



# Half-Year Report 2008

# Corporate Profile

Newron (SWX: NWRN) is a clinical-stage biopharmaceutical company headquartered in Bresso near Milan, Italy, with fully owned subsidiaries in Basel, Switzerland, and Bristol, UK. Newron's mission is to develop and commercialize novel therapies for diseases of the Central Nervous System (CNS) and pain.

Newron is undertaking phase III trials with safinamide for the treatment of Parkinson's disease in conjunction with its partner, Merck Serono, which has exclusive worldwide rights to develop, manufacture and commercialize the compound in Parkinson's disease, Alzheimer's disease, and other therapeutic applications.

Recently, Newron reported exciting results for its compound ralfinamide in patients with Nerve Compression and Entrapment conditions, of which Neuropathic Low Back Pain (NLBP) represents the most common indication. There are no approved drugs for the treatment of NLBP. Newron expects to commence a phase IIb/III in NLBP later in 2008.

In May 2008, Newron acquired Hunter-Fleming Ltd., a private UK-based biopharmaceutical company developing new medicines to treat neurodegenerative and inflammatory disorders, adding three compounds in various phases of clinical development and one discovery program to Newron's development pipeline. The most advanced compound, HF0220, currently is in an ongoing phase II safety and tolerability study exploring biological markers in patients with Alzheimer's disease.

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# Half-Year 2008 Highlights

## **Exciting phase II results with ralfinamide in Neuropathic Low Back Pain (NLBP)**

- significant and clinically relevant improvement in
  - VAS/Likert scales: mean change and responder rates
  - Patient-rated Activities of Daily Living
  - Disruption of Sleep
- NLBP: prevalence of almost 8% – no drugs approved to date
- NLBP: accounts for about 60% of all neuropathic pain diagnoses
- future development plans discussed with major health authorities

## **Safinamide patent protection: EPO intention-to-grant letter on safinamide plus levodopa therapy in Parkinson's disease**

## **Completion of patient enrolment in phase III clinical trial with safinamide in mid to late-stage Parkinson's disease**

## **Acquisition of Hunter-Fleming Ltd.**

## **Data Safety and Monitoring Board recommends continuation of phase II study for HF0220 in patients with Alzheimer's disease**

## **Appointment of senior industry experts as nonexecutive Members of the Board of Directors**

## **Inclusion into SWX Swiss Performance Index**

## **Inclusion into SWX SXI indices\***

\* Post end of reporting period

# Shareholders' Letter



Rolf Stahel



Luca Benatti

Dear Shareholder,

Newron's management has made further progress in advancing the company's clinical projects and has succeeded in broadening the pipeline by completing the acquisition of Hunter-Fleming Ltd. whilst at the same time staying within the guidance presented to the markets at the beginning of the year, protecting the cash reserves from the IPO.

**Ralfinamide shows strong efficacy in Neuropathic Low Back Pain patients in phase II – a major opportunity in an indication offering blockbuster potential, where there are no drugs approved**

On April 15, 2008, we 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/NewronRalfinamidePhaseIIresultsApril16.pdf>).

The trial had been designed to include patients with multiple 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, the compound showed statistically significant superiority compared with placebo on the mean change in the patient-rated Visual Analog Scale (VAS) and Likert Scale – measures of the severity of pain. Responder rates were significantly increased compared to placebo and patients did experience a significant improvement in the quality of sleep and their performance of daily activities.

A recent 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).

Management sees these as very exciting results as they demonstrate the benefits of ralfinamide in a large population of patients for whom no other neuropathic pain treatments have been

shown to be effective. Using a high threshold to determine the clinical relevance of the benefit, i.e., 50% reduction of pain, significant differences between ralfinamide and placebo were noted. Based on the magnitude of the reduction in pain, significant benefits were also noted in the quality of sleep, daily activities, and type of pain. The robustness of the effect was noted across different analyses populations. As these data were derived from almost 100 patients with NCET, the results can be considered predictive for future trials. As a large number of these patients experience low back pain due to a neuropathic component, the benefits demonstrated suggest that ralfinamide may provide a unique therapeutic benefit for patients with Neuropathic Low Back Pain (NLBP), an indication accounting for about 60% of all neuropathic pain diagnoses.

Newron's regulatory affairs management has spent considerable effort in meeting authorities in Europe and North America to obtain agreement on the further development of ralfinamide. The company is getting ready to start a phase IIb/III trial of three months' treatment duration during 2008 in patients with NLBP, which could potentially turn out to be one of two pivotal trials required for approval in this indication.

Currently, no drugs are approved by health authorities for use in NLBP. If further development is successful, ralfinamide could become the first approved drug for NLBP, allowing fast penetration of and attractive pricing in this large market with a prevalence of almost 8% of the population.

