash outflows using interest rates of government securities with maturities approximating those of the related liability. Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are recognized immediately in the income statement.

### Pension costs

The Group and its employees pay contributions to the state defined contribution pension plan on a mandatory basis. Once the contributions have been paid, the Group has no further payment obligations. The regular contributions paid by the Group constitute net periodic costs for the year in which they are due and as such are included in staff costs.

# Share-based compensation

The Group operates an equity-settled, share-based compensation plan (Employees Stock Option Plan). As stated by IFRS 2, the cost of equity-settled transactions is recognized, together with a corresponding increase in equity, over the period in which the performance and/or service condition are fulfilled, ending on the date on which the relevant employees become fully entitled to the award ("the vesting date"). The cumulative expense recognized for equitysettled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The total amount to be expensed over the vesting period is measured by reference to the fair value at the date on which the options were granted.

Cash-settled share-based compensation

The Group operates a cash-settled, share-based compensation plan (Stock Appreciation Right). The fair value of the employee services received in exchange for the grant of the options is recognized, as stated by IFRS 2, as an expense and a corresponding amount is booked as a long-term liability. The total amount to be expensed over the vesting period is determined by reference to the fair value of the options granted. The corresponding social security contribution is recognized as an expense as the related options are exercised.

At each reporting date, the fair value of the liability is remeasured and any change in fair value is recognized in the income statement of the period. The total net cost recognized in respect of the transaction will be the amount paid to settle the liabilities.

### T Revenue recognition

Revenue comprises the sale of licences and is recognized when the Group assigns the rights of ownership to the customer, and collectability of the related receivables is reasonably assured.

Receipts of upfront payments and other similar non-refundable payments relating to the sale or licensing of products or technology are initially reported as deferred income and recognized as income on a straight-line basis over the estimated period of the collaboration required to finalize the development period.

The incremental costs directly attributable to entering into the collaboration agreements are recognized as deferred cost and amortized over the relevant period of collaboration.

The reimbursements received in relation to the licensing and collaboration agreement with Merck Serono are booked as a decrease of the related costs incurred.

# **U** Grants

Grants relating to income are recognized in the income statement over the period necessary to match them with the costs they are intended to compensate. Grants are recognized at their fair value where there is a reasonable assurance that the grant will be received and the Group will comply with all attached conditions.

# 3 Financial risk management

### A Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk, credit risk, liquidity risk and interest rate risk. The Group's overall risk management programme focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance. Risk management, such as identification, evaluation and management of financial risks, is carried out by the Group's finance department under the policies approved by the Board of Directors. The Board has provided written principles for overall risk management, as well as written policies covering specific area such as investing excess liquidity. There is no use of valuation techniques for financial assets or liabilities.

# Foreign exchange rate risk

The Group operates internationally and is exposed to foreign exchange risk arising from various exposures, primarily with respect to the Swiss francs, UK pounds and US dollars. Foreign exchange risk arises from future purchase and service transactions, recognized assets and liabilities and net investments in foreign operations. To manage foreign exchange risk the Group maintains foreign currency cash balances to cover anticipated future requirements. The Group did not enter into foreign exchange contracts or other financial instruments in order to hedge its foreign exchange risk.

# Credit risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instruments or costumer contract, leading to a financial loss. The Group is exposed to credit risk from its operative activities since its receivables are related to only one partner. Credit risk from balances with banks and financial institutions is managed by the Group's finance department in accordance with the Group's policies: consequently cash and cash equivalents are held with financial institutions with A+ or higher ranking (please refer to note 18 for additional information).

### Liquidity risk

Management monitors the Group's cash position on rolling forecasts based on expected cash flow to enable the Group to finance research and development

activities. The Group's principal source of liquidity is its cash reserves which were obtained through the issuing of new shares at IPO and subsequently. The Group's policy states to invest these funds in low risk investments including interest bearing deposits. The financial status at December 31, 2010 assures that the Group's operatons will be funded well into 2012, not taking into account further revenue streams. The ability of the Group to maintain adequate cash reserves to sustain its activities in the medium term is highly dependent on the Group's ability to raise further funds from the outlicensing of its development stage products and the issuance of new shares. Consequently, the Group is exposed to significant liquidity risk in the medium term.

The table below shows the maturities of the liquidity-relevant financial liabilities as of December 31, 2010:

Maturity table	Less than 3 months	3 to 12 months	1 to 5 years	Over 5 years
Short-term borrowings	-	-	-	-
Trade and other payables	4,235			
Total	4,235			

The table below shows the maturities of the liquidity relevant financial liabilities as of December 31, 2009:

Maturity table	Less than 3 months	3 to 12 months	1 to 5 years	Over 5 years
Short-term borrowings	-	281	-	-
Trade and other payables	7,428	-	-	
Total	7,428	281	-	

### Interest rate risk

The Group is not exposed to interest rate risk fluctuations. The Group's borrowings are essentially divided into a loan received from the government at subsidized interest rates, which are unlikely to exceed the market rate in the foreseeable future, and a loan received at a fixed interest rate that expired on August 2009.

# 4 Critical accounting estimates, assumptions and judgements

The preparation of this consolidated financial information requires management to apply accounting methods and policies that are based on difficult or subjective judgements, estimates based on past experience and assumptions determined to be reasonable and realistic based on the related circumstances. The application of these estimates and assumptions affects the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the balance sheet date and the reported amounts of income and expenses during the reporting period. Actual results may differ from these estimates given the uncertainty surrounding the assumptions and conditions upon which the estimates are based. Below are summarized the Group's accounting estimates that require the most subjective judgement of management in making assumptions or estimates regarding the effects of matters that are inherently uncertain and for which changes in conditions may significantly affect the results reported in the financial statements.

Estimates and judgements are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

# Share-based compensation expense and cash-settled share-based compensation

The Group has granted share options to some of its employees, directors and consultants. The options granted have different vesting, maturity and exercise dates. Since there is no market for trading share options, management must use a fair value method to value them. Fair value methods require management to make several assumptions, the most significant of which are the selection of a fair value model, share price volatility and the average life of an option. The fair value of each of the share options has been determined separately by an external appraiser using an enhanced binomial model. Estimates have been based on Group history or market data where appropriate. There is no certainty that the results of a fair value method would be the value at which the share options would be traded for cash. Should different assumptions be used, the expenditure recognized could

be different. Additional information is reported at note 2 "S Employee benefits".

### **Cost accruals**

The Group has numerous contracts with subcontractors who carry out research and development activities. The invoicing dates on these contracts do not coincide with the financial year-end. Thus, management has to exercise estimations as to the progress of work done under the contracts and apportion the cost to the different periods.

