

# Half-Year Report 2013

## Corporate profile

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

Based on the phase III results of safinamide for the treatment of Parkinson's disease, Newron is working to expedite the global filing of the compound, together with its partners. Zambon Group has the rights to commercialise safinamide globally, excluding Japan and other key Asian territories, and Meiji Seika has the rights to develop and commercialise safinamide in Japan and other key Asian territories. Newron's additional projects are primarily addressed towards highly promising treatments for rare disease patients and are at various stages of clinical development, including sNN0031 for patients with Parkinson's disease, non-responsive to oral drug treatments, sarizotan for patients with Rett's syndrome, sNN0029 for patients with ALS, ralfinamide for patients with specific pain indications, and NW-3509 as potential first add-on therapy for the treatment of patients with schizophrenia.

www.newron.com

# Half-Year 2013 Highlights

Ph III data on safinamide presented at the following congresses:

- 65th Annual Meeting of the American Academy of Neurology (AAN),
  March (San Diego, USA)
- 9th International Congress on Mental Dysfunction & Other Non-Motor Features in Parkinson's Disease and Related Disorders, April (Seoul, South Korea)
- 17th International Congress of Parkinson's Disease and Movement Disorders, June (Sydney, Australia)

Meetings with all relevant regulatory authorities completed in Europe; completion within short, in the US; expected regulatory submission for marketing authorization of safinamide in the US and Europe confirmed for O4 2013

Ongoing support of partner Meiji Seika Pharma Co., Ltd., who are proceeding with their conduct of clinical development of safinamide in Japan

Encouraging data from the first Phase I/II safety and efficacy study of sNN0031, a novel drug candidate for treatment of patients with Parkinson's disease, non-responsive to oral drug therapy, presented at the 17th International Congress of Parkinson's disease and Movement Disorders

Award of up to EUR 2.5 million from The Wellcome Trust to support Phase I/II development of sNN0029 for patients with Amyotrophic Lateral Sclerosis (ALS)

Subscription of newly issued shares for EUR 1.7 million by two existing long term shareholders, in execution of subscription undertakings by Zambon

Integration of former NeuroNova (now Newron Sweden) successfully completed

Ulrich Köstlin elected new non-executive Chairman, Robert Leslie Holland and Bo Jesper Hansen joining as non-executive directors



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## Shareholders' Letter







Stefan Weber

Dear Shareholder,

We are pleased to report on a number of key events in the first half of 2013, all of which have a positive influence on Newron's future.

Our clinical team has been preparing and presenting further Phase III data for safinamide, our lead asset, at major scientific congresses. This data further validates the excellent results we gained from the MOTION and SETTLE studies, which completed the Phase III programme for safinamide as add-on therapy for patients with Parkinson's disease.

So far this year, data on safinamide has been presented at the 65th Annual Meeting of the American Academy of Neurology (AAN), March (San Diego, USA), the 9th International Congress on Mental Dysfunction & Other Non-Motor Features in Parkinson's Disease and Related Disorders, April (Seoul, South Korea), and the 17th International Congress of Parkinson's Disease and Movement Disorders, June (Sydney, Australia).

The data presented demonstrated that safinamide significantly improves both motor function in early Parkinson's disease patients on a single dopamine agonist at a stable dose and motor fluctuations in mid-to late stage PD patients on levodopa and other PD drugs at a stable dose. The data also showed safinamide significantly improves Quality of Life (QoL) during long term treatment in patients with both early and advanced Parkinson's disease, as well as responder rates in patients on levodopa and other PD drugs at a stable dose. Finally, in the studies safinamide was well tolerated with low drop-out rates.

As a result, awareness has grown in the medical community that safinamide offers an exciting new treatment option for patients with early and mid- to late stage Parkinson's disease. We are working closely with our partner Zambon and the regulatory authorities to prepare the filing in the US and Europe, expected during Q4 2013. We anticipate the sub-licencing of safinamide by Zambon to a partner for the US pre or post filing, in order to maximize the opportunity in this important market.

For Japan and Asia, we continue to collaborate with our partner Meiji Seika Pharma Co., Ltd. to support the development of safinamide in their license territory.

We have also made good progress with the rest of our pipeline. For example, in June we presented encouraging data from the first Phase I/II safety and efficacy study of sNN0031 at the 17th International Congress of Parkinson's disease and Movement Disorders. sNN0031 is a novel drug candidate for the treatment of Parkinson's disease patients who no longer respond to oral therapy, designed to act on neural stem and progenitor cells in the brain. sNN0031 had already shown to restore motor function and improve neurochemical deficits in models of PD.

In February we received an award of up to EUR 2.5 million from the Wellcome Trust to support Phase I/II clinical development of our experimental compound sNN0029 for the treatment of patients with Amyotrophic Lateral Sclerosis (ALS). The trial is expected to start during H2 2013.

On the organisational side, the integration of former NeuroNova (now: Newron Sweden), based in Stockholm and acquired at the end of 2012, has been completed. Cost synergies have been realized, and new processes have been agreed to use the full competence of the entire organisation in order to successfully develop the company's assets.

