Newron
Pharmaceuticals

Half-Year Report 2016

Corporate profile

Newron (SIX: NWRN) is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central nervous system (CNS) and pain. The Company is headquartered in Bresso near Milan, Italy. Xadago® (safinamide) has received marketing authorization for the treatment of Parkinson's disease in the European Union and Switzerland and is commercialized by Newron's Partner Zambon. US WorldMeds holds the commercialization rights in the U.S. Meiji Seika has the rights to develop and commercialize the compound in Japan and other key Asian territories. In addition to Xadago® for Parkinson's disease, Newron has a strong pipeline of promising treatments for rare disease patients at various stages of clinical development, including sarizotan for patients with Rett syndrome 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

Half-Year 2016 Highlights

- Xadago® (safinamide) launch by Zambon for patients with Parkinson's disease in
  - Switzerland
  - Spain
  - Italy
  - Belgium
  - Denmark
  - Sweden
  - the U.K.
  - Luxembourg

- Complete Response Letter from the U.S. FDA for Xadago®

- Phase II study of Evenamide (NW-3509) presentation at 5th Biennial Schizophrenia International Research Society Conference

- IND Approval for Sarizotan for Treatment of Rett Syndrome by the U.S. FDA

- STARS trial design presentation at U.S. Rett Syndrome Symposium

- Initiation of burden of disease study for Rett Syndrome patients and families

Post-Period Events

- Xadago® launch in The Netherlands and Norway for patients with mid- to late-stage Parkinson's disease by Zambon

- Initiation of STARS potentially pivotal study for patients with Rett Syndrome in the U.S.

- U.S. FDA clearance to re-submit US NDA for Xadago® (safinamide)

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Shareholders' Letter

Dr. Ulrich Köstlin

Stefan Weber

Dear Shareholder,

we are pleased to report that the past six months have been a successful period for Newron. Following last year's European approval of Xadago® (safinamide) and the launch in the first EU territory, Germany, 2016 thus far has seen the launch of Xadago® in several key European markets by our partner Zambon. With our development product sarizotan, we initiated the potentially pivotal STARS study in patients with Rett syndrome suffering from respiratory symptoms.

During the first half of 2016, Xadago® was launched by Zambon in Switzerland, Spain, Italy, Belgium, Denmark, Sweden, the U.K., Luxembourg and post period, in The Netherlands and Norway. The series of launches means that a substantially increased number of patients across Europe, including by now four of the five key EU pharmaceutical territories, can be treated using Xadago®, the first New Chemical Entity in ten years to receive Marketing Authorization from the EU Commission for the treatment of Parkinson's disease. Since Xadago® was first launched in Germany roughly twelve months ago, we have generated cumulated royalty revenues of EUR 1.3 million on product sales by Zambon, with revenues growing at a steady rate of about 50% each quarter over the previous quarter.

In March, we were disappointed to receive a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) for Xadago®. However, post-period we announced alongside our partners U.S. WorldMeds and Zambon that the FDA no longer required Newron to perform any studies to clinically evaluate the potential abuse liability or dependence/withdrawal effects of Xadago®, that were the key subject of the CRL. As no additional data/studies/analyses for efficacy or safety in patients with Parkinson's disease had been required under the CRL, we will now expedite re-submission of the New Drug Application (NDA) to the U.S. FDA still in 2016, and look forward to approval to enter the U.S. market.

In May, we received the FDA's approval of our Investigational New Drug (IND) application for the evaluation of sarizotan for the treatment of patients with Rett syndrome and in July, post period, we initiated the Sarizotan Treatment of Apneas in Rett Syndrome (STARS) study. This is a potentially pivotal clinical study to evaluate the efficacy, safety and tolerability of sarizotan in patients with Rett syndrome suffering from respiratory symptoms. The

initiation of the STARS study is an exciting milestone in our development program for sarizotan and we look forward to reporting the results of the trial in due course.

As part of our wider commitment to addressing the needs of Rett syndrome patients, as announced in June, we are sponsoring a study to evaluate the burden of disease experienced by patients with this debilitating condition and their families. The study will be comprised of two global surveys, one to be completed by 500 caregivers and the other by 50 physicians. Both will examine patient burden, with the caregiver survey additionally evaluating caregiver burden. The surveys are being developed in accordance with regulatory guidance, with the final versions being used for data collection in the United States, the United Kingdom, Italy and Germany.

Newron is continuously strengthening its development and marketing resources, in particular in the United States, and prepares to commercialize sarizotan directly.