# **Capitalization of development costs**

IAS 38 requires the capitalization of development costs upon the completion of certain requirements about commercial and technical feasibility of projects, the availability of adequate funding resources and the ability to measure costs reliably. All development costs incurred till December 31, 2010 have been treated as expenses as commercial and technical feasibility continues to be assessed. There are no intangible assets in relation to development expenditure.

### **Deferred tax assets**

Deferred tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized. In determining the recognition of deferred tax assets and liabilities, the Group's assessment of future taxable income, available taxable temporary differences, tax planning and applicable limitations on the use of tax loss carry-forwards are factors taken into account. The Group has incurred losses since inception and the availability of future taxable profits against which such an asset may be offset is uncertain. Accordingly, no deferred tax assets have been recognized. Should different events and assumptions be used, the deferred tax assets recognized could be different.

# Impairment of property, plant and equipment

The Group has incurred losses since inception, and management considers this a sufficient indicator of the necessity of annual impairment tests. As of the year-end, management assessed the fair values less costs to sell the property, plant and equipment. These were estimated to be higher than the assets' net book value, and no impairment has been accounted for.

Impairment of intangible assets with indefinite useful lives

Intangible assets with indefinite useful lives are not amortized but are tested for impairment annually either individually or at the cash generating unit level in accordance with IAS 36. The Group's impairment test for intangible assets with indefinite useful lives is based on a calculation performed with a discounted cash flow model. The cash flows are derived from the Group's budget and do not include restructuring activities that the Group is not committed to or significant future investments that will enhance the asset base of the cash generating unit being tested. According to this model, management performed at year-end an impairment analysis to assess the sustainability of the assets' values and impairment has been accounted for as disclosed in note 14. The key assumptions used to determine the recoverable amount for the different cash generating units are further explained in the notes 13 and 14.

### 5 Licence income

(In thousand euro)	For the year ended December 31		
	2010	2009	
Licence income	626	946	

Licence income of EUR 626 (2009: EUR 946) is entirely referable to the down-payment received from Merck Serono International SA in October 2006, which is being recognized as revenue on a straight-line basis over the estimated period of collaboration required to finalize the development of safinamide. The portion of the down-payment in excess of the recognized revenue has been recorded as deferred income among current and non current liabilities: additional information is reported in note 25 "Deferred income".

In 2010, the Company revised the recognition period of the payment to align it with the revised expected development period of safinamide, which has been extended from January 31, 2011 to December 31, 2011. Such a change has been accounted for prospectively as a change in estimate, resulting in a decrease of 2010 licence income of EUR 320. The change will result also in a corresponding increase of 2011 licence income of EUR 320.

### 6 Other income

(In thousand euro)	For the year ended D	ecember 31
	2010	2009
Other income	180	1,596

Other income includes EUR 34 of Grants (2009: EUR 711) and EUR 146 of Research and Development Tax Credit (2009: EUR 885), of which EUR 131 recognized by the parent company.

Grants amounting to EUR 34 entirely refers to the grant awarded to the Company from the Italian government Ministero delle Attività Produttive – M.A.P. The amount shown in Other income (EUR 34) corresponds to research and development costs which had already been incurred prior to December 31,2009. The credits related to cost incurred by other running programmes during the period ended December 31,2010 amounted to EUR 559, which has been classified as a reduction of the related research and development costs.

Research and Development Tax Credit of EUR 131 has been recognized as revenue in connection with a Law approved in June 2008 by Italian fiscal authorities, which allows asking for a partial reimbursement of certain research and development expenses incurred during 2007, 2008 and 2009. The credit has been formally recognized by tax authorities to the Company on May 6, 2009, for a maximum of EUR 3.3 million, of which up to EUR 1.6 million can be offset from October 2010 on. The Tax Credit does not expire and can be used to offset any tax disbursement including VAT and withholding taxes. The amount included in Other income (EUR 131) corresponds to the Tax Credit related to research and development costs incurred prior to December 31,2009 and recognized with the official declaration reported to the Fiscal Authorities on September 30, 2010.

### 7 Staff costs

n thousand euro)	For the year ended Dec	cember 31
	2010	2009
Wages and salaries	3,616	4,052
Pension costs – defined contribution plans	692	946
Share options granted to directors and employees	245	624
Share appreciation rights granted to directors and employees	(180)	97
Employee severance indemnity costs	238	270
Social security costs	214	281
	4,825	6,270

The average number of Group employees in 2010 was 39 (2009: 50), of whom I (2009: 2) was part-time. Effective July 5, 2010, the Company has placed 16 employees in "Cassa Integrazione Guadagni" (CIG). It is a government-supported programme under Italian law, which allows to put the employees in a "garden leave" paid by the government, for a given period of time (one year in this case, liable to extension). The employees remain employed with no material cost for the Company, thus allowing the saving of the whole cost of the workforce in CIG for the given period. From July to December the number of employees in CIG has reduced to 12 mostly because of resignations.

The decrease of EUR 1,445 is mainly related to the combined effect of the following items: (i) significant decrease in Staff costs as a consequence of the ongoing restructuring procedure (ii) one-time redundancy payments (amount included into the item "Wages and salaries") for the termination of some managers' and employees' employment agreements of about EUR 946; (iii) a positive impact on cumulated share options costs as a consequence of the resignation of some employees and (iv) a negative impact of share appreciation rights cost due to current Newron's share price.

Due to the global finance market conditions, the fair value of Company's share appreciation rights is significantly decreased: for this reason, the Company has booked an income in the profit and loss with a reduction in the related liability. The amount related to general and administration personnel is – EUR 141 (2009: EUR 71); the remaining part is related to R&D.

### 8 Research and development expenses

(In thousand euro)	For the year ended Dec	cember 31
	2010	2009
Services received from subcontractors	7,661	9,274
Staff costs	2,445	2,921
Consultancy fees	923	1,394
Material and consumables used	422	1,093
Laboratory operating lease cost	272	334
Travel expenses	222	290
Depreciation and amortization expense	3,854	3,086
Other research and development costs	123	152
	15,922	18,544

Research and development expenses related to safinamide project are reimbursed by Merck Serono according to the collaboration and licence agreement pursuant to which Newron granted Merck Serono the exclusive worldwide right and licence to develop and commercialize the compound. Accordingly, research and development expenses are presented net of costs reimbursed to Newron by Merck Serono, amounting to EUR 4,259 in 2010 (2009: EUR 5,234).

The Research and development expenses are presented also netted by all the costs that will be reimbursed by other external parties (i.e. Tax Authorities, Ministries; etc.) according to different scientific research programmes granted to the Group. As of December 2010, the company has netted the Research and development expenses for an amount equal to EUR 559 (of which EUR 443 refers to a programme granted by the Italian government Ministero dell'Industria, dell'Università e della Ricerca – M.I.U.R. – and EUR 116 refers to other minor granted projects). For additional information see also notes 6 and 17.