On the governance side, significant changes to our Board of Directors were proposed to, and accepted by our shareholders during the Shareholder meeting held in Milan on 18 April. As a result, we welcomed Ulrich Köstlin as our new non-executive Chairman, with Robert Leslie Holland and Bo Jesper Hansen joining as non-executive directors. This meant the departure of Rolf Stahel, our Chairman since 2004, to whom we owe much gratitude for his leadership, wise counsel and hard work during his tenure. Alongside, Francesco Parenti, a non-executive director and the first chairman of Newron, stood down after 14 years of valuable service. The new Board offers strong support in steering Newron through our next stages of growth.

Our two main shareholders confirmed their long-term commitment to Newron and their support for an independent Board of Directors. This puts us in a strong position during the coming years when we expect to bring safinamide to market and to see the medical potential of the follow-on compounds being disclosed.

In June, we issued new shares for about EUR 1.7 million, subscribed by two of our existing long term shareholders, who we thank for their continued support. The issue covered the obligations under the 2012 agreements with Zambon, referring to Zambon's participation in future capital increases.

In the first six months of 2013, we have invested EUR 4.4 million into drug development and preparations for regulatory submission of safinamide, up from EUR 2.4 million in 2012. Of these, EUR 3.6 million have been covered by our previous and current safinamide partners as well as by grants. Therefore, for the first six months of the year, net R&D expenses are EUR 0.8 million, in line with the expenses in 2012.

G&A expenses reached EUR 3.7 million in the first six months 2013, for the first time including the remaining operations of former NeuroNova (now: Newron Sweden) in Stockholm. In 2012 (excluding NeuroNova), G&A expenses had been at a comparable EUR 3.6 million.

Considering revenues of EUR 2.2 million during the first half year of 2013, mostly stemming from recognition of a 2012 license down-payment over the period of collaboration with our partner Zambon, the net loss for the first six months of 2013 amounts to EUR 2.4 million, compared to a profit of EUR 2.7 million in 2012, which was due to one-time effects.

With EUR 21.8 million of cash in the bank plus EUR 7.5 million contractually committed by Zambon, the European Union and The Wellcome Trust to support our development projects and regulatory work, we continue to be sufficiently funded well into 2015, beyond expected key value inflexion points and inflow of related material milestone payments.

Newron is poised for a bright future and we look forward to the upcoming global filing of safinamide and to continuing to develop and build our innovative product portfolio. These achievements will position Newron as a leader in the development of new treatments for patients with CNS disease.

Yours sincerely

Dr. Ulrich Köstlin

Chairman

Chief Executive Officer

# Interim Condensed Consolidated Financial Statements

For the six months ended June 30, 2013

# **Auditors' Report**



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### Auditor's review report on the interim condensed consolidated financial statements

To the Board of Directors of Newron Pharmaceuticals S.p.A.

#### Introduction

We have reviewed the accompanying interim condensed consolidated financial statements, (comprising the interim consolidated statement of financial position, the interim consolidated income statement, the statement of comprehensive income, changes in shareholders' equity and cash flows and related explanatory notes) of Newron Pharmaceuticals S.p.A. and its subsidiaries (the "Newron Group") for the sixmonth period ending June 30, 2013. 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.

#### Scope of review

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.

#### Conclusion

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 6, 2013

Paolo Zocchi

(Partner)

# **Interim Condensed Consolidated Income Statement**

| (In thousand euro, except per share information)                         |      | For the six months ended | June 30 |
|--|------|--------------------------|---------|
|  | Note | 2013                     | 2012    |
| Licence income   | 6    | 1,799                    | 7,078   |
| Other income   |      | 353                      | 0       |
| Revenue  |      | 2,152                    | 7,078   |
| Research and development expenses net of grants and other reimbursements | 7    | (837)                    | (782)   |
| Marketing and advertising expenses                                       |      | (11)                     | (2)     |
| General and administrative expenses                                      | 8    | (3,710)                  | (3,609) |
| Operating result   |      | (2,406)                  | 2,685   |
| Financial result net   |      | (36)                     | 25      |
| Result before tax  |      | (2,442)                  | 2,710   |
| Income tax expense   |      | (4)                      | (5)     |
| Net income / (loss)  |      | (2,446)                  | 2,705   |
| Earnings / (loss) per share  |      |                          |         |
| Basic and diluted  | 9    | (0.21)                   | 0.33    |
| Weighted average number of shares (thousands)                            |      |                          |         |
|  |      | 11,391                   | 8,312   |

# **Interim Condensed Consolidated** Statement of Comprehensive Income

| (In thousand euro)  | For the six months ended J | une 30 |
|---|----------------------------|--------|
|   | 2013                       | 2012   |
| Net income / (loss) for the period  | (2,446)                    | 2,705  |
| Other comprehensive income to be reclassified to profit or loss in subsequent periods: Currency translation differences | (70)                       | (4)    |
| Net other comprehensive income to be reclassified to profit or loss in subsequent periods                               | (70)                       | (4)    |
| Other comprehensive income / (loss), net of tax   | (70)                       | (4)    |
| Total comprehensive income / (loss) for the period  | (2,516)                    | 2,701  |