We were pleased to present a poster on Evenamide (NW-3509), our new generation antipsychotic that acts through pathways that are not targeted by current treatments or other putative antipsychotics, earlier this year. We did so in April at the 5th Biennial Schizophrenia International Research Society Conference with the abstract "Evenamide (NW-3509), a Putative Antipsychotic, Targets Abnormal Electrical Activity and Glutamatergic Abnormalities in Improving Psychotic Symptoms in Patients with Schizophrenia in a Phase II, Placebo-controlled Trial". The research presented at this conference is another positive step in the development of Evenamide which we welcome ahead of phase II study results anticipated in Q4 this year.

So far this year we have been proud to support Rare Disease Day, the World Parkinson's Disease Awareness Day, as well as the Rett Symposium. These global initiatives are helping to raise awareness of rare diseases and Parkinson's disease respectively and we fully support their mission to improve the lives of both rare disease and Parkinson's disease patients.

In the first six months of 2016, Newron has invested EUR 9.2 million into drug development and preparations for regulatory submission of safinamide, up from EUR 7.6 million in 2015. The increase is mostly due to the Phase II study with Evenamide in patients with schizophrenia and the preparations of the potentially pivotal study with sarizotan in Rett Syndrome. Of these R&D expenses, EUR 1.0 million has been reimbursed by our safinamide partner Zambon. Therefore, for the first six months of the year, net R&D expenses are EUR 8.2 million, up from 2015 expenses of EUR 4.7 million. G&A expenses reached EUR 4.4 million in the first six months of 2016, up from EUR 4.1 million in 2015. Revenues for the first half of 2016 were EUR 3.9 million, up from EUR 2.0 million in 2015, including milestone payments under the collaboration with partner Zambon (EUR 3.0 million, up from EUR 1.8 million in 2015) and royalty payments on Xadago® sales, which were up to EUR 852 thousand in the first six months, from EUR 93 thousand in 2015. The net loss for the first six months of 2016 is EUR 8.8 million, compared to EUR 6.9 million in the first half of 2015. Cash and short term investments at June 30, 2016 were at EUR 34.9 million, compared to EUR 40.9 million at the beginning of the year, also reflecting the exercise in March 2016 of a purchase option for 209,364 shares by a shareholder under a 2015 subscription and option agreement, generating proceeds of EUR 3.0 million.

After a very positive six months and the exciting news received post period from the U.S. FDA on the upcoming re-submission of the U.S. NDA for Xadago®, we would once again like to thank our shareholders for their ongoing commitment and support as we enter the second half of 2016 during which we expect strong news flow. We are extremely gratified that Xadago® is now available to patients in eleven European countries generating revenues with impressive growth rates and look forward to hearing from the FDA with regards to the U.S. approval for Xadago®. Our innovative pipeline of CNS drugs is progressing well and we look forward to reporting the data from these studies as we continue to build and strengthen our position as a leading player in the CNS disease area.

Yours sincerely

Dr. Ulrich Köstlin
Chairman

Stefan Weber
Chief Executive Officer

Unaudited interim condensed consolidated financial statements

For the six months ended June 30, 2016

Auditors' Report

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Review report on the interim condensed consolidated financial statements

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

Introduction

We have reviewed the interim condensed consolidated financial statements, comprising the interim condensed consolidated statement of financial position as of June 30, 2016, the interim condensed consolidated statements of income, the interim condensed consolidated statement of comprehensive income, the interim condensed consolidated statement of changes in equity and cash flows for the period then ended and the related explanatory notes of Newron Pharmaceuticals S.p.A. and its subsidiaries (the "Newron Group"). The Directors of Newron Pharmaceuticals S.p.A. are responsible for the preparation of the interim condensed consolidated financial statements in conformity with the International Financial Reporting Standard applicable to 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 Engagement 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim condensed consolidated financial statements 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 on the interim condensed consolidated financial statements.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim condensed consolidated financial statements of Newron Group as of June 30, 2016, are not prepared, in all material respects, in accordance with the International Financial Reporting Standard applicable to interim financial reporting (IAS 34).

Milan, September 12, 2016

EY S.p.A.

