

# Half-Year Report 2014

# Corporate profile

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

Following the submission of the Marketing Authorization Application (MAA) for safinamide for the treatment of Parkinson's disease to the European Medicines Agency (EMA) in December 2013, to Swissmedic in March, 2014 as well as the New Drug Application (NDA) to the US FDA, Newron is working towards global approval of the compound, together with its partners. Zambon Group has the rights to commercialize safinamide globally, excluding Japan and other key Asian territories where Meiji Seika has the rights to develop and commercialize the compound. Newron's additional projects are based on highly promising treatments for rare disease patients and are at various stages of clinical development, including sarizotan for patients with Rett syndrome, sNN0031 for patients with Parkinson's disease, non-responsive to oral drug treatments, sNN0029 for patients with ALS and ralfinamide for patients with specific rare pain indications. Newron is also developing NW-3509 as the potential first add-on therapy for the treatment of patients with positive symptoms of schizophrenia.

[www.newron.com](http://www.newron.com)

# Half-Year 2014 Highlights

- Application for Authorization of safinamide submitted to Swissmedic by Zambon as the Authorization holder
- New results with NW-3509, demonstrating potential of unique mechanism to benefit poor responders to antipsychotics in patients with schizophrenia, presented at the 4th Biennial Schizophrenia International Research Society (SIRS) Conference
- CHF 22.2 million raised in private placements to existing and new institutional shareholders in Europe and the USA
- Safinamide New Drug Application (NDA) submitted to the US Food and Drug Administration (FDA)

## Post-period events

- Refusal to File letter received from US FDA for safinamide, based on organization and navigation problems with filing dossier
- Newron establishes US operations through Newron Pharmaceuticals US, Inc., located in Morristown, New Jersey
- Newron shares to be included into the SXI Life Sciences® and the SXI Bio+Medtech® indices, effective September 22



# Table of Contents

<b>Shareholders' Letter</b> .....	4
<b>Interim condensed consolidated financial statements</b> .....	7
Auditors' Report .....	8
Interim Condensed Consolidated Statement of profit or loss .....	10
Interim Condensed Consolidated Statement of Comprehensive Income .....	10
Interim Condensed Consolidated Statement of Financial Position .....	11
Interim Condensed Consolidated Statement of Changes in Equity .....	12
Interim Condensed Consolidated Statement of Cash Flow .....	13
Notes to the Interim Condensed Consolidated Financial Statements .....	14
<b>Information for Investors</b> .....	24

# Shareholders' Letter



Dr. Ulrich Köstlin



Stefan Weber

Dear Shareholder,

The first half of 2014 has been a period of intense activity on our lead asset, safinamide.

Our key focus has been to work with our partner Zambon in completing the application dossiers for safinamide to the authorities in both Europe and the US. These have been submitted, although outside of this period, we have received a Refusal to File (RTF) letter from the US Food and Drug Administration (FDA). Whilst this is disappointing, based on the recent meeting we had with FDA, we confirm our confidence that we can speedily resolve the organization and navigation problems which the FDA has with the submission documentation, and refile the dossier as soon as reasonably practicable.

In the EU, the process towards potential approval of safinamide is fully on track and we are confident that a decision on the submission will be received within the 12 months' review period, around year's end 2014.

The submission of safinamide to the US FDA for the indications "safinamide as add-on therapy to a stable dose of a single dopamine agonist" in early Parkinson's disease patients and "safinamide as add-on therapy to levodopa alone or in combination with other Parkinson's disease treatments" in mid-to late stage Parkinson's disease patients was made in May 2014. Upon preliminary review, the FDA identified some organization and navigation problems, relating to the hyperlinking of tables, folders and the organization of the table of contents in the submission, as well as the conformation of the Package Insert to FDA guidelines. The RTF letter does not relate to the acceptability of the clinical data, and no judgment is made on the efficacy or safety of safinamide.

Following on from the submission in December 2013 of the Marketing Authorization Application (MAA) for safinamide to the European Medicines Agency, in April we reported Zambon's submission to Swissmedic for approval in Switzerland. These cover the indications "safinamide as add-on therapy to a stable dose of a single dopamine agonist" in early Parkinson's disease patients and "safinamide as add-on therapy to levodopa alone or in combination with other Parkinson's disease treatments" in mid-to late stage Parkinson's disease patients.