**Safinamide – patent position strengthened by granting of patent on combination therapy; first phase III study in mid to late-stage PD to evaluate efficacy and safety, ongoing; patient enrolment completed**

We develop safinamide in conjunction with Merck Serono, which has exclusive worldwide rights to develop, manufacture and commercialize the compound in Parkinson's disease (PD), Alzheimers' disease (AD) and other therapeutic applications.

A patent application directed at the use of safinamide and levodopa for the treatment of PD has been granted by the European Patent Office. This patent will extend protection in Europe to 2024. The same combination therapy patent for safinamide in PD was filed in the US as well and, if granted as in the EU, would extend further the IP protection in the US, which currently lasts up to 2013, and if the supplementary extension is obtained, the protection could be extended to 2018.

Also, the safinamide phase III development program was significantly advanced, with Newron announcing in May that patient enrolment was completed in the first phase III clinical trial that will evaluate the efficacy and safety of safinamide as add-on therapy to a stable dose of levodopa for the treatment of patients with mid to late-stage PD.

The primary endpoint of this six-month (24 weeks) study is the increase in mean daily "on time" ("on time" without dyskinesia plus "on time" with minor dyskinesia) during an 18-hour period as recorded in patients' diaries. The study will also evaluate changes in cognitive function. All patients completing this six-month study meeting eligibility criteria may enter an 18 month (78-week), double-blind extension study to determine the efficacy and safety of long-term treatment with safinamide.

This first phase III study in mid to late-stage PD patients will see the last patient treated by mid-November, and topline results of the study should be reported upon completion of the initial analysis of the data, expected during Q1/2009.

Newron and Merck Serono plan to start the second phase III study in mid to late-stage PD patients early next year and to see recruitment of patients in the second phase III study in early PD patients accelerate. Both studies have experienced a delay in execution largely due to analyses done by Merck Serono to ensure that the clinical supplies of safinamide were within appropriate specifications with respect to applicable Health Authority requirements. Based on analytical data subsequently available, confirming that the clinical supplies of safinamide were actually within appropriate specifications, Newron and Merck Serono are now expediting the start and further conduct of the studies. Merck Serono is currently preparing a resubmission of the preclinical and clinical trial documentation to reflect the new data and update the health authorities. Merck Serono will update the status of activities in due course.

#### **NW3509 on track**

NW3509 has confirmed its efficacy in further models of mania and has shown efficacy in models of memory impairment. These effects may possibly translate in activity against information processing and cognition deficit in bipolar patients.

#### **Execution of corporate strategy – acquisition of Hunter-Fleming closed**

On May 13, 2008, Newron completed the acquisition of Hunter-Fleming Ltd. (HF), Bristol, a private, UK based biopharmaceutical company developing new medicines to treat neurodegenerative and inflammatory disorders. Upon closing, Hunter-Fleming shareholders in their totality received about 3.1% of new Newron shares from a capital increase, with additional milestones of no more than EUR 17 m in new Newron shares potentially adding to that in the next years. The milestones are strictly linked to development and commercialization success mostly of HF0220, the lead compound, currently being developed in Alzheimer's disease (AD).

The acquisition is consistent with Newron's growth strategy, enlarging Newron's clinical-stage pipeline, particularly in the area of neuroinflammation.

Hunter-Fleming provides a pipeline of three compounds in various phases of clinical development and one in discovery:

HF0220: a broad spectrum neuroprotective agent with

- an ongoing phase II safety and tolerability study exploring biological markers in patients with Alzheimer's disease
- a phase II study in rheumatoid arthritis to be initiated in the near future

HF0420: a low molecular weight oligosaccharide in phase I for prevention of anticancer therapy-induced neuropathy

HF0299: a naturally occurring human steroid in phase I with potential in the treatment of neuropathic pain

HF1220: a second-generation neuroprotective compound series in discovery phase

Newron has also acquired a nondilutable 17% equity holding in a Special Purpose Vehicle (SPV) set up to develop a late preclinical compound in asthma.

**Below, the pipeline of Newron post acquisition of HF, showing in blue the Newron compounds and in green the HF compounds**