Paolo Zocchi
(Partner)

Interim Condensed Consolidated Statement of profit or loss

(In thousand Euro, except per share information)	Note	For the six months ended June 30 2016 (unaudited)	2015 (unaudited)
Licence income	6	3,039	1,800
Royalties	7	852	93
Other income		17	86
Revenue		3,908	1,979
Research and development expenses	8	(8,240)	(4,723)
Marketing and advertising expenses		(143)	(41)
General and administrative expenses	9	(4,402)	(4,058)
Operating result		(8,877)	(6,843)
Financial result net	10	134	(68)
Result before tax		(8,743)	(6,911)
Income tax		(11)	(12)
Net loss		**(8,754)**	**(6,923)**
Loss per share			
Basic and Diluted	11	**(0.64)**	**(0.52)**
Weighted average number of shares (thousands)			
		13,722	**13,395**

Interim Condensed Consolidated Statement of Comprehensive Income

(In thousand Euro)	Note	For the six months ended June 30 2016 (unaudited)	2015 (unaudited)
Net loss for the period		(8,754)	(6,923)
Other comprehensive income to be reclassified to profit or loss in subsequent periods:			
Net loss on available-for-sale assets	14/15	(20)	(10)
Exchange differences on translation of foreign operations		(32)	116
Net other comprehensive income to be reclassified to profit or loss in subsequent periods, net of tax		**(52)**	**106**
Other comprehensive income not to be reclassified to profit or loss in subsequent periods:			
Actuarial (loss) on benefit plan for employees		(37)	4
Net other comprehensive income not to be reclassified to profit or loss in subsequent periods		**(37)**	**4**
Other comprehensive loss for the period, net of tax		(89)	110
Total comprehensive loss for the period		**(8,843)**	**(6,813)**

(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, 2016 (unaudited)	As of December 31, 2015 (audited)
Assets			
Non-current assets			
Property, plant and equipment		118	79
Intangible assets	12	264	265
Non-current receivables		65	62
		447	406
Current assets			
Inventories		38	38
Receivables and prepayments	13	3,350	3,005
Available for sale financial assets	14	4,422	4,920
Cash and cash equivalents	15	30,457	36,011
		38,267	43,974
Total assets		**38,714**	**44,380**
Shareholders, equity			
Share capital	16	2,890	2,844
Share premium and other reserves	17	37,319	61,580
Share option reserve	18	6,396	5,392
Retained earnings		(13,405)	(31,914)
Translation differences		(822)	(790)
Total shareholders, equity		32,378	37,112
Liabilities			
Non-current liabilities			
Deferred tax liability		75	75
Long-term borrowings	19	182	364
Employee severance indemnity		176	316
		433	755
Current liabilities			
Short-term borrowings	19	363	362
Trade and other payables		5,540	6,151
		5,903	6,513
Total liabilities		6,336	7,268
Shareholders, equity and liabilities		**38,714**	**44,380**

(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, 2015		2,609	40,903	3,559	(830)	(16,980)	29,261
Net loss						(6,923)	(6,923)
Other comprehensive losses					116	(6)	110
Total comprehensive loss for the period		0	0	0	116	(6.929)	(6,813)
Previous year loss allocation			(7,900)			7,900	0
Issue of shares	16/17	169	23,260				23,429
Issuing costs	17		(409)				(409)
Exercise of options	16/17	23	658				681
Exercise of options – reclassification of reserves	17		402	(402)			0
Share option scheme	18			960			959,70
Balance at June 30, 2015		2,800	56,915	4,117	(714)	(16,010)	47,108
Balance at January 1, 2016		2,844	61,580	5,392	(790)	(31,914)	37,112
Net loss						(8,754)	(8,754)
Other comprehensive gain / (loss)					(32)	(57)	(89)
Total comprehensive loss for the period		0	0	0	(32)	(8,811)	(8,843)
Previous year loss allocation			(27,320)			27,320	0
Issue of shares	16/17	42	2,999				3,041
Issuing costs	17		(184)				(184)
Exercise of options	16/17	4	142				146
Exercise of options – reclassification of reserves	17		102	(102)			0
Share option scheme	18			1,106			1,106
Balance at June 30, 2016		**2,890**	**37,319**	**6,396**	**(822)**	**(13,405)**	**32,378**

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

Interim Condensed Consolidated Statement of Cash Flow

(In thousand Euro)	Note	For the six months ended June 30 2016 (unaudited)	2015 (unaudited)
Operating activities			
Loss before tax		(8.743)	(6.911)
Adjustments for:			
Depreciation and amortisation		16	17
Grants and other non monetary income		(257)	(1,044)
Share option expenses	18	1.106	960
Employee severance indemnity expense		(98)	22
Changes in working capital:			
Inventories		0	3
Current receivables and prepayments and deferred cost (excluding grants receivable)		(353)	436
Trade and other payables and deferred income (excluding advances of grants)		(613)	477
Government grants received		0	788
Change in non-current receivables		(3)	(5)
Cash used in operating activities		(8.945)	(5.257)
Cash flows from investing activities			
Disposal of financial assets	14	498	1.470
Purchase of property, plant and equipment		(56)	(15)
Purchase of intangible assets		0	(1)
Interest received	10	128	51
Net cash flows from investing activities		570	1,505
Cash flows from financing activities			
Repayment of borrowings	19	(182)	(180)
Proceeds from issue of shares	16/17	3.187	24,110
New shares issuing costs	17	(184)	(409)
Net cash flows from financing activities		2,821	23,521
Net increase in cash and cash equivalents		(5,554)	19,769
Cash and cash equivalents at January 1,		36,011	18,756
Cash and cash equivalents at the end of the year		**30,457**	**38,525**