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

New mechanistic and behavioral studies with our compound NW-3509 confirmed its potential for use in patients with schizophrenia. These studies, together with preliminary results from an ongoing US Phase I study, were presented at the 4th Biennial Schizophrenia International Research Society (SIRS) Conference on Monday 7th April, 2014 in Florence, Italy. The results confirmed NW-3509's selectivity to block voltage gated sodium channels (VGSCs) based on the evaluation of over 130 targets including receptors, channels, transporters and enzymes. This blockade leads to the inhibition of excessive glutamate release that has not been addressed by current antipsychotics. These effects make NW-3509 unique and give it the potential to improve inadequate response when used in conjunction with marketed antipsychotics. By end of the current year, Newron plans to initiate a placebo-controlled safety and efficacy trial in schizophrenic patients who are poor responders to current treatment.

In April we completed a capital increase resulting in gross proceeds of CHF 18.6 million, following the subscription by institutional investors of 1,183,597 newly issued shares. The fundraising was supported by current institutional shareholders and institutional investors joining from Europe and the USA, including J.P. Morgan Asset Management, Aviva, Investor AB and Swisscanto. Already in January, we had announced the placement of 211,473 shares left from a prior capital increase with J.P. Morgan Asset Management, resulting in proceeds of CHF 3.6 million. The net proceeds from the fundraisings will be primarily used to accelerate the development of our pipeline of innovative CNS therapeutics, including three Phase II compounds for orphan indications; sarizotan for patients suffering from Rett Syndrome, sNN0031 for patients with Parkinson's disease no longer responding to oral therapy, sNN0029 for patients with Amyotrophic Lateral Sclerosis (ALS), as well as NW-3509, in development as add-on therapy for patients with positive symptoms in schizophrenia.

We much appreciated the notification by SIX Swiss Exchange that effective September 22, Newron's shares will be included into the SXI Life Sciences® and the SXI Bio+Medtech® indices, promising to increase trading volume in the stock, and attracting new investors to the story, directly and indirectly.

Just post closing of the reporting period, we have announced the creation of Newron Pharmaceuticals, Inc., a 100% owned subsidiary in the USA, and its start of operations, including the hiring of two senior industry experts in drug development. The operations in Morristown will play a key role in broadening our in-house resources in clinical development of CNS therapies, and in expanding our interactions with the FDA. Furthermore, the subsidiary will serve as the site for the future commercial operations of Newron for our clinical-stage portfolio of orphan compounds.

In the first six months of 2014, we have invested Euro 6.5 million into drug development and preparations for regulatory submission of safinamide, up from Euro 4.4 million in 2013.

Of these, Euro 3.8 million have been covered by our safinamide partner Zambon as well as by grants. Therefore, for the first six months of the year, net R&D expenses are Euro 2.6 million, up from 2013 expenses of Euro 0.8 million.

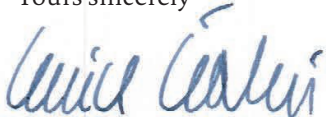
G&A expenses reached Euro 3.5 million in the first six months of 2014, down from Euro 3.7 million in the 2013 reporting period.

At revenues of Euro 1.4 million during the first half year of 2014, stemming from recognition of a 2012 license down-payment over the period of collaboration with our partner Zambon, as well as the US submission milestone, the net loss for the first six months of 2014 amounts to Euro 4.6 million, compared to Euro 2.4 million in 2013.

With Euro 31.4 million of cash and short term investments, we show a healthy cash position, which we expect to take the Company well into 2016, beyond expected key value inflexion points.

We are excited by the chance of seeing our first development compound safinamide being approved for marketing in the EU within a few months from the date of this letter, and following a successful refiling in the US, also in the US, later next year. At the same time, we are looking forward to continuing the development and building of our innovative product portfolio during the rest of this year. We are fully committed to Newron's success as a leader in the development of new treatments for CNS diseases.

Yours sincerely



Dr. Ulrich Köstlin  
Chairman



Stefan Weber  
Chief Executive Officer



# Interim condensed consolidated financial statements

For the six months ended June 30, 2014

# Auditors' Report

## **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 condensed consolidated statement of financial position, the interim condensed consolidated statement of profit and loss, the interim condensed consolidated statement of comprehensive income, the interim condensed consolidated statement of changes in equity and the interim condensed consolidated statement of cash flows and related explanatory notes) of Newron Pharmaceuticals S.p.A. and its subsidiaries (the "Newron Group") for the six-month period ending June 30, 2014. 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 12, 2014

Reconta Ernst & Young S.p.A.