	Lead	Preclinical	Phase I	Phase II	Phase III
<b>Safinamide</b>					
Adjunctive to dopamine agonist Early-stage PD	[Blue bar spanning Lead, Preclinical, Phase I, Phase II]				
Adjunctive to levodopa Mid to late-stage PD	[Blue bar spanning Lead, Preclinical, Phase I, Phase II]				
<b>Ralfinamide</b>					
Neuropathic Low Back Pain	[Blue bar spanning Lead, Preclinical, Phase I, Phase II]				
Inflammatory Pain	[Blue bar spanning Lead, Preclinical, Phase I]				
<b>HF0220</b>					
Alzheimer's disease	[Green bar spanning Lead, Preclinical, Phase I, Phase II]				
Rheumatoid Arthritis	[Green bar spanning Lead, Preclinical, Phase I]				
<b>HF0420</b>					
Anticancer therapy-induced-neuropathy	[Green bar spanning Lead, Preclinical, Phase I]				
<b>HF0299</b>					
Neuropathic pain	[Green bar spanning Lead, Preclinical, Phase I]				
<b>NW-3509</b>					
CNS-related disorders/pain	[Blue bar spanning Lead, Preclinical]				
<b>HF1220 Series</b>					
Neuroprotection	[Green bar spanning Lead, Preclinical]				
<b>IC</b>					
CNS-related disorders/pain	[Blue bar spanning Lead, Preclinical]				

Notes:

Newron is undertaking phase III trials with safinamide for the treatment of PD on behalf of its partner Merck Serono

IC= Ion Channel Program

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

In the mean time, the integration of the Hunter-Fleming operations has been successfully completed and the remaining team at the Bristol site together with their counterparts in Basel and Bresso are evaluating the detailed development plans for all compounds.

Newron's broadenend pipeline is expected to generate major clinical newsflow within the next 15 months on safinamide, ralfinamide, HF0220 and NW3509 as well as the potential for a licensing opportunity for ralfinamide.



### Changes in BoD structure

With the term of the previous members of the Board of Directors (BoD) expiring, the shareholders appointed the BoD for the period ending with the approval of the financial statements for the year 2010. The opportunity was used to establish a BoD with new, independent, and highly experienced experts recognized within the major disciplines of the global pharmaceutical industry. Rolf Stahel, Dr. Luca Benatti, Dr. Francesco Parenti, Hervé Guérin, Renée Aguiar-Lucander and Dr. Hans-Joachim Lohrisch were reelected to Newron's Board of Directors. Newly elected to the Board were Dr. Patrick Langlois, Ragnar Linder and Professor Dr. Hanns Moehler, replacing former Board members Axel Bolte, Laurent Ganem and Dr. Alexandra Goll. The Board expressed appreciation for the significant contribution of the departing Board colleagues.

### Interim financial statements

The enclosed interim financial statements for the first time provide a consolidated view on the Newron group, consisting of Newron Pharmaceuticals S.p.A., Milan, Newron Suisse S.A., Basel, and Hunter-Fleming Ltd., Bristol.

In the first six months of 2008, Newron has significantly increased its development costs for ralfinamide, NW3509 as well as the new HF compounds, fully in line with the guidance given to financial markets. The development cost increased from EUR 2.8 m from previous period to EUR 5.1 m in the current period, both net of safinamide development cost as reimbursed by our partner Merck Serono of EUR 5.6 m (2007) and EUR 5.3 m (current period). In addition, 2008 R&D expense has been reduced by an R&D tax credit of EUR 0.4 m. Therefore, the current period's gross R&D expense increased to EUR 10.8 m, compared to EUR 8.4 m in 2007, reflecting the broadening of the pipeline and the further development of compounds. Due to the restructuring of Hunter-Fleming, post acquisition, a one-time expense of about EUR 1.3 m has impacted G&A expenses. The cash position as per June 30 was impacted by two items: Repayment of a significant part of HF debt post acquisition of the company and the late payment by a development partner of EUR 2.9 m, due in June, but arriving at our bank accounts only in early July.

As a result, for the reporting period the Newron group shows a net loss of EUR 7.3 m and net cash used in operating activities of EUR -12.7 m, resulting in a cash and cash equivalent position of EUR 47.6 m per June 30, 2008.

### Outlook

Newron's management expects ralfinamide to start a phase IIb/III study within the coming months, exploring the efficacy and safety of the compound in Neuropathic Low Back Pain, potentially becoming one of two pivotal trials in the indication. An outlicensing of ralfinamide could occur, given attractive terms, any time between now and the time when interested third parties will have reviewed the results of the upcoming phase IIb/III study.

Safinamide is being evaluated in phase III safety and efficacy studies in mid to late-stage Parkinson's disease patients, to assess effects on increase of on-time, reduction of off-time, and improvement in motor function and cognition, with additional assessments of safety. Topline results of the study should be reported upon completion of the initial analysis of the data, expected during Q1/2009.

Newron and Merck Serono plan to start the second phase III study in mid to late-stage PD patients early next year and expect to see recruitment of patients in the second phase III study in early PD patients accelerate.

HF0220 will produce additional safety and tolerability data in a small phase II study in Alzheimer's disease. Further evaluation of the potential of the compound could lead to the start of a phase II safety and biomarker efficacy study in Rheumatoid Arthritis.

NW3509 might move into clinical development.