(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 under the Delaware rules, based in Morristown, New Jersey (USA);
- Newron Sweden AB, a fully owned biotechnology company based in Stockholm (Sweden) developing new medicines to treat illnesses caused by necrosis of the Central Nervous System (CNS);
- Hunter-Fleming Limited, a fully owned biopharmaceutical company based in Brixham (United Kingdom) and focused on neurodegenerative and inflammatory disorders;
- Newron Suisse SA, a fully owned clinical development subsidiary based in Zurich (Switzerland).

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 International Reporting Standard (since August 3, 2015 previously at the Main Standard) 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, 2016, were authorised for issuance by the Board of Directors (Board) on September 9, 2016.

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, 2016 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, 2015.

Considering the Group's current cash position and the level of spending according to management's plan and budget, the Directors believe that the Group will be able to meet its obligations as they fall due for a period of at least 12 months from the date of signing of the interim condensed consolidated financial statements. 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, 2015, except for the adoption of new standards and interpretations effective as of January 1, 2016. The Group has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.

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

Amendments to IFRS 11 Joint Arrangements: Accounting for Acquisitions of Interests

The amendments to IFRS 11 require that a joint operator accounting for the acquisition of an interest in a joint operation, in which the activity of the joint operation constitutes a business, must apply the relevant IFRS 3 Business Combinations principles for business combination accounting. The amendments also clarify that a previously held interest in a joint operation is not re-measured on the acquisition of an additional interest in the same joint operation if joint control is retained. In addition, a scope exclusion has been added to IFRS 11 to specify that the amendments do not apply when the parties sharing joint control, including the reporting entity, are under common control of the same ultimate controlling party. The amendments apply to both the acquisition of the initial interest in a joint operation and the acquisition of any additional interests in the same joint operation and are prospectively effective for annual periods beginning on or after January 1, 2016, with early adoption permitted.

These amendments do not have any impact on the Group as there has been no interest acquired in a joint operation during the period.

Amendments to IAS 16 and IAS 38: Clarification of Acceptable Methods of Depreciation and Amortization

The amendments clarify the principle in IAS 16 Property, Plant and Equipment and IAS 38 Intangible Assets that revenue reflects a pattern of economic benefits that are generated from operating a business (of which the asset is a part) rather than the economic benefits that are consumed through use of the asset. As a result, a revenue-based method cannot be used to depreciate property, plant and equipment and may only be used in very limited circumstances to amortise intangible assets. The amendments are effective prospectively for annual periods beginning on or after January 1, 2016, with early adoption permitted. These amendments do not have any impact to the Group given that the Group has not used a revenue-based method to depreciate its noncurrent assets.

Annual Improvements 2012–2014 Cycle

IFRS 5 Non-current Assets Held for Sale and Discontinued Operations

Assets (or disposal groups) are generally disposed of either through sale or distribution to owners. The amendment clarifies that changing from one of these disposal methods to the other would not be considered a new plan of disposal, rather it is a continuation of the original plan. There is, therefore, no interruption of the application of the requirements in IFRS 5. This amendment must be applied prospectively.

IFRS 7 Financial Instruments: Disclosures

(i) Servicing contracts

The amendment clarifies that a servicing contract that includes a fee can constitute continuing involvement in a financial asset. An entity must assess the nature of the fee and the arrangement against the guidance for continuing involvement in IFRS 7 in order to assess whether the disclosures are required. The assessment of which servicing contracts constitute continuing involvement must be done retrospectively. However, the required disclosures would not need to be provided for any period beginning before the annual period in which the entity first applies the amendments.

(ii) Applicability of the amendments to IFRS 7 to condensed interim financial statements

The amendment clarifies that the offsetting disclosure requirements do not apply to condensed interim financial statements, unless such disclosures provide a significant update to the information reported in the most recent annual report. This amendment must be applied retrospectively.

IAS 19 Employee Benefits

The amendment clarifies that market depth of high quality corporate bonds is assessed based on the currency in which the obligation is denominated, rather than the country where the obligation is located. When there is no deep market for high quality corporate bonds in that currency, government bond rates must be used. This amendment must be applied prospectively.