Since inception, no development costs have been capitalized with the exception of the Intangible assets recognized in the context of the purchase price allocation process related to the acquisition of Hunter-Fleming Limited in 2008.

The Depreciation and amortization expense has been analysed in note 14.

### 9 General and administrative expenses

(In thousand euro)	For the year ended December 31	
	2010	2009
Staff costs	2,380	3,349
Consultancy and other professional services	1,895	2,431
Intellectual properties	1,227	1,371
Travel expenses	323	314
Operating lease cost	203	282
Depreciation and amortization expense	95	135
Other expenses	328	586
	6,451	8,468

General and administrative expenses decreased in 2010 by EUR 2,017. The decrease is mainly related to the following items: (i) a decrease in Staff costs as a consequence of restructuring process (please refer also to note 7); (ii) a decrease of Consultancy and other professional services costs and (iii) a decrease in Intellectual properties costs both for consultants' services and annual fees payable to patent authorities.

### 10 Financial income, net

(In thousand euro)	•	For the year ended December 31	
	2010	2009	
Interest income	31	270	
Interest expense	(5)	(45)	
Foreign exchange gains	35	41	
Foreign exchange losses	(84)	(48)	
Other costs, net	(10)	(13)	
	(33)	205	

Financial income decreased by EUR 238 with respect to prior year as a consequence of: (i) the reduction of financial resources invested and the significant decrease in average investment return rates and (ii) a negative impact of the foreign exchange rates fluctuations. The Group invested available financial resources pursuant to the policy approved by the Board of Directors as described in note 2 "L Investments". See also note 18 "Cash and cash equivalents".

# 11 Income tax expense

As of December 31, 2010 Newron Suisse SA has accrued income taxes of EUR 12 (2009: EUR 27). According to the impairment of in-process R&D detailed in note 14, the Company has released EUR 1,140 of deferred tax liabilities as a tax profit; the balance at year end is a net revenue of EUR 1.128.

# 12 Loss per share

The basic loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of ordinary and preferred (if any) shares during the year. Preferred shares were included in the calculation as they had similar rights to those of the ordinary shareholders.

(In thousand euro)	For the year ended December 31	
	2010	2009
Net loss attributable to shareholders	(20,545)	(23,481)
Weighted average number of shares (thousands)	6,614	6,085
Loss per share - basic (in euro)	(3.11)	(3.86)

The only category of potential ordinary shares are the share options granted to employees and directors. During the presented periods, these were antidilutive, as their conversion would have decreased the loss per share. Thus, the values of the basic and diluted loss per share coincide. In case of future profits, options granted to employees (as of today n. 284,254 - see also note 21) may have a dilutive effect on the net profit per share.

# 13 Property, plant and equipment

(In thousand euro)	Leasehold improvements	Laboratory and office equipment	Total
Cost			
At January 1, 2009	498	1,565	2,063
Additions	0	64	64
Government grants	0	(84)	(84)
Disposals	0	(72)	(72)
Exchange differences	0	(17)	(17)
At December 31, 2009	498	1,456	1,954
Accumulated depreciation			
At January 1, 2009	(493)	(1,090)	(1,583)
Additions	(5)	(183)	(188)
Disposals	0	58	58
At December 31,2009	(498)	(1,215)	(1,713)
Net book value	0	241	241
Cost			
At January 1, 2010	498	1,456	1,954
Additions	0	7	7
Disposals	0	(3)	(3)
Exchange differences	0	6	6
At December 31, 2010	498	1,466	1,964
Accumulated depreciation			
At January 1, 2010	(498)	(1,215)	(1,713)
Additions	0	(125)	(125)
Disposals	0	2	2
At December 31,2010	(498)	(1,338)	(1,836)
Net book value	0	128	128

The Group has incurred significant losses since inception. As a result, property, plant and equipment were reviewed for impairment. Management assessed that the property, plant and equipment fair value less costs to sell exceeds its carrying amount, and no impairment write-down is required.

### 14 Intangible assets

	Licences and software	In-process R&D	Total
Cost			
At January 1,2009	285	11,933	12,218
Additions	0	0	0
At December 31, 2009	285	11,933	12,218
Accumulated amortization			
At January 1, 2009	(229)	0	(229)
Impairments	0	(2,989)	(2,989)
Additions	(21)	0	(21)
At December 31, 2009	(250)	(2,989)	(3,239)
Net book value – Newron Group	35	8,944	8,979
Cost			
At January 1, 2010	285	11,933	12,218
Additions	36	0	36
At December 31, 2010	321	11,933	12,254
Accumulated amortization			
At January 1, 2010	(250)	(2,989)	(3,239)
Impairments	0	(3,800)	(3,800)
Additions	(27)	0	(27)
At December 31, 2010	(277)	(6,789)	(7,066)
Net book value – Newron Group	44	5,144	5,188

Upon the acquisition of Hunter-Fleming Ltd. in 2008, an amount of EUR 11,933 was allocated to 4 different development projects based on a risk-adjusted Net Present Value (NPV) assessment. These projects have been classified as in-process R&D.

IAS 36 requires assessing an asset not in use for impairment on an annual basis by comparing the carrying value to its recoverable amount. The recoverable amount is the higher of the fair value less cost to sell and the value in use. Management used a risk-adjusted NPV assessment to test for impairment the above intangible assets. The assessment was performed based on industry average rates for successful development of the projects to the market (5% by end of drug discovery, 13% by end of preclinical development, 21% by end of clinical phase I, 46% by end of clinical phase II and 76% by end of clinical phase III), a usual discount rate to future cash-in and outflows (15% p.a.), the properties of the compounds and their target product profile, the sales potential as well as comparable transaction terms for licensing of the compounds usually after phase II proof of concept.

The following table shows the results of the Net Present Value (NPV) assessment:

Project	Development phase	Book value 2009	Allocated value	Write-off	Deferred tax effect
HF0220	Clinical phase II	5,044	5,044	0	0
HF0299	Clinical phase I	3,069	50	(3,019)	906
HF1220	Discovery	831	50	(781)	234
		8,944	5,144	(3,800)	1,140

The impairment test resulted in an impairment of EUR 3,800 which includes EUR 3,019 and EUR 781 respectively related to HF0299 and HF1220. As the development activities for the 2 compounds have been slowed down, a decrease in NPV is the result.

As uncertainty remains as to whether a final and successful market registration will be achieved, a risk of additional future adjustments to the carrying amount of the above in-process R&D stays.