Management confirms the expenditure guidance for 2008.



Rolf Stahel  
Chairman



Luca Benatti  
Chief Executive Officer

# Interim Condensed Consolidated Financial Statements


For the six months ended June 30, 2008

**AUDITOR'S REVIEW REPORT ON THE INTERIM  
CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****To the Board of Directors of  
Newron Pharmaceuticals S.p.A.**

1. We have reviewed the interim condensed consolidated financial statements of Newron Pharmaceuticals S.p.A. and its subsidiaries (the "Newron Group") as of June 30, 2008, comprising the balance sheet, the statement of income, changes in shareholders' equity and cash flows and the related explanatory notes. The Board of Directors is responsible for the preparation and presentation of these interim condensed consolidated financial statements in accordance with International Financial Reporting Standard IAS 34 Interim Financial Reporting ("IAS 34"). Our responsibility is to express a conclusion on these interim condensed consolidated financial statements based on our review.
2. We conducted our review in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.
3. Based on our review, nothing has come to our attention that causes us to believe that the accompanying interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with IAS 34.

Milan, September 5, 2008

Reconta Ernst &amp; Young S.p.A.

  
Paolo Zocchi  
(Partner)

# Interim Consolidated Income Statement

(In thousand euro, except per share information)	Note	For the six months ended June 30	
		2008 unaudited	2007 unaudited
Licence income	5	1,310	2,152
Other income	6	737	33
<b>Revenues</b>		<b>2,047</b>	<b>2,185</b>
Research and development expenses	7	(5,108)	(2,811)
Marketing and advertising expenses		(72)	(55)
General and administrative expenses	8	(5,297)	(4,503)
<b>Operating loss</b>		<b>(8,430)</b>	<b>(5,184)</b>
Financial income	9	1,142	1,209
<b>Loss before tax</b>		<b>(7,288)</b>	<b>(3,975)</b>
Income tax expense		(4)	0
<b>Net loss</b>		<b>(7,292)</b>	<b>(3,975)</b>
<b>Loss per share</b>			
	Basic and diluted	<b>(1.24)</b>	<b>(0.68)</b>

(The accompanying notes are an integral part of these financial statements.)

# Interim Consolidated Balance Sheet

(In thousand euro)	Note	As of	
		June 30, 2008	December 31, 2007
		unaudited	audited
<b>Assets</b>			
Non-current assets			
Property, plant and equipment		578	433
Intangible assets	4	11,991	32
Available-for-sale investments	4	584	0
Non-current receivables	10	587	387
		13,740	852
Current assets			
Inventories		521	523
Receivables and prepayments	11	8,866	5,836
Cash and cash equivalents	12	47,637	63,157
		57,024	69,516
<b>Total assets</b>		<b>70,764</b>	<b>70,368</b>
<b>Shareholders' equity</b>			
Share capital	13	1,204	1,167
Share premium	14	60,746	66,978
Share option reserve		2,257	2,091
Retained earnings		(9,659)	(12,836)
Translation differences		(25)	0
<b>Total shareholders' equity</b>		<b>54,523</b>	<b>57,400</b>
<b>Liabilities</b>			
Non-current liabilities			
Deferred income		670	1,973
Deferred tax liability	4	3,755	0
Long-term borrowings		673	561
Employee cash-settled share-based liabilities		301	281
Employee severance indemnity		487	380
		5,886	3,195
Current liabilities			
Deferred income		2,628	2,635
Short-term borrowings		868	272
Trade and other payables		6,859	6,866
		10,355	9,773
<b>Total liabilities</b>		<b>16,241</b>	<b>12,968</b>
<b>Total equity and liabilities</b>		<b>70,764</b>	<b>70,368</b>

(The accompanying notes are an integral part of these financial statements.)

# Interim Consolidated Statement of Changes in Shareholders' Equity

(In thousand euro) Unaudited	Note	Share capital	Share premium	Share option reserve	Foreign currency transla- tion reserve	Retained earnings	Total
Balance at January 1, 2007		1,164	82,148	1,803	0	(17,257)	67,858
Previous year loss allocation			(15,509)			15,509	0
Share option scheme				137			137
Issue of shares – 2003 option plan		3	339	(55)			287
Net loss						(3,975)	(3,975)
<b>Balance at June 30, 2007</b>		<b>1,167</b>	<b>66,978</b>	<b>1,885</b>	<b>0</b>	<b>(5,723)</b>	<b>64,307</b>
Balance at January 1, 2008		1,167	66,978	2,091	0	(12,836)	57,400
Previous year loss allocation			(10,469)			10,469	0
Share option scheme				166			166
Issue of shares – Hunter-Fleming Ltd. acquisition	13, 14	37	4,656				4,693
Issuing cost			(419)				(419)
Currency translation differences					(25)		(25)
Net loss						(7,292)	(7,292)
<b>Balance at June 30, 2008</b>		<b>1,204</b>	<b>60,746</b>	<b>2,257</b>	<b>(25)</b>	<b>(9,659)</b>	<b>54,523</b>

(The accompanying notes are an integral part of these financial statements.)