# **Interim Condensed Consolidated** Statement of Financial Position

| (In thousand euro)                   |      | As of         | D                 |
|--------------------------------------|------|---------------|-------------------|
|                                      | Note | June 30, 2013 | December 31, 2012 |
| Assets                               |      |               |                   |
| Non-current assets                   |      |               |                   |
| Property, plant and equipment        |      | 77            | 72                |
| Intangible assets                    | 10   | 11,212        | 11,199            |
| Available for sale investments       |      | 584           | 584               |
| Non-current receivables              |      | 44            | 45                |
|                                      |      | 11,917        | 11,900            |
| Current assets                       |      |               |                   |
| Inventories                          |      | 228           | 233               |
| Receivables and prepayments          | 11   | 3,191         | 3,271             |
| Cash and cash equivalents            | 12   | 21,766        | 29,243            |
|                                      |      | 25,185        | 32,747            |
| Total assets                         |      | 37,102        | 44,647            |
| Shareholders' equity                 |      |               |                   |
| Share capital                        | 13   | 2,325         | 2,277             |
| Share premium and other reserves     | 14   | 28,933        | 31,333            |
| Share option reserve                 | 15   | 1,932         | 1,541             |
| Retained earnings                    |      | (7,643)       | (7,549)           |
| Translation differences              |      | (64)          | 6                 |
| Total shareholders' equity           |      | 25,483        | 27,608            |
| Liabilities                          |      |               |                   |
| Non-current liabilities              |      |               |                   |
| Deferred tax liability               |      | 3,531         | 3,531             |
| Long-term borrowings                 | 16   | 1,267         | 1,447             |
| Employee severance indemnity         |      | 444           | 476               |
|                                      |      | 5,242         | 5,454             |
| Current liabilities                  |      |               |                   |
| Deferred income                      |      | 2,091         | 4,396             |
| Other current financial liabilities  |      | 0             | 539               |
| Short-term borrowings                | 16   | 356           | 355               |
| Trade and other payables             |      | 3,930         | 6,295             |
|                                      |      | 6,377         | 11,585            |
| Total liabilities                    |      | 11,619        | 17,039            |
| Shareholders' equity and liabilities |      | 37,102        | 44,647            |

# **Interim Condensed Consolidated** Statement of Changes in Equity

| (In thousand euro)                          | Note  | Share<br>capital | Share<br>premium<br>& other<br>reserves | Share<br>option<br>reserve | Foreign<br>currency<br>translation<br>reserve | Retained<br>earnings | Total   |
|---|-------|------------------|---|----------------------------|---|----------------------|---------|
| Balance at January 1, 2012                  |       | 1,453            | 12,826                                  | 4,152                      | (52)  | (11,795)             | 6,585   |
| Net income                                  |       |                  |   |                            |   | 2,705                | 2,705   |
| Other comprehensive income                  |       |                  |   |                            | (4)   |                      | (4)     |
| Total comprehensive income for the period   |       | 1,453            | 12,826                                  | 4,152                      | (56)  | (9,090)              | 9,286   |
| Previous year loss allocation               |       |                  | (6,617)                                 |                            |   | 6,617                | 0       |
| Issue of shares                             |       | 145              | 1,630                                   |                            |   |                      | 1,775   |
| Advance payment for future capital increase |       |                  | 1,724                                   |                            |   |                      | 1,724   |
| Share option scheme                         |       |                  |   | 174                        |   |                      | 174     |
| Balance at June 30, 2012                    |       | 1,598            | 9,563                                   | 4,326                      | (56)  | (2,473)              | 12,959  |
| Balance at January 1,2013                   |       | 2,277            | 31,333                                  | 1,541                      | 6   | (7,549)              | 27,608  |
| Net loss                                    |       |                  |   |                            |   | (2,446)              | (2,446) |
| Other comprehensive income                  |       |                  |   |                            | (70)  |                      | (70)    |
| Total comprehensive loss for the period     |       | 2,277            | 31,333                                  | 1,541                      | (64)  | (9,995)              | 25,092  |
| Previous year loss allocation               |       |                  | (2,352)                                 |                            |   | 2,352                | 0       |
| Advance payment for future capital increase | 14    |                  | (1,724)                                 |                            |   |                      | (1,724) |
| Issue of shares                             | 13/14 | 48               | 1,676                                   |                            |   |                      | 1,724   |
| Share option scheme                         | 15    |                  |   | 391                        |   |                      | 391     |
| Balance at June 30, 2013                    |       | 2,325            | 28,933                                  | 1,932                      | (64)  | (7,643)              | 25,483  |