Enrico Lenzi  
(Partner)

# Interim Condensed Consolidated Statement of profit or loss

(In thousand euro, except per share information)

	Note	For the six months ended June 30	
		2014 (unaudited)	2013 (unaudited)
Licence income	6	1,300	1,799
Other income		100	353
<b>Revenue</b>		<b>1,400</b>	<b>2,152</b>
Research and development expenses	7	(2,620)	(837)
Marketing and advertising expenses		(47)	(11)
General and administrative expenses	8	(3,498)	(3,710)
<b>Operating result</b>		<b>(4,765)</b>	<b>(2,406)</b>
Financial result net		174	(36)
<b>Result before tax</b>		<b>(4,591)</b>	<b>(2,442)</b>
Income tax expense		(5)	(4)
<b>Net loss</b>		<b>(4,596)</b>	<b>(2,446)</b>
<b>Loss per share</b>			
Basic and diluted	9	(0.37)	(0.21)
<b>Weighted average number of shares (thousands)</b>		<b>12,324</b>	<b>11,391</b>

# Interim Condensed Consolidated Statement of Comprehensive Income

(In thousand euro)

		For the six months ended June 30	
		2014 (unaudited)	2013 (unaudited)
Net loss for the period		(4,596)	(2,446)
Other comprehensive income to be reclassified to profit or loss in subsequent periods:			
Net gain on available-for-sale assets	13 / 14	147	0
Income tax effect		(41)	0
		106	0
Exchange differences on translation of foreign operations		(234)	(70)
Income tax effect		0	0
		(234)	(70)
<b>Net other comprehensive income to be reclassified to profit or loss in subsequent periods</b>		<b>(128)</b>	<b>(70)</b>
Other comprehensive income not to be reclassified to profit or loss in subsequent periods:			
Actuarial gain / (loss) on benefit plan for employees		(13)	0
Income tax effect		4	0
		(9)	0
<b>Net other comprehensive income not to be reclassified to profit or loss in subsequent periods</b>		<b>(9)</b>	<b>0</b>
Other comprehensive loss for the period, net of tax		(137)	(70)
<b>Total comprehensive income / (loss) for the period</b>		<b>(4,733)</b>	<b>(2,516)</b>

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

# Interim Condensed Consolidated Statement of Financial Position

(In thousand euro)

	Note	As of	
		June 30, 2014 (unaudited)	December 31, 2013 (audited)
<b>Assets</b>			
Non-current assets			
Property, plant and equipment		67	79
Intangible assets	10	9,120	9,125
Available for sale investments	11	584	584
Non-current receivables		33	33
		9,804	9,821
Current assets			
Inventories		198	301
Receivables and prepayments	12	3,234	3,070
Available for sale financial assets	13	9,124	0
Cash and cash equivalents	14	22,266	18,426
		34,822	21,797
<b>Total assets</b>		<b>44,626</b>	<b>31,618</b>
<b>Shareholders, equity</b>			
Share capital	15	2,609	2,325
Share premium and other reserves	16	40,900	28,933
Share option reserve	17	2,832	2,374
Retained earnings		(11,473)	(12,313)
Translation differences		(463)	(229)
<b>Total shareholders, equity</b>		<b>34,405</b>	<b>21,090</b>
<b>Liabilities</b>			
Non-current liabilities			
Deferred tax liability		2,905	2,905
Long-term borrowings	18	907	1,087
Employee severance indemnity		420	466
		4,232	4,458
Current liabilities			
Deferred income		1,319	2,031
Short-term borrowings	18	359	358
Trade and other payables		4,311	3,681
		5,989	6,070
<b>Total liabilities</b>		<b>10,212</b>	<b>10,528</b>
<b>Shareholders, equity and liabilities</b>		<b>44,626</b>	<b>31,618</b>