# Interim Consolidated Cash Flow Statement

(In thousand euro)	Note	For the six months ended June 30	
		unaudited 2008	unaudited 2007
Loss before tax		(7,288)	(3,975)
Adjustments for:			
Depreciation and amortization		134	96
Interest income		(1,158)	(1,226)
Grants and other nonmonetary income	6	(1,114)	(33)
Share option expenses		186	137
Employee severance indemnity expense		202	117
Changes in working capital:			
Inventories		2	865
Current receivables and prepayments and deferred cost (excluding grants receivable)		(3,080)	(1,061)
Trade and other payables and deferred income (excluding advances of grants)		(1,322)	(4,329)
Cash used in operations	16	(13,438)	(9,409)
Cash flows from operating activities			
Cash used in operations		(13,438)	(9,409)
Government grants received		695	0
Pension fund paid		(95)	(109)
Change in non-current receivables		177	0
Net cash used in operating activities		(12,661)	(9,518)
Cash flows from investing activities			
Purchase of financial assets		0	(30,000)
Purchase of property, plant and equipment		(201)	(122)
Purchase of intangible assets		(37)	(17)
Acquisition of a subsidiary, net of cash acquired	4	(4,068)	0
Interest received		1,158	932
Net cash flows from/(used in) investing activities		(3,148)	(29,207)
Cash flows from financing activities			
Net proceeds from borrowings		708	0
Proceed from issue of shares (exercise of stock option)		0	287
New shares issuing costs		(419)	0
Net cash flows from financing activities		289	287
Net increase/(decrease) in cash and cash equivalents		(15,520)	(38,438)
Cash and cash equivalents at January 1		63,157	74,765
<b>Cash and cash equivalents at the end of the six months period – Newron Group</b>		<b>47,637</b>	<b>36,327</b>

(The accompanying notes are an integral part of these financial statements.)



# Notes to the Interim Condensed Consolidated Financial Statements

## 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 Ltd., a private biopharmaceutical company based in Bristol (United Kingdom) and focused on neurodegenerative and inflammatory disorders, which has been acquired on April 24, 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 SWX Swiss Exchange, Zurich, Switzerland, under the trade name NWRN.

These interim consolidated financial statements have been approved for issuance by the Board of Directors on September 4, 2008.

## 2 Basis of presentation and accounting policies

The condensed interim consolidated financial statements of Newron Group for the six-month period ended June 30, 2008, have been prepared in accordance with IAS 34 “Interim Financial Reporting”.

These interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2007, as they provide an update of previously reported information.

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 where otherwise indicated.

The Company’s activities are not subject to seasonal fluctuations.

### Accounting policies

The accounting policies are consistent with those used in the annual consolidated financial statements for the year ended December 31, 2007. As a consequence of the acquisition of Hunter-Fleming Ltd. the Group has capitalized as intangible assets the fair value of in-progress research and development projects acquired. As previous research and development expenses are exclusively internally incurred, the accounting policy related to research and development costs has been integrated as follows:

### Research and development

Costs internally 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 internally incurred research and development costs have been treated as expenses as commercial and technical feasibility continues to be assessed.

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 initial capitalization 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.

The adoption of new Standards and Interpretation is summarized below:

- **IFRIC 11, IFRS 2 Group and Treasury Share Transactions:** Effective for annual periods beginning on or after March 1, 2007. The Group did apply IFRIC 11 from January 1, 2008, on, which did not have an impact on the Group's financial statements.
- **IFRIC 12 Service Concession Arrangements:** Effective for annual periods beginning on or after January 1, 2008. The Group did apply IFRIC 12 from January 1, 2008, on, which did not have an impact on the Group's financial statements.
- **IFRIC 14 The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interactions:** Effective for annual periods beginning on or after January 1, 2008. The Group applied IFRIC 14 since January 1, 2008, which did not have an impact on its financial statements.

### 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.

### Related-party transactions

No significant transactions with related parties have occurred in the six-month period ending June 30, 2008.

### 3 Exchange rates of principal currencies

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

(In thousand euro)	Income statements in euro (average rates) six months ended June 30,		Balance sheets in euro (rates as of) June 30,	
	2008	2007	2008	2007
CHF 1	0.62248	n/a	0.62282	n/a
GBP 1	1.26295*	n/a	1.26223	n/a

\* The consolidation of Hunter-Fleming Ltd. started as of May 1, 2008, and accordingly the Group has included in the interim consolidated financial statements the

operation of the subsidiary for the last 2 months of the semester. As a consequence the exchange rate used to consolidate Hunter-Fleming's operations corresponds to the 2 months average exchange rate of May and June 2008.