IAS 34 Interim Financial Reporting
The amendment clarifies that the required interim disclosures must either be in the interim financial statements or incorporated by cross-reference between the interim financial statements and wherever they are included within the interim financial report (e.g., in the management commentary or risk report). The other information within the interim financial report must be available to users on the same terms as the interim financial statements and at the same time. This amendment must be applied retrospectively.

Amendments to IAS 1 Disclosure Initiative
The amendments to IAS 1 clarify, rather than significantly change, existing IAS 1 requirements. The amendments clarify:

- The materiality requirements in IAS 1
- That specific line items in the statement(s) of profit or loss and OCI and the statement of financial position may be disaggregated
- That entities have flexibility as to the order in which they present the notes to financial statements
- That the share of OCI of associates and joint ventures accounted for using the equity method must be presented in aggregate as a single line item, and classified between those items that will or will not be subsequently reclassified to profit or loss

Furthermore, the amendments clarify the requirements that apply when additional subtotals are presented in the statement of financial position and the statement(s) of profit or loss and OCI. These amendments are effective for annual periods beginning on or after January 1, 2016, with early adoption permitted. These amendments do not have any impact on the Group.

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 and in the U.S. The Company does not consider the geographies to be separate segments.

4 Seasonality

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

5 Exchange rates of principal currencies

Measurement currency
The Group's consolidated financial statements are presented in euro, which is also the parent company's functional currency. For each entity, the Group determines the functional currency and items included in the financial statements of each entity are measured using that functional currency. The Group uses the direct method of consolidation and on disposal of a foreign operation, the gain or loss that is reclassified to profit or loss reflects the amount that arises from using this method.

Transactions and balances

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

Group companies

The exchange rates used are detailed in the following table:

	Income statements in Euro (average rates) Six months ended June 30		Balance sheets in Euro (rates as of)	
	2016	2015	June 30, 2016	Year-end 2015
CHF 1	0.91237	0.94634	0.92022	0.92293
GBP 1	1.28408	1.36556	1.20992	1.29207
SEK 1	0.10751	0.10707	0.10611	0.10882
USD 1	0.89611	0.89622	0.90074	0.91853

6 Licence income

(In thousand Euro)	For the six months ended June 30,	
	2016	2015
Licence income	3,039	1,800

Licence income, amounting to Euro 3,039 (2015: Euro 1,800), is related to the non-refundable milestone payments cashed-in from Zambon upon granting of pricing approval of Xadago® (safinamide) in certain European countries and identification of the U.S. partner.

7 Royalties

(In thousand Euro)	For the six months ended June 30,	
	2016	2015
Royalties	852	93

Following the European Commission approval of the use of Xadago® (safinamide) for the treatment of idiopathic Parkinson's disease, starting by May 15, 2015, Zambon has launched Xadago® in the first European country, Germany. From January 2016 on, Zambon has launched Xadago® in several other European countries among which Italy, Spain, United Kingdom and, soon after Xadago® was approved by Swissmedic as add-on therapy to levodopa alone or in combination with other therapies for patients with Parkinson's disease in mid-to late-stage and motor fluctuations, also in Switzerland. Royalties payable to Newron according to the agreement in place with Zambon, have been communicated to Newron by its partner.

8 Research and development expenses net of grants and other reimbursements

(In thousand Euro)	For the six months ended June 30,	
	2016	2015
Services received from subcontractors	2,767	1,133
Staff costs	1,331	1,610
Consultancy fees	712	818
Material and consumable used	2,933	819
Laboratory operating lease cost	173	101
Travel expenses	286	234
Depreciation, amortisation and impairment charge	0	8
Other research and development costs	38	0
	8,240	**4,723**

Staff costs amount to Euro 1,331 (2015: 1,610). The variance compared to prior period is mainly due to the following effects: a) an increase in the number of R&D employees hired by Newron Pharmaceuticals US Inc.; b) an increase in stock options' costs (for further details, please refer also to Note 18) and related social contributions expenses (in certain countries, as required by local regulation, Newron has paid – once exercised - and accrued social contribution costs on vested options) and c) a decrease in the number of R&D employees working for Newron Sweden AB following the termination of development of both sNN0029 and sNN0031.

The increases in cost of Services received from subcontractors and Material and consumable used are due to the studies and activities both on-going and started by the Group in the first half of the year to develop its own compounds; those expenses might increase in the following 6-month period. As a consequence of the decision taken in June 2016 to terminate the agreement with Merck KGaA regarding the purchase of additional drug substance (sarizotan), the Company has paid to Merck KGaA a fee of Euro 650 (for further details, please refer to Note 22) and recognized to profit and loss additional Euro 500 booked in 2015 as Prepayments.