# **Interim Condensed Consolidated Statement of Cash Flow**

| (In thousand euro)  |      | For the six months ended . | June 30 |
|---|------|----------------------------|---------|
|   | Note | 2013                       | 2012    |
| Income / (loss) before tax  |      | (2,442)                    | 2,710   |
| Adjustments for:  |      |                            |         |
| Depreciation and amortisation   |      | 17                         | 24      |
| Grants and other non monetary income and losses                                     |      | (2,014)                    | (48)    |
| Share option expenses and cash-settled liabilities                                  | 15   | 391                        | 172     |
| Employee severance indemnity expense  |      | 23                         | 99      |
| Changes in working capital:   |      |                            |         |
| Inventories   |      | 5                          | 19      |
| Current receivables and prepayments and deferred cost (excluding grants receivable) |      | (73)                       | (4,140) |
| Trade and other payables and deferred income (excluding advances of grants)         |      | (3,624)                    | 8,112   |
| Cash provided by / (used for) operations  |      | (7,717)                    | 6,915   |
| Operating activities  |      |                            |         |
| Cash provided by / (used for) operations  |      | (7,717)                    | 6,915   |
| Government grants received  |      | 430                        | 45      |
| Pension fund paid   |      | (12)                       | (81)    |
| Change in non-current receivables   |      | 0                          | (147)   |
| Net cash provided by / (used for) operating activities                              |      | (7,299)                    | 6,732   |
| Financing activities  |      |                            |         |
| Net proceeds from borrowings  | 16   | (178)                      | (177)   |
| Proceeds from issue of shares   |      | 0                          | 1,775   |
| Advance payment for future capital increase   |      | 0                          | 1,725   |
| Net cash flows from / (used in) financing activities                                |      | (178)                      | 3,323   |
| Net increase/(decrease) in cash and cash equivalents                                |      | (7,477)                    | 10,088  |
| Cash and cash equivalents at January 1  |      | 29,243                     | 5,367   |
| Cash and cash equivalents at June 30  |      | 21,766                     | 15,455  |

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

#### (In thousand euro unless otherwise stated)

#### 1 Corporate information

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

- Newron Pharmaceuticals S.p.A. ("Newron" or "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 fully owned clinical development subsidiary based in Basel (Switzerland) established during 2007;
- Newron Sweden AB (former NeuroNova AB until June 24, 2013), a fully owned bio-technology company based in Stockholm (Sweden) developing new medicines to treat illnesses caused by necrosis of the Central Nervous System (CNS), which has been acquired on December 17, 2012.
- Hunter-Fleming Limited, a fully owned 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 SIX Swiss Exchange, Zurich, Switzerland, under the trade name NWRN.

The interim condensed consolidated financial statements of Newron Group for the six months ended June 30, 2013, were authorised for issuance by the Board of Directors (Board) on September 5th 2013.

## 2 Basis of presentation and changes to the Group's accounting policies

The interim condensed consolidated financial statements of the Group for the six-months period ended June 30, 2013 have been prepared in accordance with IAS 34 "Interim Financial Reporting".

The interim condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's consolidated financial statements for the year ended December 31, 2012.

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

The presentation currency is Euro. All figures included in these interim condensed consolidated financial statements and notes thereto are rounded to the nearest Euro thousand except where otherwise indicated.

## New standards, interpretations and amendments adopted by the Group

The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's annual financial statements for the year ended December 31, 2012, except for the adoption of new standards and interpretations effective as of January 1, 2013.

The following amendments to IFRSs standards did not have any impact on the accounting policies, financial position or performance of the Group:

IAS 1 Presentation of Items of Other Comprehensive Income – Amendments to IAS 1 The amendments to IAS I introduce a grouping of items presented in other comprehensive income (OCI). Items that could be reclassified (or recycled) to profit or loss at a future point in time (e.g., net gain on hedge of net investment, exchange differences on translation of foreign operations, net movement on cash flow hedges and net loss or gain on available-for-sale financial assets)

now have to be presented separately from items that will never be reclassified (e.g., actuarial gains and losses on defined benefit plans and revaluation of land and buildings). The amendment affected presentation only and had no impact on the Group's financial position or performance.

IAS 32 Tax effects of distributions to holders of equity instruments (Amendment)

> The amendment to IAS 32 Financial Instruments: Presentation clarifies that income taxes arising from distributions to equity holders are accounted for in accordance with IAS 12 Income Taxes. The amendment removes existing income tax requirements from IAS 32 and requires entities to apply the requirements in IAS 12 to any income tax arising from distributions to equity holders. The amendment did not have an impact on the interim condensed consolidated financial statements for the Group, as there is no tax consequences attached to cash or noncash distribution.

IAS 34 Interim financial reporting and segment information for total assets and liabilities (Amendment) The amendment clarifies the requirements in IAS 34 relating to segment information for total assets and liabilities for each reportable segment to enhance consistency with the requirements in IFRS 8 Operating Segments. Total assets and liabilities for a reportable segment need to be disclosed only when the amounts are regularly provided to the chief operating decision maker and there has been a material change in the total amount disclosed in the entity's previous annual consolidated financial statements for that reportable segment. 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, United Kingdom and Sweden. Since the Company does not consider the geographies to be separate segments and no changes occurred compared to previ-ous annual consolidated financial statements, the amendment of IAS 34 does not have an impact on the Group.

IFRS 7 Financial Instruments: Disclosures Offsetting Financial Assets and Financial Liabilities Amendments to IFRS 7

The amendment requires an entity to disclose information about rights to set-off financial instruments and related arrangements (e.g., collateral agreements). The disclosures would provide users with information that is useful in evaluating the effect of netting arrangements on an entity's financial position. The new disclosures are required for all recognised financial instruments that are set off in accordance with IAS 32. The disclosures also apply to recognised financial instruments that are subject to an enforceable master netting arrangement or similar agreement, irrespective of whether the financial instruments are set off in accordance with IAS 32. As the Group is not setting off financial instruments in accordance with IAS 32 and does not have relevant offsetting arrangements, the amendment does not have an impact on the Group.