The exchange rate used to translate Hunter-Fleming's opening Balance Sheet as of May 1, 2008, is equal to GBP 1 = EUR 1.26558.

### 4 Business combination

#### Acquisition of Hunter-Fleming Ltd.

On April 24, 2008, the Group approved the acquisition of 100% of the voting shares of Hunter-Fleming Ltd., a private biopharmaceutical company based in Bristol (United Kingdom) developing new medicines to treat neurodegenerative and inflammatory disorders. The total cost of the combination was EUR 5,315 and comprised i) EUR 4,694 paid to former Hunter-Fleming shareholders by means of newly issued Newron shares (n. 185,742 ordinary shares with par value of EUR 0.20 per share and a premium of EUR 25.07 per share. For further details, please refer to note 13), ii) costs of EUR 621 directly attributable to the acquisition. In addition, the Company and Hunter-Fleming agreed on further performance-based milestones related to the progression of Hunter-Fleming programs, up to a maximum of EUR 17 million. The directors considered the achievement of the agreed milestones as not probable. Accordingly, as stated by IFRS 3 as for contingent considerations, the corresponding earn-out has not been accounted for. The interim consolidated financial statements include the results of Hunter-Fleming for the two-month period from May 1, 2008, to June 30, 2008.

The acquisition has been accounted for using the purchase method, as stated by IFRS 3. The purchase price has been allocated based on a preliminary estimate of the fair value of assets acquired and liabilities assumed at the date of acquisition. The purchase price allocation of the identifiable assets and liabilities of Hunter-Fleming as at the date of acquisition and the carrying amounts immediately before the acquisition were:

(In thousand euro)	Purchase price allocation euro	Previous carrying value euro
<b>Assets</b>		
Non-current assets	12,568	51
Property, plant and equipment	51	51
Intangible assets	11,933	0
Available-for-sale investments	584	0
<b>Current assets</b>		
Trade and other receivables	366	366
Prapayments	191	191
<b>Total assets</b>	<b>13,124</b>	<b>608</b>
<b>Liabilities</b>		
Non-current liabilities	3,980	225
Interest-bearing borrowings	225	225
Deferred tax liabilities	3,755	0
<b>Current liabilities</b>		
Interest-bearing borrowings	1,988	1,988
Bank account	441	441
Trade and other payables	1,401	1,401
<b>Total liabilities</b>	<b>7,809</b>	<b>4,055</b>
<b>Net assets</b>	<b>5,315</b>	<b>(3,447)</b>
<b>Purchase price</b>	<b>5,315</b>	

Intangible assets recognized in the context of the purchase price allocation process, amounting to EUR 11,933, entirely refer to in-process research and development (“IPR&D”) projects. In particular, the Company acquired 4 projects which relate to the development of new medicines to treat neurodegenerative and inflammatory disorders (three compounds in clinical development and one in discovery).

As a result of the acquisition, the Group will also hold a minority interest (17%) in Trident, a Special Purpose Vehicle (SPV) set up to develop a late-preclinical compound in asthma. Such investment has been classified among available-for-sale investments for an amount of EUR 584.

Deferred tax liabilities of EUR 3,755 have emerged in connection with the values allocated to intangible assets and available for sale investments.

The purchase price has been paid to former Hunter-Fleming shareholders by means of newly issued Newron shares as described above. The financial negative effect of the operation is equal to EUR 4,068 of which EUR 621 are costs directly attributable to the acquisition and EUR 3,447 is the net financial debt acquired.

Since the date of acquisition, Hunter-Fleming has contributed EUR 2,384 to the net losses of the Group. If the combination had taken place at the beginning of the year, the losses for the Group would have been EUR 8,599.

### 5 Licence income

Licence income of EUR 1,310 (2007: EUR 2,152) 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.

### 6 Other income

Other income includes EUR 93 of Grants (2007: EUR 33) and EUR 644 of Research and Development Tax Credit (2007: EUR 0).

In June 2008, the Italian fiscal authorities approved the final operating rules to allow the companies to ask for a partial reimbursement of certain research and development expenses. The approved law refers to the research and development costs incurred during 2007, 2008 and 2009 and identifies all the relevant costs, the structure of the report to be submitted to the competent authorities and the reimbursement procedure. The arising Tax Credit does not expire and can be used to offset any tax disbursement (including VAT and withholding taxes) which the company will have to incur after the filing of the report. The amount shown in Other income (EUR 644) corresponds to the Tax Credit estimated as for research and development costs incurred in 2007. The credit related to costs incurred during the 6-month period ended June 30, 2008, has been estimated at EUR 377; such an amount has been classified as a reduction of the related research and development costs.