# 15 Available-for-sale investment

Available-for-sale investment of EUR 584 (2009: EUR 584) is entirely represented by a minority interest (17%) held in a Special Purpose Vehicle (SPV) – Trident Pharmaceuticals Inc. – set-up to develop a late-preclinical compound in asthma. The investment was acquired in 2008 upon finalization of the Hunter-Fleming deal.

As the value of the investment is completely depending on the value of its core asset, a development compound in preclinical phase, the same methodology as under note 14 was applied for the impairment test.

The impairment test of the recoverable amount of the available-for-sale investment performed did not result in the requirement to recognize impairment of the carrying value of the asset. As uncertainty remains as to whether a final and successful market registration will be achieved, a risk of future adjustments to the carrying amount stays.

### **16 Non-current receivables**

(In thousand euro)	As of December 31	
	2010	2009
Deferred costs	0	10
Guarantee deposits for leases	126	126
	126	136

# 17 Receivables and prepayments

(In thousand euro)	As of December 31	
	2010	2009
Receivables	498	1,040
Government grants receivable	2,066	1,669
Prepayments	475	1,822
Deferred costs	51	123
VAT receivable	31	101
Other receivables	1,502	2,309
	4,623	7,064

The amount classified as Receivables mostly refers to the accruals related to the reimbursement of safinamide's research and development costs incurred in relation to the Merck Serono agreement. The item "Other receivables" includes EUR 1,297 (2009: EUR 2,155) of Research and Development Tax Credit of which EUR 1,282 refers to the Company.

# Government grants receivable includes:

(In thousand euro)	Approved amounts	Approved amounts in %	Receivables
Law n° 46 of February 17, 1982			
Grants for technological R & D			
Income grant	673	100	673
Collections as at December 2010			(604)
Net receivables as per Law 46			69
D.D. 2187 year 2003			
Grants for scientific research	284	70	199
Collections as at December 2010	<del></del>		(170)
Net receivables as per D.D. 2187			29
DGR n. 4032 – January 24, 2007			
Grants for scientific research	1,059	30	318
Net receivables as per DGR n. 4032			318
DM 593 – August 8, 2000 – Art. 10			
Grants for scientific research			
Income grant	3,035	55	1,658
			1,658
European Community-FP7-HEALTH-2007-2.2.1-8: From mood disorders to experimental models			
Grants for scientific research			
Income grant	198	35	69
Collections as at December 2010			(90)
			(21)
Lombardy district – B.U.R.L. n.12 March 20, 2008			
Grants for scientific research			
Income grant	295	30	88
Collections received during 2010			(75)
0			13
			2,066

# 18 Cash and cash equivalents

(In thousand euro)	As of December 31	
	2010	2009
Cash at bank and in hand	4,522	3,499
Short-term investments	3,565	19,190
	8,087	22,689

The "Short-term investments" are highly liquid investments easily convertible into cash, not subject to significant changes in value and with no withdrawal penalty. Newron Group's liquidity, including the funds received on February 16, 2011 (please refer to note 32) is about EUR 12 million.

# 19 Share capital

As of December 31, 2009, the subscribed share capital was equal to EUR 1,311,510.40, divided into 6,557,552 ordinary shares with nominal value equal to EUR 0.20 each. The authorized share capital is equal to EUR 1,425,997.60 (divided into n. 7,129,988 ordinary shares).

Following the signature of the equity funding agreement with YA Global Investments L.P. the Company's share capital increased, over the last twelve months, by EUR 9,286.20 issuing 46,431 ordinary shares with a par value of Euro 0.20 and varying premium; the related amounts were paid-up by YA Global Investments L.P.

On December 16, 2010, a Board of Director's meeting resolved to increase Newron's share capital by a nominal amount of EUR 132,079.00 corresponding to n. 660,395 of Newron's ordinary shares with a par value of EUR 0.20 per share and a premium of EUR 3.99; the fully paid-in funds were equal to EUR 2,767,018.16.

As of December 31, 2010, the subscribed share capital was equal to EUR 1,452,875.60, divided into 7,264,378 ordinary shares with nominal value equal to EUR 0.20 each. The authorized share capital is equal to EUR 1,622,875.60 (divided into n. 8,114,378 ordinary shares).

A summary of the changes in share capital is as follows:

(In euro)	Total
As of December 31, 2008 – Newron Group	1,204,101.60
- issue of ordinary shares (SEDA executions)	19,408.80
- issue of ordinary shares (capital increase)	88,000.00
As of December 31, 2009 – Newron Group	1,311,510.40
- issue of ordinary shares (SEDA executions)	9,286.20
- issue of ordinary shares (capital increase)	132,079.00
As of December 31, 2010 - Newron Group	1,452,875.60

# 20 Share premium and other reserves

(In thousand euro)	As of Dec	As of December 31	
	2010	2009	
At the beginning of the year	52,399	60,948	
Loss allocation	(18,893)	(14,790)	
Issue of shares	3,210	6,241	
Share capital issue costs	(166)	0	
At the end of the period	36,551	52,399	

### 21 Share options

To incentivize the efforts of employees, directors and certain consultants directed at the growth of the Company and its subsidiaries in the medium term, the Group has approved four Share Option Plans: the first in October 2003 (ESOP 2003); the second in July 2004 (ESOP 2004) expired on April 2009; the third in June 2007 (ESOP 2007) and the fourth in April 2009 (ESOP 2009). The options have been awarded free of charge.

On January 22, 2010, the Board of Directors granted to certain employees and consultants of the Group 47,000 options at an exercise price equal to EUR 13.43 each; those options will be vested on January 22, 2012, and will expire on December 31, 2012.

By December 31, 2010, options to acquire a total of 47,135 shares under the 2003 plan had expired and were automatically converted – as stated by the Board of Directors during the meetings held on March 10 and April 16, 2009 – into options to acquire a total of 1,875 and 33,476 shares under the 2007 and 2009 plan respectively. These stock options will vest by April 16, 2012, expire by December 31, 2012, and can be exercised at a price of EUR 11.50.

During the year 2010 some employees left the Company waiving a total of 17,501 options granted under the 2007 plan.

A summary of the granted options is as follows:

	<b>Employee Share Option Plans</b>			
	2003	2007	2009	Total
At January 1	69,135	96,004	101,400	266,539
Granted		48,875	33,476	82,351
Waived	0	(17,501)	0	(17,501)
Expired	(47,135)	0	0	(47,135)
At December 31	22,000	127,378	134,876	284,254

The Group's Board of Directors cannot grant further options under the ESOP 2003 and 2004 plans.

The options granted are recognized as personnel expenses over the original vesting period; the changes approved during 2009 have been accounted for based on rules set for by IFRS 2 Share based compensation and will result, in the next 2 years, in additional fair value of awards granted totalling EUR 421.