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

# Interim Condensed Consolidated Statement of Changes in Equity

(In thousand euro)	Note	Share capital	Share premium	Share option reserve	Foreign currency translation reserve	Retained earnings	Total
Balance at January 1, 2013		2,277	31,333	1,541	6	(7,549)	27,609
Net loss						(2,446)	(2,446)
Other comprehensive losses					(70)		(70)
Total comprehensive loss for the period		0	0	0	(70)	(2,446)	(2,516)
Previous year loss allocation			(2,352)			2,352	0
Advance payment for future capital increase			(1,724)				(1,724)
Issue of shares		48	1,676				1,724
Share option scheme				391			391
Balance at June 30, 2013		2,325	28,933	1,932	(64)	(7,643)	25,484
Balance at January 1, 2014		2,325	28,933	2,374	(229)	(12,313)	21,090
Net loss						(4,596)	(4,596)
Other comprehensive losses					(234)	97	(137)
Total comprehensive loss for the period		0	0	0	(234)	(4,499)	(4,733)
Previous year loss allocation			(5,339)			5,339	0
Issue of shares	15 / 16	279	17,956				18,235
Issuing costs			(809)				(809)
Exercise of options	15 / 16	5	117				122
Exercise of options – reclassification of reserves	16		42	(42)			0
Share option scheme	17			499			499
Balance at June 30, 2014		2,609	40,900	2,832	(463)	(11,473)	34,405

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

# Interim Condensed Consolidated Statement of Cash Flow

(In thousand euro)		For the six months ended June 30	
	Note	2014 (unaudited)	2013 (unaudited)
Income / (loss) before tax		(4,591)	(2,442)
Adjustments for:			
Depreciation and amortisation		16	17
Grants and other non monetary income		(844)	(2,308)
Share option expenses	17	499	391
Employee severance indemnity expense and other non monetary expenses		341	317
Changes in working capital:			
Inventories		104	5
Current receivables and prepayments and deferred cost (excluding grants receivable)		(918)	(73)
Trade and other payables and deferred income (excluding advances of grants)		278	(3,624)
Cash from / (used in) operations		(5,115)	(7,717)
Cash flows from operating activities			
Cash used in operations		(5,115)	(7,717)
Government grants received		718	430
Pension fund paid		(46)	(12)
Net cash from / (used in) operating activities		(4,443)	(7,299)
Cash flows from investing activities			
Purchase of financial assets	14	(9,124)	0
Purchase of property, plant and equipment		(5)	0
Interest received		43	0
Net cash flows from / (used in) investing activities		(9,086)	0
Cash flows from financing activities			
Net proceeds from borrowings	18	(179)	(178)
Proceeds from issue of shares	15 / 16	18,357	0
New shares issuing costs		(809)	0
Net cash flows from / (used in) financing activities		17,369	(178)
Net increase / (decrease) in cash and cash equivalents		3,840	(7,477)
Cash and cash equivalents at January 1,		18,426	29,243
Cash and cash equivalents at the end of the period		22,266	21,766

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

# 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 Pharmaceuticals US Inc., a fully owned clinical development subsidiary, incorporated on June 6, 2014 under the Delaware rules, based in Morristown, New Jersey (USA) the activities of which started on July 8, 2014;
- Newron Sweden AB (former NeuroNova AB until June 24, 2013), a fully owned biotechnology 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;
- Newron Suisse SA, a fully owned clinical development subsidiary based in Basel (Switzerland) established during 2007.

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, 2014, were authorised for issuance by the Board of Directors (Board) on September 11, 2014.

## 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, 2014 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, 2013.

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 31 December 2013, except for the adoption of new standards and interpretations effective as of January 1, 2014.

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

#### Investment Entities

(Amendments to IFRS 10, IFRS 12 and IAS 27)

These amendments provide an exception to the consolidation requirement for entities that meet the defi-



inition of an investment entity under IFRS 10 Consolidated Financial Statements. The exception to consolidation requires investment entities to account for subsidiaries at fair value through profit or loss.

#### Offsetting Financial Assets and Financial Liabilities – Amendments to IAS 32

These amendments clarify the meaning of “currently has a legally enforceable right to set-off” and the criteria for non-simultaneous settlement mechanisms of clearing houses to qualify for offsetting.

#### Novation of Derivatives and Continuation of Hedge Accounting – Amendments to IAS 39

These amendments provide relief from discontinuing hedge accounting when novation of a derivative designated as a hedging instrument meets certain criteria.

#### Recoverable Amount Disclosures for Non-Financial Assets – Amendments to IAS 36

These amendments remove the unintended consequences of IFRS 13 Fair Value Measurement on the disclosures required under IAS 36 Impairment of Assets. In addition, these amendments require disclosure of the recoverable amounts for the assets or cash-generating units (CGUs) for which an impairment loss has been recognised or reversed during the period.