## 7 Research and development expenses

(In thousand euro)	For the six months ended June 30,	
	2008	2007
Services received from subcontractors	2,312	849
Staff costs	1,683	1,138
Consultancy fees	499	363
Material and consumable used	307	217
Laboratory operating lease cost	224	197
Depreciation and amortization expense	76	40
Other research and development costs	7	7
	<b>5,108</b>	<b>2,811</b>

Research and development expenses related to the 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. All other research and development expenses are partially reimbursed by the Italian Fiscal Authorities as detailed in note 6. Accordingly, research and development expenses are presented net of costs reimbursed by Merck Serono, amounting to EUR 5,268 in the first semester 2008 (2007: EUR 5,553) and by Italian Fiscal Authorities, amounting to EUR 377 in the same period.

The total increase of EUR 2,297 is mostly due to i) a significant increase (EUR 1,463) in Services received from subcontractors, with particular reference to ralfinamide preclinical and clinical trials and to the newly acquired Hunter-Fleming projects, ii) an increase (EUR 545) in Staff costs as a consequence of the establishment of Newron Suisse SA and of the purchase of Hunter-Fleming Ltd.

Since inception, no internally incurred research and development costs have been capitalized.

## 8 General and administrative expenses

(In thousand euro)	For the six months ended June 30,	
	2008	2007
Staff costs	2,674	1,112
Consultancy and other professional services	1,316	1,496
Intellectual properties	454	247
Travel expenses	325	262
Operating lease cost	90	64
Depreciation and amortization expense	58	52
Other expenses	380	1,270
	<b>5,297</b>	<b>4,503</b>

General and administrative expenses increased in 2008 by EUR 794. The increase is mainly (EUR 672) related to the combined effect of the following items: (a) significant increase (EUR 1,562) in Staff costs as a consequence of a higher headcount and of Hunter-Fleming restructuring and (b) decrease in Other expenses (EUR 890), since in 2007 the company paid the first milestone relating to the Purdue settlement agreement signed on June 29, 2007 (while no disbursement related to the Purdue settlement has been incurred in the first semester 2008).

## 9 Financial income

Financial income of EUR 1,142 (2007: EUR 1,209) is generated by the investment of the IPO proceeds in highly liquid investments. Net financial income has slightly decreased with respect to 2007 as a consequence of the decrease of net financial resources invested and the increase of the investment return rate.

## 10 Non-current receivables

(In thousand euro)	As of	
	June 30, 2008	December 31, 2007
Deferred costs	84	247
R&D tax credit	377	0
Guarantee deposits for leases	126	140
	<b>587</b>	<b>387</b>

As for Research and Development Tax Credit, please refer to note 6. Since this amount can be offset against tax disbursements starting from October 2009, it has been classified as a non-current receivable.

## 11 Receivables and prepayments

(In thousand euro)	As of	
	June 30, 2008	December 31, 2007
Receivables	5,761	1,896
Government grants receivable	155	850
Prepayments	917	1,572
Deferred costs	330	330
VAT receivable	669	1,002
Other receivables	1,034	186
	<b>8,866</b>	<b>5,836</b>

Receivables are entirely represented by the accruals related to the reimbursement of safinamide's research and development costs. According to the collaboration agreement in force from 2006, such costs will be reimbursed to the Group by Merck Serono. The Company collected in

July 2008 an amount of EUR 2.9 million out of the balance outstanding as of June 30, 2008. Such an amount refers to the reimbursement of the first-quarter expenses. First-quarter reimbursement was collected last year before June 30, 2007.

In February 1999 the Company submitted to the Ministry of Education, University and Research (MIUR) a project containing an application for a grant pursuant to law n. 451 of July 19, 1994. The related agreement awarded Newron a grant covering both “research” expenses, for a total of EUR 5,546 thousand (equal to 75% of the maximum admissible cost) and “training” expenses, equal to 100% of costs incurred. The project started on June 2001 and was completed on 19 June 2004. In May 2008 the Company collected EUR 695 from MIUR as final balance of the above-mentioned project.

Other receivables include the current portion of the research and development Tax Credit (EUR 644).

## 12 Cash and cash equivalents

(In thousand euro)	As of	
	June 30, 2008	December 31, 2007
Cash at bank and in hand	2,201	4,861
Short-term investments	45,436	58,296
	<b>47,637</b>	<b>63,157</b>

The “Short-term investments” are highly liquid investments easily convertible into cash, not subject to significant changes in value and with no withdrawal penalty.