In 2010, option grants resulted in personnel net expenses of EUR 245 as a consequence of the combined effects of the following items: a cost of EUR 68 related to the original vesting period; a cost of EUR 448 related to the new fair value and a "revenue" of EUR 271 related to the cumulated cost of the employees that left the Company during 2010. R&D personnel expenses are equal to EUR 94 (2009: EUR 182) while EUR 422 refers to G&A personnel (2009: EUR 442).

Exercise price (in euro)	Number outstanding	Weighted- average remaining contractual life (years)	Number exercisable
11.50	161,004	2.00	0
11.66	6,000	2.00	0
13.43	46,500	2.00	0
17.81	4,500	2.00	0
35.03	22,000	1.00	22,000
36.83	44,250	1.47	44,250
	284,254		66,250

# 22 Deferred tax liabilities

	As of December 31	
	2010	2009
Deferred tax liabilities, gross	2,858	3,755
Write-off's effect on deferred tax liabilities	(1,140)	(897)
	1,718	2,858

Deferred tax liabilities decreased by EUR 1,140 as a consequence of the write-off of the relevant intangible assets as reported in note 14.

# 23 Employee cash-settled share based compensation

The Company's Board of Directors approved on June 18, 2007, a Stock Appreciation Right Plan (SARP 2007). The Plan involves assigning, by no later than December 31, 2008, to one or more recipients, an overall maximum of 213,000 option rights granting the right to obtain, at the exercise date, the payment of an amount calculated on the basis of the differential variation of the value of the ordinary shares of Newron S.p.A. ("Phantom Options").

The Phantom Options provide the recipient with the right to obtain from the Group, at the exercise date, payment of a gross amount equal to the positive differential variation between the official price registered on the SIX Swiss Exchange as at the exercise date, multiplied by the number of granted options, provided that in any event that the differential cannot be higher than 150% of the initial price. It should be highlighted that the differential is usually taxable income for the recipients. At the payment date, the Company will apply the deductions and applicable welfare contribution, by paying to the recipient the net amount. The differential is calculated based on the variation (positive) of the ordinary share price of Newron Pharmaceuticals S.p.A. between the grant date and the exercise date.

Exercise of the Phantom Options by the recipients is permitted solely following the date marking 3 years following the grant date. The exercisable Phantom Options can be exercised within two years from the exercise start date but no later than December 31, 2012.

As of December 31, 2010, the Board of Directors granted 113,750 phantom options as follows:

	Option granted	Exercise price (euro)
At January 1	122,000	36,83
Waived	(8,250)	36,83
At December 31	113,750	

Additional information is reported in note 7 "Staff costs". With respect to future changes applying to the Stock Appreciation Right Plan under the 2009 Share Option Plan, please refer to note 21.

# 24 Employee severance indemnity

Some Group companies provide for its employee severance indemnities (as required, for example, under Italian legislation), which is considered to be a defined benefit scheme.

The principal assumptions used for the purpose of the Company's actuarial valuation were as follows:

	December 31, 2010
Actuarial assumptions	
Discount rate	4.50%
Inflation rate	2.00%
Future salary increase	1.50%
Future pension (TFR) increase	3.00%

Based on the present value of the estimated obligation, the amount recognized on the balance sheet in respect of the Group's defined benefit plan amounted to EUR 587 thousand in 2010 (2009: EUR 620) and the movements are as follows:

(In thousand euro)	As of Dece	As of December 31	
	2010	2009	
Balance as at the beginning of the year	620	600	
Total expense charged in the income statement	238	270	
Indemnity paid during period, leavers and transfers out	(271)	(250)	
Balance as at the end of the year	587	620	

Amounts recognized under Staff costs in the income statement are as follows:

(In thousand euro)	As of Dece	As of December 31	
	2010	2009	
Current service cost	219	248	
Interest expense on obligation	19	22	
	238	270	

### 25 Deferred income

Deferred income relates to the upfront payment received from Merck Serono International SA. Please refer also to note 5 for additional details.

# **26 Borrowings**

(In thousand euro)	As of Dece	As of December 31	
	2010	2009	
At beginning of year	281	909	
Repayment	(281)	(628)	
Total borrowings	0	281	
Short term	0	281	

In each period considered, borrowings comprise a loan received from the Italian government. The total loan initially approved amounted to EUR 1,621, however as the project was completed ahead of schedule this was reduced to EUR 1,540.

Interest on this loan is charged at a subsidised rate of I.012% per annum. The fifth and final instalment, equal to EUR 281, was paid in November 2010.

# 27 Trade and other payables

(In thousand euro)	As of Dece	As of December 31	
	2010	2009	
Trade payables	2,210	3,573	
Accrued expenses	1,451	2,393	
Pension contribution payable	227	474	
Social security	117	150	
Other payables	230	838	
	4,235	7,428	

### 28 Deferred income taxes

The Group's accounts include the following significant temporary differences from the tax bases of the relevant assets and liabilities:

(In thousand euro)	•	For the year ended December 31	
	2010	2009	
Other (IAS 19)	(163)	(185)	
Total taxable differences	(163)	(185)	
Other minor	1	181	
IPO expenses	0	1'524	
Deferred income	400	1'027	
Total deductible differences	401	2'733	
Net temporary differences	238	2'548	
Tax losses carried forwards	108'544	103'104	
Total differences	108'782	105'652	
Deferred tax asset	29'969	29'149	

The above deferred tax asset has been measured using the average tax rates that are expected to apply to the taxable profit of the periods in which the temporary differences are expected to reverse and has not been recognized in the consolidated financial statements due to uncertainties concerning the availability of future taxable profits against which such an asset may be offset, also considering the expiring dates of the tax losses.

Tax loss carry-forwards expire as follows:

(In thousand euro)	December 31, 2010
Year of expiration:	
2011	8,530
2012	15,774
2013	17,807
2014	24,352
2015	19,706
No expiry date	22,375
	108,544

The loss identified as "No expiry date" includes EUR 6,008 related to Newron Pharmaceuticals S.p.A. (since they relate to the start-up costs) and EUR 16,367 related to Hunter-Fleming Ltd (equal to GBP 14,089 translated at the year-end exchange rate EUR I equal to GBP 0.8608).

The "Tax loss carry-forwards" balance increased by EUR 5,440 due to the combined effects of the following items: (a) exchange rate effect on Hunter-Fleming Ltd tax losses that results in an increase equal to EUR 503; (b) expiration of 2005 tax losses (EUR 14,500) and (c) insertion of 2010 tax losses equal to EUR 19,706.

