



Half-Year Report 2018

Corporate profile

Newron is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system. The Company is listed on the Swiss Stock Exchange SIX (ticker symbol: NWRN). Newron is headquartered in Bresso near Milan, Italy, with a subsidiary in Morristown, NJ, USA.

Xadago/safinamide has received marketing authorization for the treatment of Parkinson's disease in the European Union, Switzerland and the USA, and is commercialized by Newron's partner Zambon. US WorldMeds holds the commercialization rights in the USA. Meiji Seika has the rights to develop and commercialize safinamide in Japan and other key Asian territories.

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 Evenamide as the potential first add-on therapy for the treatment of patients with positive symptoms of schizophrenia.

More information about the Company is available on www.newron.com

Half-Year 2018 Highlights

Sarizotan

- Update provided on STARS (Sarizotan Treatment of Apneas in Rett Syndrome) Phase III study for the treatment of Rett syndrome – progress has been made with patient enrolment, completion expected in H2 2018 and study results by the end of H1 2019
 - As per August 27, 117 patients qualified for inclusion into study, 109 of 129 randomized to treatment
- Newron continues to support annual Global Rare Disease Day®
- Newron maintained its commitment to work on the first Burden of Disease (BOD) study with the global Rett syndrome community
 - Implementation aligned with STARS study

Evenamide

- Newron completed discussions with regulatory authorities in Europe, the USA and Canada to design two potentially pivotal efficacy studies – one in patients with schizophrenia experiencing worsening of psychosis on atypical antipsychotics, another in treatment-resistant schizophrenia patients not responding to the antipsychotic drug clozapine (20-35k patients in the US)
 - Studies expected to initiate in H1 2019
 - Further details to be disclosed during R&D day on October 31

Xadago/safinamide

- Primary endpoint met in Phase II/III clinical study of safinamide as add-on therapy to levodopa in patients with Parkinson's disease, conducted by Newron's partner Meiji Seika Pharma together with Eisai Co. in Japan
- Meiji Seika Pharma plans to file for market approval of safinamide with the Japanese Pharmaceutical and Medical Device Agency in H2 2018
- Dossiers for marketing authorization currently under review in Australia, Brazil, Canada, Colombia and Israel
- US WorldMeds in discussions with Medicare in the US
- Zambon leading discussions on additional distribution agreements in Europe and Middle East
- Zambon in advanced discussions with US FDA on the design of a potentially pivotal efficacy study to evaluate the effects of Xadago in patients with levodopa induced dyskinesia (PD LID)

Corporate

- Coverage of Newron stock initiated by Kempen
- Cash (incl. Other current financial assets) as at June 30, 2018: EUR 50.6 million
- Evaluation of non-dilutive funding opportunities ongoing
- Approval by shareholders of all resolutions at 2018 Annual General Meeting, including granting the Board of Directors
 - the ability to issue shares and/or convertible bonds, up to EUR 1,426,987.60
 - powers to create American Depositary Shares and to list them on the Nasdaq or on any other market in the United States of America

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Shareholder Letter



Dr. Ulrich Köstlin



Stefan Weber

Dear Shareholder,

We are pleased to report that the past six months have been a period of continued positive development for Newron, as we advanced our development products, sarizotan and Evenamide, and our marketed drug, Xadago/safinamide. Most notably, during the period we made significant strides in the enrolment of our STARS (Sarizotan Treatment of Apneas in Rett Syndrome) pivotal study in patients with Rett syndrome, 117 patients qualified for enrolment and 109 were randomized to treatment by the end of August, and completion of the enrolment of 129 patients is expected during the remaining months of 2018. We also made material progress towards initiating a Phase III development program with Evenamide, by completing discussions with the regulatory authorities in the EU, the US and Canada; details will be announced during an R&D day in New York City on October 31, 2018. In Japan, safinamide, under development and commercialisation by our partner Meiji Seika, together with Eisai, met its primary endpoint in a Phase II/III study as an add-on to levodopa in patients suffering from Parkinson's disease. Our partner is moving towards filing for approval with the Japanese Pharmaceutical and Medical Device Agency. This adds to the regulatory filings already submitted by our partners in Canada, Australia, Latin America and Israel. Our partner Zambon is in advanced discussions with the US FDA on the design of a potentially pivotal efficacy study to evaluate the effects of Xadago in patients with levodopa induced dyskinesia (PD LID).