Consolidated Financial Statements and IAS 27 Separate Financial Statements IFRS 10 establishes a single control model that applies to all entities including special purpose enti-ties. IFRS 10 replaces the parts of previously existing IAS 27 Consolidated and Separate Financial Statements that dealt with consolidated financial statements and SIC-12 Consolidation - Special Pur-pose Entities. IFRS 10 changes the definition of control such that an investor controls an

IFRS 10

investee when it is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. To meet the definition of control in IFRS 10, all three criteria must be met, including: (a) an investor has power over an investee; (b) the investor has exposure, or rights, to variable returns from its involvement with the investee; and (c) the investor has the ability to use its power over the investee to affect the amount of the investor's returns. IFRS 10 had no impact on the consolidation of investments held by the Group.

IFRS 11 Joint Arrangements and IAS 28 Investment in Associates and Joint Ventures IFRS 11 replaces IAS 31 Interests in Joint Ventures and SIC-13 Jointly-controlled Entities -Non-monetary Contributions by Venturers. IFRS II removes the option to account for jointly controlled entities (JCEs) using proportionate consolidation. Instead, ICEs that meet the definition of a joint venture under IFRS II must be accounted for using the equity method. IFRS 11 had no impact on the Group.

IFRS 12 Disclosure of Interests in Other Entities IFRS 12 sets out the requirements for disclosures relating to an entity's interests in subsidiaries, joint arrangements, associates and structured entities. None of these disclosure requirements are applica-ble for interim condensed consolidated financial statements, unless significant events and transactions in the interim period requires that they are provided. Accordingly, the Group has not made such dis-closures.

IFRS 13 Fair Value Measurement IFRS 13 establishes a single source of guidance under IFRS for all fair value measurements. IFRS 13 does not change when an

entity is required to use fair value, but rather provides guidance on how to measure fair value under IFRS when fair value is required or permitted. The application of IFRS 13 has not materially impacted the fair value measurements carried out by the Group. IFRS 13 also requires specific disclosures on fair values, some of which replace existing disclosure requirements in other standards, including IFRS 7 Financial Instruments: Disclosures. Some of these disclosures are specifically required for financial instruments by IAS 34.16A(j), thereby affecting the interim condensed consolidated financial statements period.

In addition to the above-mentioned amendments and new standards, IFRS I First-time Adoption of International Financial Reporting Standards was amended with effect for reporting periods starting on or after January 1, 2013. The Group is not a first-time adopter of IFRS, therefore, this amendment is not relevant to the Group.

The Group has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.

#### 3 Seasonality

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

#### 4 Exchange rates of principal currencies

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

|      | Income statements in<br>Euro (average rates)<br>Six months ended June 30, |         | Balance sheet<br>(rates as of) | s in euro        |
|------|---|---------|--------------------------------|------------------|
|      | 2013  | 2012    | June 30,<br>2013               | Year end<br>2012 |
| CHF1 | 0.81307   | 0.83001 | 0.81050                        | 0.82836          |
| GBP1 | 1.17536   | 1.21578 | 1.16659                        | 1.22534          |
| SEK1 | 0.11722   | n/a     | 0.11393                        | 0.11652          |

#### 5 Information on prior year business combination

On December 17, 2012, the Group acquired the 100% of the voting shares of NeuroNova AB (Newron Sweden AB, starting from June 24, 2013), a private biopharmaceutical company based in Stockholm (Sweden) that develops new medicines to treat illnesses caused by necrosis of the Central Nervous System (CNS).

The acquisition was accounted for using the acquisition method, as stated by IFRS 3. As of the date of the issuance of the interim condensed consolidated financial statements of Newron Group for the six months ended June 30, 2013, no new information were obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. Accordingly, the Group has not amended the Purchase Price Allocation which is however still to be considered as provisional, based on the provision of IFRS 3.

#### 6 Licence income

| (In thousand euro) | For the six months ended June 30, |       |
|--------------------|-----------------------------------|-------|
|                    | 2013                              | 2012  |
| Licence income     | 1,799                             | 7,078 |

Licence income, amounting to Euro 1,799 (2012: Euro 7,078), is related to the down-payment - amounting to a total of Euro 5 million – received from Zambon Company S.p.A. in May 2012, which is being recognised as revenue on a straight-line basis over the estimated period of collaboration required to finalise the development of safinamide, prepare the applications and file for marketing approval in Europe and the U.S.. The portion of the down-payment in excess (equal to Euro 914) of the recognised revenue has been recorded as "Deferred income" among current liabilities.