# 29 Commitments and contingent liabilities

Operating lease commitments - whereby the Group is the lessee

The Company leases both the offices and laboratories from Zambon Immobiliare S.p.A. Both contracts were renewed for additional 6 years and will last till September 30, 2014, and February 14, 2015, respectively. As a consequence of the ongoing restructuring process the Company, starting from mid August 2010, has reduced by 50% its laboratories' dimensions; the yearly rent has decreased proportionally. Newron Suisse SA leases its offices from Livit AG. Starting from January 2011 the offices' dimensions have been reduced; the annual rent has decreased accordingly. The lease will expire on July 31, 2012. Hunter-Fleming Limited did lease its offices from Regus. The lease expired on February 2010 and wasn't renewed.

During the year ended December 31, 2010, EUR 475 was recognized as net expense in the income statement in respect of operating leases (2009: EUR 615).

The future aggregate minimum lease payments under non-cancellable operating leases are as follows:

(In thousand euro)	As of Dece	As of December 31	
	2010	2009	
No later than 1 year	444	684	
Later than 1 year and not later than 5 years	1,164	2,737	
	1,608	3,421	

Should the Company decide to leave its offices, it has to pay 6-months remittance period only.

### Other commitments

The Company has entered into contracts for clinical development with CROs. The Company compensates the CROs for the services provided on a regular basis. The expenditure contracted for at the balance sheet date but not yet incurred is equal to EUR 3 million. Should the Group decide to close any of these contracts, this will not incur material penalty fees.

# **Contingent liabilities**

The achievement of certain future development milestones related to the ralfinamide project will trigger the assignment of the Purdue patents for an amount of EUR 2,250 and further milestone-based payments to Purdue up to EUR 1,300. The directors considered the achievement of the agreed development milestones as not probable.

The Company and Hunter-Fleming agreed on further performance-based milestones related to the progression of Hunter-Fleming programmes, up to a maximum of EUR 17 million. The directors considered the achievement of the agreed milestones as not probable.

# 30 Financial instruments by category

As of December 31, 2010	Loans and receivables	Assets at fair value through profit or loss	Held-to- maturity investments	Available- for-sale financial assets	Liabilities at fair value through profit or loss	Other financial liabilities at amortized cost
Assets						
Cash and cash equivalents	8,087	-				-
Financial assets		-		584		-
Receivables and prepayments	4,097	-				
Total	12,184	-	-	584	-	-
Liabilities						
Trade and other payables	-	-				4,235
Short-term borrowings	-	-		-		-
Total	-	-	-	-	-	4,235
As of December 31, 2009	Loans and	Assets at fair value	Held-to-	Available-	Liabilities	Other financial
	receivables	through profit or loss	maturity investments	for-sale financial assets	at fair value through profit or loss	liabilities at amortized cost
Assets	receivables	through profit or		financial	through profit or	liabilities at amortized
Assets  Cash and cash equivalents	22,689	through profit or		financial	through profit or	liabilities at amortized
		through profit or		financial	through profit or	liabilities at amortized
Cash and cash equivalents		through profit or	investments	financial assets	through profit or	liabilities at amortized
Cash and cash equivalents Financial assets	22,689	through profit or	investments	financial assets	through profit or	liabilities at amortized
Cash and cash equivalents Financial assets Receivables and prepayments	22,689	through profit or	1,605	financial assets	through profit or	liabilities at amortized
Cash and cash equivalents Financial assets Receivables and prepayments Total	22,689	through profit or	1,605	financial assets	through profit or	liabilities at amortized
Cash and cash equivalents Financial assets Receivables and prepayments Total Liabilities	22,689	through profit or	1,605	financial assets	through profit or	liabilities at amortized cost

# 31 Related-party transactions

### i) Related entity

During 2002, the Company contributed EUR 26 to the capital of Consorzio Italbiotec (formerly Roberto Lepetit) ("the Consortium"). The Consortium is a non-profit partnership. Its main objective is to promote research and development in the medical and pharmaceutical field. It also undertakes research and other projects for the benefit of the partners, who have joint control, as well as other interested parties.

Management has decided not to consolidate the Company's interest in the Consortium and, furthermore, to write down its value to EUR 1.00 for the following reasons:

- the Consortium is a non-profit enterprise;
- it does not propose to make any distributions to the partners;
- the Company may not reclaim any part of its contribution to the Consortium if it decides to withdraw;
- no decision has been made as to how the net assets are to be divided should the Consortium cease operations.

If the Consortium reports a loss in the year-end financial results, the Company must fund one-fourth of such loss, the remaining loss being funded by the three other partnering companies.

As of December 31, 2010, the Consortium had net equity of EUR 166 (2009: EUR 157) and a net profit of EUR 9 (2009: net profit of EUR 4).

ii) Purchases from related parties Not applicable.

# iii) Key management personnel

The total remuneration of key management personnel is as follows:

(In thousand euro)	•	For the year ended December 31	
	2010	2009	
Salaries	1,355	1,774	
Bonuses	0	324	
Social security contributions	272	470	
Share option compensation	67	482	
One time payments	834	0	
Employee severance indemnity	76	92	
	2,603	3,142	

### 32 Events after the balance sheet date

In 2008 Newron was awarded a EUR 5 million grant by the Italian government's Ministero dell' Istruzione, dell' Università e della Ricerca – M.I.U.R. – towards a EUR 5.3 R&D programme ongoing at the company. The grant supports the research and identification of novel compounds for the treatment of diseases of the Central Nervous System.

About 40% of the grant is non-reimbursable. The rest bears interest of 0.5% per year and is required to be fully repaid within 10 years from the grant date. On February 16, 2011 the Company cashed-in the first reimbursement equal to a total of EUR 3.7 million of which EUR 2.1 million will bear interest while the remaining amount is a lump sum.

# **Auditors' Report**



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# Independent auditors' report

To the Shareholders of Newron Pharmaceuticals S.p.A.

- 1. We have audited the consolidated financial statements of Newron Pharmaceuticals S.p.A. and its subsidiaries (the "Group") as of and for the year ended December 31, 2010, comprising the statement of financial position, the statement of income, statement of comprehensive income, statement of changes in equity and cash flows and the related explanatory notes. The preparation of these financial statements in compliance with International Financial Reporting Standards is the responsibility of the Group's management. Our responsibility is to express an opinion on these financial statements based on our audit.
- 2. Our audit was made in accordance with International Standards on Auditing. In accordance with such standards, we planned and performed our audit to obtain the information necessary to determine whether the consolidated financial statements are materially misstated and if such financial statements, taken as a whole, may be relied upon. We were not engaged to perform an audit of the Group's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, as well as assessing the appropriateness and correct application of the accounting principles and the reasonableness of the estimates made by management. We believe that our audit provides a reasonable basis for our opinion.

For our opinion on the consolidated financial statements of the prior year, which are presented for comparative purposes, reference should be made to our report dated February 27, 2010.