**IFRIC 21** IFRIC 21 is effective for annual periods beginning on or after 1 January 2014 and is applied retrospectively. It is applicable to all levies imposed by governments under legislation, other than outflows that are within the scope of other standards (e.g., IAS 12 Income Taxes) and fines or other penalties for breaches of legislation. The interpretation clarifies that an entity recognises a liability for a levy no earlier than when the activity that triggers payment, as identified by the relevant legislation, occurs. It also clarifies that a levy liability is accrued progressively only if the activity that triggers payment occurs over a period of time, in accordance with the relevant legislation. For a levy that is triggered upon reaching a

minimum threshold, no liability is recognised before the specified minimum threshold is reached. The interpretation requires these same principles to be applied in interim financial statements.

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

### 3 Operating segments

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, Sweden and, since July 8 2014, also in USA through a fully owned subsidiary, incorporated under the Delaware rules, based in Morristown, New Jersey (USA). The Company does not consider the geographies to be separate segments.

### 4 Seasonality

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

### 5 Exchange rates of principal currencies

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

	Income statements in euro (average rates)		Balance sheets in euro (rates as of)	
	Six months ended June 30,		June 30, 2014	Year end 2013
	2014	2013		
CHF 1	0.81870	0.81307	0.82264	0.81460
GBP 1	1.21752	1.17536	1.24766	1.19947
SEK 1	0.11169	0.11722	0.10898	0.11288

### 6 Licence income

(In thousand euro)	For the six months ended June 30,	
	2014	2013
Licence income	1,300	1,799

Licence income, amounting to Euro 1,300 (2013: Euro 1,799), is related to: a) the last portion of 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 period of collaboration required to finalise the development of safinamide, prepare the applications and file for marketing approval in Europe and the U.S. and b) the non-refundable milestone payment cashed-in from Zambon S.p.A. upon the submission to the Food and Drug Administration (FDA) of the safinamide New Drug Application (NDA).

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

(In thousand euro)	For the six months ended June 30,	
	2014	2013
Services received from subcontractors	712	17
Staff costs	594	553
Consultancy fees	681	62
Material and consumable used	441	56
Laboratory operating lease cost	99	105
Travel expenses	74	33
Depreciation, amortisation and impairment expense	8	9
Other research and development costs	11	2
	<b>2,620</b>	<b>837</b>

Staff costs amount to Euro 594 (2013: Euro 553). The difference compared to prior period is mainly due to the following effects: a) an increase in stock options' costs (please refer also to Note 17) and b) a decrease in personnel expenses, due to higher hours dedicated to safinamide – in both filing (within May 29, 2014) and post filing activities – and other granted projects.

The material increases in Services received from subcontractors, Consultancy fees and Material and consumable used are due to the studies and activities started by the Group in the first half of the year to develop its compounds.

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. Since the submission of the safinamide

dossier to the European Medicines Agency (EMA) and to the Food and Drug Administration (FDA), Newron is also supporting Zambon in managing the post-filing regulatory review. Based on the amended agreement, Zambon is reimbursing to Newron all the expenses incurred in providing such assistance, including personnel expenses which are invoiced at cost plus mark-up.

Research and development expenses are also presented net of the costs that are 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 amounting to Euro 3,837 (2013: Euro 3,600).

The table below shows the net effects:

(In thousand euro)	For the six months ended June 30,	
	2014	2013
Research and development expenses, gross	6,457	4,437
Granted project	(360)	(398)
Reimbursed by Zambon	(3,477)	(3,202)
	<b>2,620</b>	<b>837</b>

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 ended June 30,	
	2014	2013
Staff costs	1,188	1,127
Consultancy and other professional services	1,422	1,488
Intellectual properties	571	654
Travel expenses	90	125
Operating lease cost	51	53
Depreciation and amortisation expense	8	8
Other expenses	168	255
	<b>3,498</b>	<b>3,710</b>

Staff costs slightly increased in the six months period ending June 30, 2014, due to the increase in stock options' cost (please refer also to Note 17).

Consultancy and other professional services and Other expenses were slightly higher in 2013 as the Group was involved in various activities to integrate the newly acquired Newron Sweden AB.

## 9 Earnings/Loss per share

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

(In thousand euro)	For the six months ended June 30,	
	2014	2013
Net loss attributable to shareholders	(4,596)	(2,446)
Weighted average number of shares (thousands)	12,324	11,391
Loss per share – basic and diluted (in Euro)	(0.37)	(0.21)

The only category of potential ordinary shares are the stock options granted to certain employees, directors and consultants. As of June 30, 2014 Group' employees and consultants were under a temporary interruption (the so called "black-out period") of their exercising rights. Thus, given that at June 30, 2014, there were no exercisable stock options, the values of basic and diluted earnings per share coincide.