Increases in Operating Lease cost and Travel expenses are respectively related to additional space rented in an archiving facility company to store our clinical data and study materials and increased number of travels done to meet the relevant regulatory authorities in both Europe and the U.S.

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. Since the submission of the safinamide dossier 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. Ministries, Foundations, etc.), based on certain scientific research programmes granted to the Group. Accordingly, research and development expenses are presented net of total reimbursements amounting to Euro 1,034 (2015: Euro 2,840).

The table below shows the net effects:

(In thousand Euro)	For the six months ended June 30,	
	2016	2015
Research and development expenses, gross	9,274	7,563
Granted project	0	(1,253)
Reimbursed by Zambon	(1,034)	(1,587)
	8,240	**4,723**

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.

9 General and administrative expenses

(In thousand Euro)	For the six months ended June 30,	
	2016	2015
Staff costs	1,827	1,572
Consultancy and other professional services	1,656	1,469
Intellectual properties	551	679
Travel expenses	109	98
Operating lease cost	116	85
Depreciation and amortisation expense	16	9
Other expenses	127	146
	4,402	**4,058**

Staff costs increased in the six month period ended June 30, 2016, due to: a) the increase in headcounts and b) the increase in stock options' cost (for further details, please refer also to Note 18) and in related social contributions expenses (in certain countries, as required by local regulation, Newron has paid – once exercised - and accrued social contribution costs on vested options).

The decrease in Intellectual properties expenses is mainly due to the validation of some patents in all the European countries occurred in 2015.

Operating lease cost includes the six months' rent for the new offices in Morristown, New Jersey, USA.

10 Financial result, net

(In thousand Euro)	For the six months ended June 30,	
	2016	2015
Interest income, net	128	51
Foreign exchange gains/ (losses), net	41	(84)
Other costs, net	(35)	(35)
	134	**(68)**

Interest income increased due to interests paid by Zambon to Newron on certain milestones as stated in the licencing agreement signed in May 2014.

The high liquidity of the financial markets and the uncertainty linked to certain events affecting the economy, have limited Newron's financial incomes.

11 Loss per share

The basic 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,	
	2016	2015
Net loss attributable to shareholders	(8,754)	(6,923)
Weighted average number of shares (thousands)	13,722	13,395
Loss per share – basic and diluted (in Euro)	(0.64)	(0.52)

The only category of potential ordinary shares are the stock options granted to certain employees, directors and consultants. During the presented periods, these were anti-dilutive, as their conversion would have decreased the losses per shares. Thus, the values of basic and diluted earnings per share coincide.

In case of future profits, options granted to employees, directors and certain consultants (as of today n. 910,200 – see also Note 18) may have a dilutive effect on the net profit per share.

12 Intangible assets

Intangible assets of Euro 264 are almost entirely represented by In-Process Research and Development ("IPR&D") projects (250 Euro), as detailed below:

Company	Project	Development phase	Book value
Hunter-Fleming Ltd	HF0220	Clinical phase II	50
	HF0299	Clinical phase I	50
	HF1220	Clinical phase I	50
Newron Sweden AB	sNN0029	Clinical phase I	50
	sNN0031	Clinical phase II	50
			250

IPR&D projects are disclosed at their carrying amount net of impairment charges accounted for in previous periods. IAS 36 requires assessing an asset not in use for impairment on an annual basis and when circumstances indicate the carrying value may be impaired by comparing the carrying value to its recoverable amount. Management performed a full impairment test of the above assets for the 2015 year-end closing. As of June 30, 2016, no impairment indication for the assets was identified.

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 projects stays.

13 Receivables and prepayments

(In thousand Euro)	As of	
	June 30, 2016	December 31, 2015
	unaudited	audited
Receivables	1,112	1,219
Government grants receivable	264	264
Prepayments	1,727	1,076
VAT receivable	199	393
Other receivables	48	53
	3,350	**3,005**

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 Zambon, and royalties.

Prepayments increased because of the R&D studies and activities both on-going and started by the Group in the first half of the year to develop its own compounds.

14 Available for sale financial assets – current

(In thousand Euro)	As of	
	June 30, 2016	December 31, 2015
	unaudited	audited
Listed bonds	4,422	4,920
	4,422	**4,920**

The decrease is due to a sale of a corporate bond occurred during the first six months of 2016.

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

All acquired securities are in line with the Group's investment policy.

15 Cash and cash equivalents

(In thousand Euro)	As of	
	June 30, 2016	December 31, 2015
	unaudited	audited
Cash at bank and in hand	20,232	26,203
Short-term investments	10,225	9,808
	30,457	**36,011**

The "Short-term investments" 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's 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) amounts approximately to Euro 35 million (Euro 41 million as at December 31, 2015). The variance compared to 2015 year-end is mainly explained by the combined effects of the R&D expenditures of the period partially offset by the proceeds obtained through the increase in share capital occurred in March 2016, as detailed in Note 16 and 17.