### 7 Research and development expenses net of grants and other reimbursements

| (In thousand euro)                    | For the six month | ns ended June 30, |
|---------------------------------------|-------------------|-------------------|
|                                       | 2013              | 2012              |
| Services received from subcontractors | 17                | 80                |
| Staff costs                           | 553               | 543               |
| Consultancy fees                      | 62                | 54                |
| Material and consumable used          | 56                | 17                |
| Laboratory operating lease cost       | 105               | 64                |
| Travel expenses                       | 33                | 11                |
| Depreciation and amortisation expense | 9                 | 1                 |
| Other research and development costs  | 2                 | 12                |
|                                       | 837               | 782               |

Since May 14, 2012, research and development expenses borne by the Group to complete the development of safinamide, prepare the applications and file for marketing approval in Europe and the U.S. are reimbursed by Zambon S.p.A.. Research and development expenses are also presented net of the costs that will be reimbursed by other external parties (i.e. Tax Authorities, Ministries, etc.) based on certain scientific research programmes granted to the Group. Accordingly, research and development expenses are presented net of reimbursements totalling Euro 3,600 (2012: Euro 1,655). The table below shows the net effects:

| (In thousand euro)   | For the six months e | nded June 30 |
|--|----------------------|--------------|
|  | 2013                 | 2012         |
| Research and development expenses gross                                  | 4,437                | 2,437        |
| Government grants received   | (398)                | 0            |
| Reimbursed by Merck<br>Serono and/or Zambon                              | (3,202)              | (1,655)      |
| Research and development expenses net of grants and other reimbursements | 837                  | 782          |

The increase in Staff costs is basically explained by an increase in headcounts, as a consequence of the acquisition of Newron Sweden AB occurred in December 2012. The increase in Material and consumable as well as in the overall amount of research and development expenses is related to the acquisition of Newron Sweden AB. Since inception, no development costs have been capitalised with the exception of the Intangible assets recognized in the context of the purchase price allocation processes of Hunter-Fleming Ltd and Newron Sweden AB.

#### 8 General and administrative expenses

| (In thousand euro)                          | For the six months en | ded June 30, |
|---|-----------------------|--------------|
|   | 2013                  | 2012         |
| Staff costs                                 | 1,127                 | 1,589        |
| Consultancy and other professional services | 1,488                 | 1,326        |
| Intellectual properties                     | 654                   | 380          |
| Travel expenses                             | 125                   | 107          |
| Operating lease cost                        | 53                    | 75           |
| Depreciation and amortisation expense       | 8                     | 24           |
| Other expenses                              | 255                   | 108          |
|   | 3,710                 | 3,609        |

General and administrative expenses are substantially in line with 2012 figures. Staff costs decreased by Euro 462 mainly due to the combined opposite effect of i) an increase in the number of employees as a consequence of the acquisition of Newron Sweden AB and ii) a onetime bonus of approximately Euro 484 recognised to a leaving manager in 2012.

Increases in Consultancy and other professional services as well as in Intellectual properties and Travel expenses are mainly related to the acquisition of Newron Sweden AB.

#### 9 Earnings / Loss per share

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

| (In thousand euro)                                    | For the six months | ended June 30, |
|---|--------------------|----------------|
|   | 2013               | 2012           |
| Net income / (loss) attrib-<br>utable to shareholders | (2,446)            | 2,705          |
| Weighted average number of shares (thousands)         | 11,391             | 8,312          |
| Income / (loss) per share –<br>basic (in Euro)        | (0.21)             | 0.33           |

The only category of potential ordinary shares are the stock options granted to certain employees, directors and consultants which were not exercisable as of June 30, 2013. Thus, the values of basic and diluted earnings per share coincide.

### 10 Intangible assets

Intangible assets of Euro 11,212 are almost entirely represented by in-process research and development projects (II,185 Euro), as detailed below:

#### **Hunter-Fleming Ltd**

| Project | Development<br>phase | Allocated<br>value |
|---------|----------------------|--------------------|
| HF0220  | Clinical phase II    | 4,260              |
| HF0299  | Clinical phase I     | 50                 |
| HF1220  | Discovery            | 50                 |
|         |                      | 4,360              |

#### **Newron Sweden AB**

| Project | Development<br>phase | Acquisition date<br>fair value |
|---------|----------------------|--------------------------------|
| sNN0029 | Clinical phase I     | 1,469                          |
| sNN0031 | Clinical phase II    | 5,356                          |
|         |                      | 6,825                          |

IAS 36 requires assessing an asset not in use for impairment on an annual basis by comparing the carrying value to its recoverable amount. Management performed a full Impairment test of the above assets at December 31, 2012. As of June 30, 2013 no impairment indication for the assets was identified. Accordingly, management will perform a full impairment test of in-process research and development projects at year-end.

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 IPR&D stays.

#### 11 Receivables and prepayments

| (In thousand euro)           | As of            |                      |  |
|------------------------------|------------------|----------------------|--|
|                              | June 30,<br>2013 | December 31,<br>2012 |  |
|                              | unaudited        | audited              |  |
| Receivables                  | 1,827            | 1,511                |  |
| Government grants receivable | 264              | 460                  |  |
| Prepayments                  | 421              | 508                  |  |
| Deferred costs               | 147              | 437                  |  |
| VAT receivable               | 303              | 291                  |  |
| Other receivables            | 229              | 64                   |  |
|                              | 3,191            | 3,271                |  |

Receivables are almost entirely represented by the accruals related to the reimbursement of safinamide's research and development costs as these expenses are charged by the Group to its partners. The above receivables have been cashed in for approximately 1.5 million during July 2013.