## 10 Intangible assets

Intangible assets of Euro 9,120 are almost entirely represented by in-process research and development projects (Euro 9,100), as detailed below:

### Hunter-Fleming Ltd

Project	Development phase	Allocated value
HF0220	Clinical phase II	2,175
HF0299	Clinical phase I	50
HF1220	Discovery	50
		<b>2,275</b>

### Newron Sweden AB

Project	Development phase	Allocated purchase price
sNN0029	Clinical phase I	1,469
sNN0031	Clinical phase II	5,356
		<b>6,825</b>

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, 2013. As of June 30, 2014, 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 Available for sale financial assets – non current

Available for sale financial assets of Euro 584 (2013: Euro 584) is entirely represented by a minority interest held in Trident Pharmaceuticals Inc. set-up to develop novel immunomodulatory drug products for the treatment of autoimmune disorders and allergic diseases. The investment was part of the 2008 acquisition of Hunter Fleming. During the first half of 2014 Trident Pharmaceuticals, Inc. agreed on a new financing with both new investors and existing investors. Following the tranche 1 and 2 closings held during the second quarter, our ownership in Trident declined to 13.41% as of June 30, 2014 (2013: 17%).

Management performed a full Impairment test on the carrying amount of the investment in Trident Pharmaceuticals Inc. at December 31, 2013. As of June 30, 2014, despite the dilution, management believes that no impairment indication for the asset was identified. Accordingly, management will perform a full impairment test of investment in Trident Pharmaceuticals Inc. at year-end.

## 12 Receivables and prepayments

(In thousand euro)	As of	
	June 30, 2014	December 31, 2013
	unaudited	audited
Receivables	2,181	1,003
Government grants receivable	264	982
Prepayments	346	294
Deferred costs	0	48
VAT receivable	285	507
Other receivables	158	236
	<b>3,234</b>	<b>3,070</b>

Receivables are almost entirely represented by the accruals related to the reimbursement of safinamide's costs as these expenses are charged by the Group to its partner. The above receivables have been cashed in for approximately 2 million during July and August 2014.

Government grants receivable decreased as a consequence of the cash-in of an instalment of approximately Euro 718 related to the project (sNN0029) financed by the Wellcome Trust.

## 13 Available for sale financial assets – current

(In thousand euro)	As of	
	June 30, 2014	December 31, 2013
	unaudited	audited
Listed bonds	4'293	0
Short-term time-deposit	4'831	0
	<b>9'124</b>	<b>0</b>

The Group, during the first six months, acquired Italian and foreign listed government and corporate bonds, whereas "Short-term time deposit" refers to a liquid investment with a duration of 3 or 6 months.

Gain and losses arising from the adjustment to the fair value were recognized in the comprehensive income.

All acquired securities and time-deposits are in line with the Group's investment policy.

## 14 Cash and cash equivalents

(In thousand euro)	As of	
	June 30, 2014	December 31, 2013
	unaudited	audited
Cash at bank and in hand	11,916	12,969
Short-term deposits	10,350	5,457
	<b>22,266</b>	<b>18,426</b>

The "Short-term deposits" are highly liquid investments easily convertible into cash, not subject to significant changes in value and with no withdrawal penalty. Gain and losses arising from the adjustment to the fair value were recognized in the comprehensive income. All acquired short term deposits are in line with the Group's investment policy.

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 ongoing research and development activities.

Group's liquidity (Available for sale financial assets plus Cash and cash equivalent) is slightly above Euro 31 million.

## 15 Share capital

As of December 31, 2013, Newron's outstanding share capital was Euro 2,324,900.80, consisting of 11,624,504 ordinary shares with a nominal value of Euro 0.20 each. There is no authorized share capital.

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

(In euro)	Total
As of December 31, 2012	2,277,195.40
– issue of ordinary shares (Capital Increase)	47,705.40
As of December 31, 2013	2,324,900.80
– issue of ordinary shares (Capital Increase)	42,294.60
– issue of ordinary shares (Capital Increase)	236,719.40
– issue of ordinary shares (Stock options exercise)	4,593.00
As of June 30, 2014	2,608,507.80

On April 18, 2013, the extraordinary shareholders' meeting resolved, among other items, to increase the Company's share capital by up to Euro 90,000.00 (i.e. within the limit of the 10% of existing share capital), corresponding to up to 450,000 new Newron ordinary shares with a par value of Euro 0.20 per share. The extraordinary shareholders' meeting resolved to exclude any preemptive rights to the Company's current shareholders to subscribe such capital increase. In 2013, existing shareholders, among which Zambon, subscribed 238,527 shares. On January 31, 2014, J.P. Morgan Asset Management has subscribed the remaining 211,473 ordinary shares (nominal value equal to Euro 0.20) by means of a private placement.