16 Share capital

As of December 31, 2015, the subscribed share capital was equal to Euro 2,843,834.40, divided into 14,219,172 ordinary shares with par value equal to Euro 0.20 each. There is no authorised share capital.

A summary of the changes occurred during the last 18 months in share capital is as follows (amounts are shown in Euro):

(In Euro)	Total
As of December 31, 2014 – Newron Group	2,608,507.80
– issue of ordinary share (Capital Increase)	168,614.40
– issue of ordinary share (Capital Increase)	41,872.80
– issue of ordinary share (Stock options exercise)	24,839.40
As of December 31, 2015 – Newron Group	2,843,834.40
– issue of ordinary share (Capital Increase)	41,872.80
– issue of ordinary share (Stock options exercise)	4,020.40
As of June 30, 2016 – Newron Group	**2,889,727.60**

On March 24, 2015, 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 260,850.00 Euro, corresponding to up to 1,304,250 new Newron' ordinary shares with a par value of 0.20 Euro per share. The extraordinary shareholders' meeting resolved to exclude any pre-emptive rights to the Company's current shareholders to subscribe such capital increase. The Company as of April 30, and November 20, 2015 announced that existing shareholders and new international institutional investors - including a leading US-based biotechnology and healthcare specialist fund – have subscribed respectively 843,072 and 209,364 ordinary shares (nominal value equal to Euro 0.20) by means of private placements.

Under the agreement signed on November 20, 2015, the abovementioned US-based fund held an option to subscribe additional 209,364 newly issued ordinary shares no later than June 30, 2016: the subscription price was governed by the March 24, 2015 extraordinary shareholders' meeting authorization. The fund subscribed the additional newly issued ordinary shares on March 23, 2016.

During the six-month period ending on June 30, 2016, certain stock option holders have exercised their right: accordingly, the Company issued 20,102 new ordinary shares (par value equal to Euro 0.20 each).

As of June 30, 2016, the subscribed share capital was equal to Euro 2,889,727.60, divided into 14,448,638, ordinary shares with a par value equal to Euro 0.20 each. There is no authorised share capital.

17 Share premium

(In thousand Euro)	As of	
	June 30, 2016	December 31, 2015
	unaudited	audited
At the beginning of the year	61,580	40,903
Loss allocation	(27,320)	(7,900)
Issue of shares	2,999	28,149
Issue of shares (exercise of options)	142	710
Reclassification from share option reserve	102	419
Share capital issue costs	(184)	(701)
At the end of the period	**37,319**	**61,580**

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.

18 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 among which ESOP 2011, ESOP 2013; ESOP 2014 and ESOP 2015 are still valid. All options have been awarded free of charge.

During the six-month period ended at June 30, 2016 (see note 23 Events after balance sheet date for additional info) the Board did not grant options.

The Group's Board of Directors can grant further options under ESOP 2015.

A summary of the granted options is as follows:

	Employee Share Option Plans				
	2011	**2013**	**2014**	**2015**	**Total**
At January 1, 2015	107,264	481,996	187,775	0	777,035
Granted	0	0	0	277,464	277,464
Exercised	(51,813)	(72,384)	0	0	(124,197)
At December 31, 2015	55,451	409,612	187,775	277,464	930,302
Exercised	0	(17,875)	(2,227)	0	(20,102)
At June 30, 2016	**55,451**	**391,737**	**185,548**	**277,464**	**910,200**

All options have been awarded free of charge and are recognised as personnel expenses over the vesting period. The increase of share option reserve is equal to Euro 1,004 and it's related to the following opposite effects: a) additional costs of the period equal to Euro 1,106 (out of which Euro 703 refers to G&A employees and the remaining to R&D ones) and b) a reclassification to Share Premium Reserve as a consequence of the options' exercise equal to Euro 102.

As of June 30, 2016, 380,091 options were vested; additional 38,247 options will vest in July 2016.

19 Borrowings

In 2008, Newron was awarded with 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 363 whereas long-term borrowings are equal to Euro 182.

20 Financial instruments by category

The following tables present the breakdown of financial assets and liabilities evaluated at fair value, by category as of June 30, 2016 and December 31, 2015 respectively.