Government grants receivable decreased mostly as a consequence of the cash-in of the final instalment of approximately Euro 233 related to the project financed by Lombardy district.

#### 12 Cash and cash equivalents

| (In thousand euro)       | As of            |                      |  |
|--------------------------|------------------|----------------------|--|
|                          | June 30,<br>2013 | December 31,<br>2012 |  |
|                          | unaudited        | audited              |  |
| Cash at bank and in hand | 15,158           | 25,602               |  |
| Short-term investments   | 3,608            | 3,641                |  |
| Short-term time deposit  | 3,000            | 0                    |  |
|                          | 21,766           | 29,243               |  |

The "Short-term investments" are highly liquid investments easily convertible into cash, not subject to significant changes in value and with no withdrawal penalty. The "Short-term time deposit" refers to a liquid investment with a duration of 3 months convertible into cash.

Management monitors the Group' cash position on rolling forecasts based on expected cash flow to enable the Group to finance research and development activities. Financial resources currently available are considered adequate to support on-going research and development activities.

#### 13 Share capital

As of December 31, 2012, Newron's outstanding share capital was EUR 2,277,195.40, consisting of 11,385,977 ordinary shares with a nominal value of EUR 0.20 each. As at 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.

A summary of the changes occurred during the last 18 months in share capital is as follows:

| (In euro)  | Total        |
|--|--------------|
| As of December 31, 2011 – Newron Group               | 1,452,875.60 |
| - issue of ordinary share (Capital Increase)         | 145,287.00   |
| - issue of ordinary share (Capital Increase)         | 159,816.00   |
| - issue of ordinary share (NeuroNova AB acquisition) | 475,000.00   |
| - issue of ordinary share (Stock options exercise)   | 44,216.80    |
| As of December 31, 2012 – Newron Group               | 2,277,195.40 |
| - issue of ordinary share (Capital Increase)         | 47,705.40    |
| As of June 30, 2013 - Newron Group                   | 2,324,900.80 |

On June 24, 2013 existing long term shareholders among which Zambon, in execution of previous subscription undertakings to be contractually finalized within June 30, 2013 - have subscribed 238,527 newly issued shares.

As of June 30, 2013, the subscribed share capital was equal to Euro 2,324,900.80, divided into 11,624,504 ordinary shares with nominal value equal to Euro 0.20 each. There is no authorised share capital.

#### 14 Share premium

| (In thousand euro)                            | As of            | As of                |  |  |
|---|------------------|----------------------|--|--|
|   | June 30,<br>2013 | December 31,<br>2012 |  |  |
| At the beginning of the year                  | 31,333           | 12,827               |  |  |
| Loss allocation                               | (2,352)          | (6,617)              |  |  |
| Advance payment for future capital increase   | (1,724)          | 1,724                |  |  |
| Issue of shares                               | 1,676            | 5,395                |  |  |
| Issue of shares (exercise of option)          | 0                | 1,125                |  |  |
| Reclassification from share option reserve    | 0                | 2,821                |  |  |
| Share capital issue costs                     | 0                | (215)                |  |  |
| Issue of shares – Acquisition of NeuroNova AB | 0                | 14,274               |  |  |
| At the end of the period                      | 28,933           | 31,333               |  |  |

As a consequence of the capital increase subscribed on June 24, Newron has reclassified the "Advance payment for future capital increase" into Share Capital (Euro 47.7) and Issue of Share (Euro 1,676) within the Share Premium reserves.

#### 15 Share option reserve

To incentivise 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 five Share Option Plans: the first in October 2003 (ESOP 2003); the second in July 2004 (ESOP 2004); the third in June 2007 (ESOP 2007); the fourth in April 2009 (ESOP 2009) and the fifth in March 2011 (ESOP 2011). On December 31, 2012 all Share Option Plans are expired except for the ESOP 2011.

On January 18, 2013 Newron' Board approved a new options plan (ESOP 2013) and assigned 493,496 new options to certain Group's employees, directors and consultants, of which 246,745 can be exercised after two years from the grant date, 123,374 after three years and the remaining 123.377 after four years. The options' strike price is 7.89 CHF (6.32 Euro as translated at the exchange rate on January 17, 2013) and its fair value is equal to 2,414 CHF (Euro 1,939).

On April 18, 2013 Newron' Board assigned further 28,500 new options under the abovementioned new option plan to certain Group's employees, directors and consultants, of which 14,250 can be exercised after two years from the grant date, 7,125 after three years and the remaining 7,125 after four years. The options' strike price is 8.11 CHF (6.66 Euro as translated at the exchange rate on April 17, 2013) and its fair value is equal to 143 CHF (Euro 117).

The fair values of both plans (January and April 2013) have been estimated on the date of grant using, among the others, the following assumptions:

| Divided yield (%)             | 0.00  |
|-------------------------------|-------|
| Expected volatility (%)       | 70.00 |
| Resignation rate expected (%) | 3.00  |

The Group's Board of Directors can grant further options under both plans.

All options have been awarded free of charge and are recognised as personnel expenses over the original vesting period. The total increase of share option reserve is equal to Euro 391.