## 13 Share capital

As of December 31, 2007, the subscribed share capital was equal to EUR 1,166,953.20, divided into 5,834,766 ordinary shares with nominal value equal to EUR 0.20 each. The authorized share capital is equal to EUR 1,275,595.20 (divided into n. 6,377,976 ordinary shares).

In connection with the acquisition of Hunter-Fleming, on April 24, 2008, the extraordinary shareholders’ meeting resolved, among other resolutions, to increase the share capital through contribution in kind of 100% of Hunter-Fleming Ltd. shares, by a maximum nominal amount of EUR 80,000, corresponding to n 400,000 of Newron’ ordinary shares with par value of EUR 0.20 per

share, also granting the Board of Directors the power to execute the above-mentioned capital increase.

Consequently, on May 5, 2008, the Board of Directors’ meeting resolved to increase Newron share capital by EUR 37,148.40 issuing 185,742 ordinary shares, with par value of EUR 0.20 per share and a premium of EUR 25.07 per share. The shares issued have been used to acquire 100% (n. 14,163,033) of Hunter-Fleming Ltd. shares officially contributed in kind into Newron Pharmaceuticals S.p.A. on May 13, 2008.

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

(In euro)	Total
As of December 31, 2006 – Newron stand alone	1,164,021.20
- issue of ordinary share (option plan)	2,932.00
As of December 31, 2007 – Newron Group	1,166,953.20
- issue of ordinary share (Hunter-Fleming acquisition)	37,148.40
As of June 30, 2008 – Newron Group	1,204,101.60

## 14 Share premium

(In thousand euro)	As of	
	June 30, 2008	December 31, 2007
At the beginning of the year	66,978	82,148
Loss allocation	(10,469)	(15,509)
Issue of shares	4,656	
Issue of shares (option)	0	284
Reclassification from share option reserve	0	55
Share capital issue costs	(419)	0
At the end of the period	<b>60,746</b>	<b>66,978</b>

Share capital issue cost includes: stamp duties, lawyers’ fees, notary public fees and other estimated issuing-related expenses.

## 15 Loss per share

The basic loss per share is calculated dividing the net loss attributable to shareholders by weighted average number of ordinary shares outstanding during the period.

(In thousand euro)	For the six months ended June 30,	
	2008	2007
Net loss attributable to shareholders	(7,292)	(3,975)
Weighted average number of shares (thousands)	5,903	5,832
Loss per share - basic (in euro)	(1.24)	(0.68)

The only categories of potential ordinary shares are the stock 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.

### 16 Events after the balance sheet date

On July 21, 2008, the Company granted n. 4,500 options (June 2007 plan) to certain employees at a strike price equal to EUR 17.81 per option. As of today, the Company has granted n. 62,000 options in relation with the June 2007 plan at an average exercise strike price of EUR 35.45.

# Information for Investors

## Share price data

Symbol	NWRN
Listing	SWX
Nominal value	EUR 0.20
ISIN	IT0004147952
Swiss Security Number (Valor)	002791431
Number of shares	6,020,508
52 week high (in CHF)	68.00 (August 29, 2007)
52 week low (in CHF)	24.50 (July 31, 2008)
Loss per share (in EUR)	1.24 (period from January 1, to June 30, 2008)
Cash and cash equivalents as at June 30 (in EUR)	47.6 m
Market capitalization (in CHF)	186.6 m (based on 6,020,508 outstanding shares and a share price of CHF 31.00, as per August 27, 2008)

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## Important Notices

This document contains forward-looking statements, including (without limitation) about (1) Newron's ability to develop and expand its business, successfully complete development of its current product candidates and current and future collaborations for the development and commercialisation of its product candidates and reduce costs (including staff costs), (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's anticipated future revenues, capital expenditures and financial resources, and (4) assumptions underlying any such statements. In some cases these statements and assumptions can be identified by the fact that they use words such as "will", "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "target", and other words and terms of similar meaning. All statements, other than historical facts, contained herein regarding Newron's strategy, goals, plans, future financial position, projected revenues and costs and prospects are forward-looking statements.

By their very nature, such statements and assumptions involve inherent risks and uncertainties, both general and specific, and risks exist that predictions, forecasts, projections and other outcomes described, assumed or implied therein will not be achieved. Future events and actual results could differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. These factors include (without limitation) (1) uncertainties in the discovery, development or marketing of products, including without limitation negative results of clinical trials or research projects or unexpected side effects, (2) delay or inability in obtaining regulatory approvals or bringing products to market, (3) future market acceptance of products, (4) loss of or inability to obtain adequate protection for intellectual property rights, (5) inability to raise additional funds, (6) success of existing and entry into future collaborations and licensing agreements, (7) litigation, (8) loss of key executive or other employees, (9) adverse publicity and news coverage, and (10) competition, regulatory, legislative and judicial developments or changes in market and/or overall economic conditions.

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