On March 27, 2014, the extraordinary shareholders' meeting resolved, among other items, to increase the Company's share capital by up to 10%, or the equivalent of an amount of up to Euro 236,719.40, corresponding to up to 1,183,597 new Newron ordinary shares with a par value of Euro 0.20 per share. The extraordinary shareholders' meeting resolved to exclude any pre-emptive rights to the Company's current shareholders to subscribe such capital increase. Existing shareholders and new international institutional investors have subscribed the above shares; the Company on April 7, 2014 announced

the completion of the placement. During the month of June 2014, certain stock option holders have exercised their right: accordingly, the Company issued 22,965 new ordinary shares (nominal value equal to Euro 0.20).

As of June 30, 2014, the subscribed share capital was equal to Euro 2,608,507.80, divided into 13,042,539 ordinary shares with nominal value equal to Euro 0.20 each. There is no authorised share capital.

## 16 Share premium

(In thousand euro)	As of	
	June 30, 2014	December 31, 2013
	unaudited	audited
At the beginning of the year	28,933	31,333
Loss allocation	(5,339)	(2,352)
Advance payment for future capital increase	0	(1,724)
Issue of shares	17,956	1,676
Issue of shares (exercise of options)	117	0
Reclassification from share option reserve	42	0
Share capital issue costs	(809)	0
At the end of the period	40,900	28,933

As a consequence of the exercise of options, the cost accrued into the Share options reserve throughout the vesting period has been reclassified into the share premium reserve.

## 17 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 during its existence, various Share Option Plans of which the following are still valid: March 2011 (ESOP 2011) and January 2013 (ESOP 2013). All options have been awarded free of charge.

On January 28, 2014 Newron' Board approved a new Options Plan (ESOP 2014) and assigned 111,281 new options to certain Group's employees, directors and consultants, out of which 55,632 can be exercised after two years from the grant date, 27,818 after three years and the remaining 27,831 after four years. The options'

strike price is settled at CHF 17.10 (Euro 13.94 as translated at the exchange rate on January 27, 2014) and its fair value is equal to CHF 1,123 (Euro 914 at granting date).

The fair values of the issued options have been estimated on the date of grant using, amongst 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 vesting period. The total increase of share option reserve is equal to Euro 458 and it's related to the following opposite effects: a) additional costs of the period equal to Euro 499 and b) a reclassification to Share Premium Reserve as a consequence of the options' exercise

For additional information, please refer to note 21 as well.

## 18 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 1), starting from July 1, 2012 and ending on January 1, 2018. The remaining part of the debt is broken-down as follows: short-term borrowings are equal to Euro 359 whereas long-term borrowings are equal to Euro 907.

## 19 Financial instruments by category

The following tables present the breakdown of financial assets and liabilities by category as of June 30, 2014 and December 31, 2013 respectively.

	Cash, loans and receivables	Assets at fair value through profit or loss	Held-to-maturity investments	Available-for-sale financial assets	Liabilities at fair value through profit or loss	Other financial liabilities at amortized cost
<b>As of June 30, 2014</b>						
<b>Assets</b>						
Available for sale financial assets – non current	–	–	–	584	–	–
Available for sale financial assets – current	9,124	–	–	–	–	–
Cash and cash equivalents	22,266	–	–	–	–	–
Trade and other receivables	2,888	–	–	–	–	–
<b>Total</b>	<b>34,278</b>	<b>–</b>	<b>–</b>	<b>584</b>	<b>–</b>	<b>–</b>
<b>Liabilities</b>						
Trade and other payables	–	–	–	–	–	4,112
Short-term borrowings	–	–	–	–	–	359
Long-term borrowings	–	–	–	–	–	907
<b>Total</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>5,378</b>

The Company has evaluated the fair value of loans and Available for sale financial assets – non current at June 30, 2014.

The Company has classified Available for sale financial assets – non current and Borrowings in Level 2 (For additional information, please refer to Note 13 and 18 respectively).