As of June 30, 2016	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
Assets						
Non Current receivables	65	–	–	–	–	–
Available for sale financial assets – non current	–	–	–	–	–	–
Available for sale financial assets – current	–	–	–	4,422	–	–
Cash and cash equivalents	30,457	–	–	–	–	–
Trade and other receivables	3,103	–	–	–	–	–
Total	**33,625**	**–**	**–**	**4,422**	**–**	**–**
Liabilities						
Trade and other payables	–	–	–	–	–	5,320
Short-term borrowings	–	–	–	–	–	363
Long-term borrowings	–	–	–	–	–	182
Total	**–**	**–**	**–**	**–**	**–**	**5,865**

The Company has classified its interest bearing Borrowings in Level 2 (For additional information, please refer to Note 19)

As of December 31, 2015	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
Assets						
Non Current receivables	62	–	–	–	–	–
Available for sale financial assets – non current	–	–	–	–	–	–
Available for sale financial assets – current	–	–	–	4,920	–	–
Cash and cash equivalents	36,011	–	–	–	–	–
Trade and other receivables	2,560	–	–	–	–	–
Total	**38,633**	**–**	**–**	**4,920**	**–**	**–**
Liabilities						
Trade and other payables	–	–	–	–	–	5,869
Short-term borrowings	–	–	–	–	–	362
Long-term borrowings	–	–	–	–	–	364
Total	**–**	**–**	**–**	**–**	**–**	**6,595**

There were no transfers between Level 1 and Level 2 during the six-month period ending on June 30 2016 and the whole year 2015.

21 Related party transactions

The following tables provide the total amount of transactions that have been entered into with related parties during the six-month period ending June 30, 2016 and June 30, 2015, as well as balances with related parties outstanding as of June 30, 2016 and June 30, 2015:

As of June 30, 2016	Sales to / Cost reimbursed by related parties	Royalties	Purchases from related parties	Amounts owed by related parties, net
Zambon (whole group)	4,388	852	82	316
As of June 30, 2015				
Zambon (whole group)	3,542	93	60	1,680

As detailed above, sales to Zambon are mainly related to: a) the non-refundable milestone payments cashed-in from Zambon upon approval – obtained from certain European countries – of the official reimbursed price of Xadago® (safinamide) and identification of the US partner and b) 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 the U.S. Royalties have started in May 2015 after the launch of Xadago in Germany and, since then, in other eight EU countries and Switzerland. Purchases from Zambon are related to the leasing of the premises located in Bresso and additional archiving space.

22 Commitments and contingent liabilities

Other commitments

The Company has entered into contracts for clinical development with external subcontractors. The Company compensates its suppliers for the services provided on a regular basis. The expenditure contracted for at the balance sheet date but not yet incurred is equal to about 11 million Euro. The Company shall not incur material penalty fees for the closure of any of its contracts. As disclosed in Note 8 the Company has decided to terminate the agreement with Merck KGaA in June 2016 under which a penalty fee amounting to Euro 650 was paid and recognized to profit & loss of the period among R&D costs (Material and consumable used)

Contingent liabilities

According to the agreements signed with Merck group, the achievement of future results related to the development of certain Newron' compounds will trigger the payment of milestones fees and other payments. As uncertainty remains upon the future results of the development of the compounds, the Directors concluded that the payment of the above milestone fees is not probable.

23 Events after the balance sheet date

On July 6 and September 1, Newron announced that its partner Zambon has launched Xadago® (safinamide respectively) in the Netherlands and Norway as an add-on to levodopa alone or in combination with other Parkinson's disease medications, in mid- to late-stage. With the addition of the Netherlands and Norway, Xadago® is now available in eleven countries: Germany, Switzerland, Spain, Italy, Belgium, Denmark, Sweden, the U.K. and Luxembourg.

As a consequence of the Complete Response Letter received from the U.S. Food and Drug Administration (FDA) on March 29, 2016, the company has met FDA and on July 26, 2016 has announced that FDA no longer requires Newron to perform any studies to clinically evaluate the potential abuse liability or dependence/withdrawal effects of Xadago®. This decision will allow Newron to re-file the New Drug Application no later than end of November 2016.

On July 27, 2016, Newron Board of Directors approved to grant additional n. 8,537 stock options from plan ESOP 2015. Options have been granted at Euro 15.22 (CHF 16.49 at the exchange rate on July 26) and will expire in March 2025.

Bresso, September 9, 2016

Stefan Weber
CEO

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, 2016	14,448,638
52-week high (in CHF)	31.35
52-week low (in CHF)	13.85
June 30, 2016 closing share price	15.20
Loss per share (in EUR)	0.64
Cash and cash equivalents, other short-term financial assets as at June 30, 2016 (in EUR 1,000)	34,879
Market capitalization as at June 30, 2016 (in CHF)	219,619,298

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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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