3. In our opinion, the consolidated financial statements of Newron Group at December 31, 2010 have been prepared in accordance with International Financial Reporting Standards; accordingly, they present clearly and give a true and fair view of the financial position, the results of operations, the changes in shareholders' equity and the cash flows of the Group for the year then ended.

Milan, March 29, 2011

Reconta Ernst & Young S.p.A.

(partner)

# **Glossary**

# **Activities of Daily Living (ADLs)**

Routine activities of everyday life that people tend to do on a daily basis without needing assistance. There are six basic ADLs: eating, bathing, dressing, toileting, transferring (walking) and continence. An individual's ability to perform ADLs is important for determining what type of long-term care (e.g. nursing home care or home care) and coverage the individual needs (i.e. government-funded health care or long-term care insurance).

### **Adjunctive treatment**

A drug added as a supplement to increase the efficacy/decrease side effects/change the pharmacokinetics (PK) of another already prescribed treatment, e.g. (i) improve efficacy of a first-line therapy, e.g. adding a dopamine agonist to patients on levodopa, (ii) improve the tolerability and safety of the first-line therapy, e.g. use of anticholinergics to patients on neuroleptics, and (iii) improve the PK/brain availability of the first-line therapy, e.g. COMT-inhibitors administered to patients on levodopa.

### **Agonist**

An endogeneous or exogeneous agent that mimics the action of hormones and/or neurotransmitters on their receptors to enhance the response. For example, dopamine agonists stimulate specific brain dopamine receptors to obtain motor response.

# Allodynia

Pain from mechanical or thermal stimuli which are not normally painful. Allodynia is not referred pain and can occur in other areas that are not stimulated.

### Alpha-aminoamide derivative

The chemical class to which both safinamide and ralfinamide belong. More specifically, it is an amide derivative of an alphaamino acid.

### Alzheimer's disease

A progressive degenerative disease of the brain of unknown etiology, characterized by diffuse atrophy throughout the brain with characteristic pathological changes suggestive of degeneration, and/or necrosis. The disease is characterized by a progressive deterioration of memory, cognitive function and changes in personality. Death usually occurs within 7 to 10 years of the time of diagnosis in most patients.

# **Benzodiazepines**

A class of drugs with hypnotic, anxiolytic, anticonvulsant, amnestic and muscle-relaxant properties, which are used for short-term relief of severe, disabling anxiety, insomnia, and muscle relaxation for surgical procedures.

### **Cannabinoid**

A group of chemicals which activate the body's cannabinoid receptors. Currently, there are three general types of cannabinoids: (i) herbal cannabinoids occur uniquely in the cannabis plant, (ii) endogenous cannabinoids are produced in the bodies of humans and other animals, and (iii) synthetic cannabinoids are similar compounds produced in a laboratory.

# **Central Nervous System (CNS)**

The nerves and cells of the brain and spinal cord.

# **Chemical scaffold**

Chemical structure subunit shared by the molecules of a given chemical class.

# **Clinical Global Impression Scale**

A scale which provides an overall assessment of the global severity of illness, and change in the clinical condition of the patients compared with pretreatment status.

# Daily motor fluctuations (the "ON/OFF" effect)

An unpredictable succession of "OFF" periods when patients experience full disability and "ON" periods when the drug being administered is successfully alleviating the patient's symptoms.

### **Dopamine**

A neurotransmitter known to have multiple functions depending on where it acts. Dopamine-containing neurons in a specific area of the basal ganglia are destroyed in Parkinson's disease victims.

# **Dopamine reuptake**

The active transport of dopamine from the synaptic cleft into the presynaptic neuron after it has performed its function of transmitting a neural impulse.

# **Dopaminergic system**

The system of nerve cells that uses dopamine as its neurotransmitter.

# **Double-blind study**

A clinical trial design in which neither the participating individuals (healthy volunteers or patients) nor the study staff know which participants are receiving the experimental drug and which are receiving placebo or another active treatment. Double-blind trials are thought to produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome.

### **Dyskinesias**

Abnormal, involuntary body movements that can appear as jerking, fidgeting, twisting, and turning movements. In the context of Parkinson's disease, dyskinesias are often the result of chronic levodopa therapy. These motor fluctuations occur in more than half of PD patients with levodopa therapy. Dyskinesias most commonly occur at the time of peak levodopa plasma concentrations and are thus referred to as peak-dose dyskinesias. As patients advance, they may evidence diphasic dyskinesias, which occur when the drug concentration rises or falls.

### **Endogenous**

Produced or synthesized within the organism.

### **EPO**

European Patent Office.

### **Executive function**

Executive function is a collection of varying abilities that involve regulatory control over thought and behaviour in the service of goal-directed or intentional action, problem-solving, and flexible shifting of actions to meet task demands. Clinical data about executive function can be obtained by observing an individual's ability to problem-solving in the natural environment and assessing how flexible a person is when faced with a changing routine.

The major executive functions include response inhibition (which permits impulse control, resistance to distraction, and delay of gratification); non-verbal working memory (which permits the holding of events in the mind and allows self-awareness across time); verbal working memory (which comprises the internalization of speech and permits self-description, questioning and reading comprehension); and self-regulation of emotion and motivation (which permits motivation, persistence toward a goal, and emotional self-control).

### **GABA**

Gamma-Amino Butyric Acid, a neurotransmitter which acts at inhibitory synapses in the brain and spinal cord.

# **Gastrointestinal**

Relating to, or affecting both stomach and intestine or their functions.

# **Glutamate**

A salt or ester of levorotatory glutamic acid. Glutamic acid is an amino acid, one of the 20 building blocks of proteins. It is involved in ammonia metabolism and serves as an excitatory neurotransmitter.

### Half-life

The time required for half the amount of a drug introduced in an organism to be metabolized or excreted; most commonly refers to drug plasma levels.

# **Inflammatory pain**

Triggered by nerve endings that become irritated when surrounded by inflamed tissue.

#### In vitro

A biological or chemical process occurring outside a living organism, i.e. conducted on cultured cells.

### In vivo

A biological or chemical process occurring inside a living organism.

### Ion channels

Poreforming proteins that help to establish and control the voltage gradient that exists across the plasma membrane of all living cells by allowing the flow of ions down their electrochemical gradient. They are present in the membranes that surround all biological cells.

### Levodopa

A drug which is used to treat Parkinson's disease which helps restore levels of dopamine, a chemical messenger in the brain responsible for smooth, coordinated movement and other motor and cognitive functions.

### Mania

Mania is a severe medical condition characterized by extremely elevated mood, energy, and unusual thought patterns.

# **MAO-B** (monoamine oxidase B)

An enzyme that is responsible for the metabolism of dopamine and phenylethylamine in the brain. Thus, inhibiting MAO-B is a therapeutic strategy for the treatment of PD.