Sarizotan: Targeting respiratory disturbances in Rett syndrome patients

We provided an update on our STARS study in June, announcing that over 100 patients, aged six and above, had qualified for inclusion into the study. By the end of August, that number had increased to 117, of which 109 patients had been randomized to treatment. Therefore, we are on track to reach our target of enrolling 129 patients during the remaining months of 2018 and expect to report results from the study by the end of H1 2019. The study is enrolling patients with Rett syndrome who present with clinically significant day time apneas during the course of the disease: these abnormalities are present in approximately 70% of Rett patients. Sarizotan has been well tolerated in Rett patients with a very low rate of discontinuation due to adverse events; very few patients have discontinued for lack of efficacy. To date, nearly 90% of patients who have completed the 24-week double-blind period have continued to receive treatment in the long-term open-label extension. We believe that the study results

will lead to the approval of the first drug to benefit key symptoms of Rett syndrome. Newron intends to commercialize sarizotan itself in key markets.

We have continued our engagement with the global Rett syndrome community this year working on the first Burden of Disease (BOD) study. Through this real-life study, we aim to collect key data to help quantify the physical, emotional, and financial challenges attributed to Rett syndrome. These data will help to identify and guide intervention programs and services designed for Rett patients. Performance of this study and presentation of its results are aligned with the STARS efficacy study.

We reiterated our support of the annual Global Rare Disease Day® in February 2018, to help raise awareness of rare diseases, and in turn improve access to treatments.

Evenamide: Novel mode of action, developed as add-on therapy to current antipsychotics for schizophrenia patients

We have made considerable progress towards initiating a Phase III development program with Evenamide by completing discussions with the regulatory authorities in the EU, the US and Canada. We plan to initiate two potentially pivotal efficacy studies in patients with schizophrenia; one in patients experiencing worsening of psychosis on atypical antipsychotics, and one in treatment-resistant schizophrenia patients not responding to the antipsychotic drug clozapine. The latter indication is affecting no more than 20,000 to 35,000 patients in the US, who can be serviced by a small commercial organization. Newron intends to commercialize Evenamide in this orphan-like indication itself. We expect to initiate the program in the first half of 2019 and will provide further details during the upcoming R&D day on October 31 in New York City.

Newron's current Pipeline

Product		Phase I	Phase II	Phase III	Market	Commercial Rights
Xadago/ safinamide ¹	EU Adjunctive therapy in PD	▶				Zambon
	US Adjunctive therapy in PD	▶				Zambon / US World Meds
	JPN Adjunctive therapy in PD	▶				Meiji Seika / Eisai
	EU / US Levodopa Induced Dyskinesia (PD LID)	▶				Zambon
Sarizotan ²	Rett syndrome (Orphan drug status)	▶				Newron
Evenamide ¹	Adjunctive therapy in Schizophrenia	▶				Newron
	Adjunctive therapy in Clozapine-TRS	▶				
Ralfinamide ¹	Orphan indication in neuropathic pain	▶				Newron

¹ Safinamide, Evenamide and ralfinamide all developed from Newron's ion channel based research

² Sarizotan was licensed from Merck KGaA

Xadago/safinamide: First new chemical entity approved in US and Europe in a decade for Parkinson's disease

Newron's royalty income from sales revenues of Xadago has increased by 54% over the prior year, which is mostly due to substantially increased sales of Xadago in the European Union and Switzerland. Royalty income from US sales of the compound remains small, even though growth rates have substantially increased, lately. We understand that US WorldMeds is currently in negotiations with Medicare in the US and would expect that increased sales revenues in the US will reflect an agreement, from 2019 onwards.