#### 16 Borrowings

In 2008 Newron was awarded a 5 million Euro grant by the Italian government's Ministero dell' Istruzione, dell' Università e della Ricerca (M.I.U.R.) Approximately 60% of the grant 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 of which 2.2 million Euro will bear interest.

The loan has to be reimbursed in two yearly instalments (July and January I), starting from July I, 2012 and ending on January 1, 2018. As of June 30, 2013, the Group paid the third instalment amounting to Euro 178. The remaining part of the debt is broken-down as follows: Shortterm borrowings are equal to Euro 356 while the Longterm borrowings are equal to Euro 1,267.

### 17 Financial instruments by category

The following tables present the breakdown of financial assets and liabilities by category as of June 30, 2013 and December 31, 2012 respectively.

Available for sale financial assets of EUR 584 is entirely represented by a minority interest (17%) held in a Special Purpose Vehicle (SPV) - Trident Pharmaceuticals Inc. - set up to develop novel immuno-modulatory

drug products (actually in clinical phase Ia) for the treatment of autoimmune disorders and allergic diseases. Since uncertainty remains as to whether a final and successful market registration of the compound developed by Trident Pharmaceuticals Inc. will be achieved, the value of the asset is periodically reviewed by comparing the carrying value to its recoverable amount through a risk-adjusted NPV analysis.

| As of June 30, 2013                 | Loans and receivables | Assets at<br>fair value<br>through<br>profit or<br>loss | Held-to-<br>maturity in-<br>vestments | Available-<br>for-sale<br>financial<br>assets | Liabilities<br>at fair value<br>through<br>profit or<br>loss | Other<br>financial<br>liabilities at<br>amortized<br>cost |
|-------------------------------------|-----------------------|---|---------------------------------------|---|--|---|
| Assets                              |                       |   |                                       |   |  |   |
| Cash and cash equivalents           | 21,766                |   |                                       |   |  |   |
| Financial assets                    |                       | _   |                                       | 584   |  |   |
| Trade and other receivables         | 2,039                 |   |                                       |   |  |   |
| Total                               | 23,805                | _   | -                                     | 584   | _  |   |
| Liabilities                         |                       |   |                                       |   |  |   |
| Trade and other payables            |                       |   |                                       |   |  | 3,930   |
| Short-term borrowings               |                       |   |                                       |   |  | 355   |
| Long-term borrowings                |                       |   |                                       |   | _  | 1,625   |
| Total                               |                       |   | _                                     | _   |  | 5,910   |
| As of December 31, 2012             |                       |   |                                       |   |  |   |
| Assets                              |                       |   |                                       |   |  |   |
| Cash and cash equivalents           | 29,243                |   | ·                                     |   |  |   |
| Financial assets                    | _                     | -   | -                                     | 584   | _  | _   |
| Trade and other receivables         | 2,326                 | _   | -                                     | _   | _  | -   |
| Total                               | 31,569                | _   | _                                     | 584   | -  | _   |
| Liabilities                         |                       |   |                                       |   |  |   |
| Trade and other payables            |                       |   |                                       |   |  | 4,536   |
| Other current financial liabilities |                       |   |                                       |   |  | 539   |
| Short-term borrowings               |                       | _   |                                       |   |  | 355   |
| Long-term borrowings                |                       | _   |                                       |   |  | 1,447   |
| Total                               |                       | _   | -                                     | _   | _  | 6,877   |

#### 18 Related party transactions

group)

The following tables provide the total amount of transactions that have been entered into with related parties during the six months period ending June 30, 2013 and June 30, 2012, as well as balances with related parties outstanding as of June 30, 2013 and June 30, 2012:

| As of<br>June 30, 2013     | Sales to<br>related<br>parties | Purchases<br>from<br>related<br>parties | Amounts owed by related parties, net | Amounts<br>owed to<br>related<br>parties |
|----------------------------|--------------------------------|---|--------------------------------------|--|
| Zambon<br>(whole<br>group) | 5,002                          | 60                                      | 1,680                                | 0  |
| As of<br>June 30, 2012     |                                |   |                                      |  |
| Zambon<br>(whole           | 2,922                          | 50                                      | 1,810                                | 2  |

As detailed in the above paragraphs, sales to Zambon are mainly related to the recognition of 2013 portion of the down-payment received upon the finalization of the Collaboration and Licence Agreement related to safinamide and to the reimbursement of the expenses borne by the Group to complete the development of the compound, prepare the applications and file for marketing approval in Europe and the U.S..

#### 19 Events after the balance sheet date

No relevant events have been occurred between the end of the reporting period and the date that the financial statements have been approved by the Board of Directors.

Bresso, September 5th, 2013

Chief Executive Officer

## 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**

| Number of fully paid-in shares as at June 30, 2013  | 11,624,504  |
|---|-------------|
| 52-week high (in CHF)   | 9.74        |
| 52-week low (in CHF)  | 4.31        |
| June 2013 closing share price   | 9.05        |
| Loss per share (in EUR)   | 0.21        |
| Cash and cash equivalents, other short-term financial assets as at June 30, 2013 (in EUR 1,000) | 21,766      |
| Market capitalization as at June 28, 2013 (in CHF)  | 105,201,761 |

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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 commercialization 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 forwardlooking 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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