# **MAO-B** inhibitor

A drug which inhibits the MAO-B enzyme activity.

### Mild Cognitive Impairment

Mild Cognitive Impairment is a general term most commonly used to describe a subtle but measurable memory disorder. According to this definition, a person with Mild Cognitive Impairment has memory problems greater than normally expected with aging, but does not show other symptoms of dementia, such as impaired judgement or reasoning.

# Mixed peripheral neuropathic pain

Peripheral neuropathic pain of different aetiologies.

# N-type calcium channels

A calcium channel subtype, belonging to the high-voltage-activated (HVA) calcium channels, that is particularly involved in the process of synaptic neurotransmitter release.

### **Nerve compression**

Harmful pressure of a nerve especially in nerves that pass over rigid prominences, i.e. a rupture disc in the lower spine causing sciatica.

### **Nerve entrapment**

When a nerve gets "stuck" to the soft tissue that surrounds it, i.e. muscles, fascia and ligaments.

# **Neurodegenerative**

Relating to or characterized by the degeneration of nervous tissue.

### **Neuro-inflammation**

Chronic sustained injury of the central nervous system, involving the response of microglial cells that contribute to further damage, worsening the disease progression.

### **Neurons**

Cells that constitute nervous tissue, that have the property of transmitting and receiving nervous impulses.

# **Neuropathic Low Back Pain (NLBP)**

Form of chronic pain initiated or caused by the presence of a primary lesion, damage or disruption to some components of sensory neurons involving the area from the lower rib cage to the gluteal folds, leading to aberrant transmission of pain signals.

# **Neuropathic pain**

The International Association for the Study of Pain (IASP) has defined neuropathic pain as "pain initiated or caused by a primary lesion or dysfunction of the nervous system". These lesions may be in the peripheral or central nervous system, and frequently both systems are involved with chronic neuropathic pain states. Examples include phantom limb and spinal cord injury pain, painful diabetic neuropathy, post-herpetic neuralgia, sciatica, trigeminal neuralgia, and drug-induced (e.g. vinca alkaloids) neuropathy.

#### **Neurotransmitter**

A chemical substance in the brain that either excites or inhibits neural function.

### **New Chemical Entity (NCE)**

A compound of a completely new chemical form, which has not been previously approved, and therefore can be patented.

### **Nociceptors**

Sensory receptors responsible for nociception, the perception of pain in response to potentially damaging stimulus.

### **NSAIDs**

Non-steroidal anti-inflammatory drugs.

### Off-label

The use of a drug for a medical condition other than for which it was officially approved and marketed.

# **Onset of action**

The length of time it takes for a medicine to start to work.

### "ON" time

During "ON" times, patients report they feel relatively fluid, clear, and in control of their movements.

Often, symptoms of PD may be invisible to all but professionals.

# Open label

A study in which all parties (patient, physician and study coordinator) are informed of the drug and dose being administered.

### **Opioids**

A synthetic drug (such as methadone) possessing narcotic properties similar to opiates but not derived from opium.

# Parkinson's disease (PD)

PD is a degenerative disorder of the central nervous system that affects the control of muscles, and so may affect movement, speech and posture. Parkinson's disease belongs to a group of conditions called movement disorders. It is often characterized by muscle rigidity, tremor, a slowing of physical movement (bradykinesia), and in extreme cases, a loss of physical movement (akinesia). The primary symptoms are the result of excessive muscle contraction, normally caused by the insufficient formation and action of dopamine, which is produced in the dopaminergic neurons of the brain. Secondary symptoms may include high-level cognitive function and subtle language problems. PD is both chronic, meaning it persists over a long period of time, and progressive.

# **Pivotal study**

Usually a phase III study which presents the data that the governmental agencies responsible for approving the marketing of pharmaceutical products (e.g. the US FDA and EMEA) use to decide whether or not to approve a drug. A pivotal study will generally be well-controlled, randomized, of adequate size, and whenever possible, double-blind.

### **Placebo**

An inactive substance designed to resemble the drug being tested. It is used as a control to rule out any psychological effects testing may present.

# **Product Candidate**

### (or Clinical Compound)

A molecule that is selected at the end of preclinical studies to be the subject of the clinical phase of development.

### Randomized/randomization

Study participants are usually assigned to groups in such a way that each participant has an equal chance of being assigned to each treatment (or control) group. Since randomization ensures that no specific criteria are used to assign any patients to a particular group, all the groups should be comparable.

### Receptor

A protein complex within a cell or on the membrane surface characterized by selective binding of a specific substance and a specific physiologic effect that accompanies the binding.

### Reuptake

Reuptake is the process by which a neurotransmitter, after it has performed its function of transmitting a neural impulse, is transported back into the cell for reuse.

# Schizophrenia

Schizophrenia is a psychiatric diagnosis that describes a neuropsychiatric and mental disorder characterized by abnormalities in the perception or expression of reality. It most commonly manifests as auditory hallucinations, paranoid or bizarre delusions, or disorganized speech and thinking with significant social or occupational dysfunction. Onset of symptoms typically occurs in young adulthood, with around 0.4 – 0.6% of the population affected. Diagnosis is based on the patient's self-reported experiences and observed behaviour.

# **Substance P**

Substance P is a neuropeptide: a short-chain polypeptide that functions as a neurotransmitter and as a neuromodulator. It is a molecule that acts as a messenger for the sensation of pain.

# Substantia nigra

An area of the brain where there are cell bodies of dopaminergic neurons projecting to the striatum, a circuit involved in motor control. The death of dopaminergic neurons in the substantia nigra is one of the causes of PD.

### **Titration-up**

Administration of small incremental doses of a drug until a desired clinical effect is reached.

# **Tricyclic**

Molecular structures which contain three rings of atoms. The term "tricyclic antidepressant" is related to imipramine, desimipramine, amitriptyline, etc.

#### **Tetrodotoxin**

A potent neurotoxin, extracted from puffer fish, that binds and blocks the great majority of sodium ion channels in cellular membranes.

### **Tetrodotoxin-resistant**

A sodium ion channel which is resistant to the blocking activity of TTX.

### **Tetrodotoxin-sensitive**

A sodium ion channel which is sensitive to the blocking activity of TTX.

# **Tyramine**

A monoamine compound derived from the amino acid tyrosine, a member of the phenethylamine family.

# **UPDRS**

The Unified Parkinson's disease Rating Scale is the standard tool for tracking Parkinson's disease progress and response to therapy, subdivided into three scales including cognitive and mood aspects (Part I), Activities of Daily Living (Part II) and motor aspects symptoms (Part III), as well as dyskinesia aspects (Part IV). A lower score indicates a better condition than a higher score.

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