	Cash, loans and receivables	Assets at fair value through profit or loss	Held-to-maturity investments	Available-for-sale financial assets	Liabilities at fair value through profit or loss	Other financial liabilities at amortized cost
<b>As of December 31, 2013</b>						
<b>Assets</b>						
Available for sale financial assets	–	–	–	584	–	–
Cash and cash equivalents	18,426	–	–	–	–	–
Trade and other receivables	2,728	–	–	–	–	–
<b>Total</b>	<b>21,154</b>	<b>–</b>	<b>–</b>	<b>584</b>	<b>–</b>	<b>–</b>
<b>Liabilities</b>						
Trade and other payables	–	–	–	–	–	3,440
Short-term borrowings	–	–	–	–	–	358
Long-term borrowings	–	–	–	–	–	1,087
<b>Total</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>4,885</b>



## 20 Related party transactions

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, 2014 and June 30, 2013, as well as balances with related parties outstanding as of June 30, 2014 and June 30, 2013:

As of June 30, 2014	Sales to / Cost reimbursed by related parties	Purchases from related parties	Amounts owed by related parties, net
Zambon (whole group)	4,878	60	58
As of June 30, 2013			
Zambon (whole group)	5,002	60	1,680

As detailed in the above paragraphs, sales to Zambon are mainly related to: a) the recognition of the portion of the down-payment received upon the finalization of the Collaboration and Licence Agreement related to safinamide; b) the non-refundable milestone payment cashed-in from Zambon S.p.A. upon the submission to the Food and Drug Administration (FDA) of the safinamide New Drug Application (NDA) and c) 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. Purchases from Zambon are related to the leasing of the premises located in Bresso and additional archiving space. (For additional information, please refer to Note 6 and 7)

## 21 Events after the balance sheet date

On July 1, 2014 Newron Pharmaceuticals US Inc. started its operations in Morristown, New Jersey, USA. The company will be responsible for interactions with the FDA and the conduct of clinical investigations of Group's compounds in the US. Furthermore, the subsidiary might serve as the site for the future commercial operations of Newron group for our clinical-stage portfolio of orphan compounds.

On July 11, 2014, Newron Pharmaceuticals S.p.A. announced that, according to SIX Swiss Exchange's notification, Newron's shares will be included in the SXI Life Sciences® and the SXI Bio+Medtech® indices effective as of September 22, 2014, promising to increase trading volume in the stock, and attracting new investors to the story, directly and indirectly.

On July 16, 2014, Newron's Board of Directors approved to grant additional n. 76,494 stock options from the ESOP 2014 Plan of which 38,246 can be exercised after two years from the grant date, 19,123 after three years and the remaining 19,125 after four years. The options' strike price is CHF 16.85 (Euro 13.88 as translated at the exchange rate on July 15, 2014). As of July 16, 2014, the Company has granted a total of n. 777,035 options.

On July 29, 2014, Newron Pharmaceuticals S.p.A. announced that it has received a Refusal to File (RTF) letter from the Food and Drug Administration (FDA) for safinamide. Upon preliminary review, the FDA identified some organization and navigation problems, relating to the hyperlinking of tables, folders and the organization of the table of contents in the submission, as well as the conformation of the Package Insert to FDA guidelines. The Refusal to File letter does not relate to the acceptability of the clinical data, and no judgment has been made on the efficacy or safety of safinamide. Newron believes that the additional information needed to support this filing is available and is working closely with the FDA to resubmit the application as quickly as possible.

Bresso, September 11, 2014



Stefan Weber  
CEO





# Information for Investors

## Stock exchange information

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

## Share price data

Number of fully paid-in shares as at June 30, 2014	13,042,539
52-week high (in CHF)	19.50
52-week low (in CHF)	8.45
June 2014 closing share price	16.15
Loss per share (in Euro)	0.37
Cash and cash equivalents, other short-term financial assets as at June 30, 2014 (in Euro 1,000)	31,390
Market capitalization as at June 30, 2014 (in CHF)	210,637,005

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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 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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## **Imprint**

### **Publisher**

Newron Pharmaceuticals S.p.A., Bresso (Mi), Italy

### **Concept**

FTI Consulting, London, UK

IRF Communications AG, Zurich, Switzerland

### **Graphic design, production and prepress**

TGG Hafen Senn Stieger, St.Gallen, Switzerland

### **Photos**

Marco Moscadelli, Studio Fotografico Moscadelli,  
Milan, Italy



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