We are pleased to hear from our partners that dossiers for marketing authorization are currently under review in Australia, Brazil, Canada, Colombia and Israel, potentially leading to additional launches in the coming quarters. Also, we understand our partner Zambon is entertaining discussions supporting the distribution of Xadago in additional territories in Europe and the Middle East. We were pleased that Meiji Seika and Eisai announced that the primary endpoint was met in a Phase II/III study with safinamide as add-on to levodopa in Japan. Meiji Seika now plans to continue the clinical trials it is conducting and submit a file for marketing approval with the Japanese Pharmaceutical and Medical Device Agency in H2 2018. We are excited by the prospect of Xadago/safinamide being made available to patients in these territories in the future.

Zambon remains on track to initiate a potentially pivotal efficacy study to evaluate the effects of Xadago in patients with levodopa induced dyskinesia (PD LID). They are in advanced discussions with the US FDA on the design of the study.

For the first six months of 2018, Newron reported a net loss of EUR 7.6 million, compared to a profit of EUR 1.6 million, in the same period in 2017 (prior year revenues included a one-time milestone payment of EUR 10.4 million). Cash used in operating activities has increased to EUR 9.4 from EUR 1.5 million in 2017. Xadago[®] royalty payments received from Zambon increased by 54% (EUR 2.0 million versus EUR 1.3 million in 2017). At the same time, Newron's R&D expenses have increased moderately to EUR 5.0 from EUR 4.6 million in 2017, largely due to the ongoing STARS study in Rett syndrome. We have again profited from Italian R&D tax credits of EUR 2.6 million that can be offset with future tax and social contribution payments by Newron, versus EUR 2.1 million in 2017. G&A expenses reached EUR 4.4 million in the first six months of 2018, unchanged from 2017 and 2016. Cash and Other current financial assets at June 30, 2018 were at EUR 50.6 million, compared to EUR 60.1 million at the beginning of the year.

We have been pleased by the initiation of analyst coverage of the Newron stock by Kempen at the beginning of 2018 and look forward to potential further coverage, as our pipeline matures.

Our shareholders approved all resolutions at the 2018 Annual General Meeting with overwhelming majority or unanimously, including granting the Board of Directors the powers to issue shares and/or convertible bonds, up to Euro 1,426,987.60 nominal value, to create American Depositary Shares and to list them on the Nasdaq or on any other market in the

United States of America. We reiterate our thanks to them, for their continued support and commitment.

2018, so far, has been another productive year for Newron. We are delighted with our progress towards the ongoing study in sarizotan and upcoming Evenamide trials and encouraged by our partners' progress globally with Xadago/safinamide. We look forward to updating you on the progress of our innovative pipeline and commercial activities throughout the rest of the year and use this opportunity to invite you to mark your calendar for our October 31, 2018, R&D day.

Yours sincerely,



Dr. Ulrich Köstlin
Chairman



Stefan Weber
Chief Executive Officer

Interim Condensed Consolidated Financial Statements

For the six months ended June 30, 2018

Auditor Report

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 interim condensed consolidated financial statements, comprising the interim condensed consolidated statement of financial position, the interim condensed consolidated statements of profit or loss, the interim condensed consolidated statement of comprehensive income, the interim condensed consolidated statement of changes in equity, the interim condensed statement of cash flows and the related explanatory notes of Newron Pharmaceuticals S.p.A. and its subsidiaries (the "Newron Group") as of June 30, 2018. The Board of Directors of Newron Pharmaceuticals S.p.A. is 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) as adopted by the European Union. Our responsibility is to express a conclusion on these interim condensed consolidated financial statements based on our review.

Scope of Review

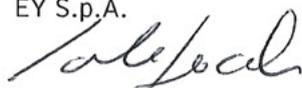
We conducted our review in accordance with International Standard on Review Engagement 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim condensed consolidated financial statements consists of making inquiries, primarily of persons 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 (ISA Italia) 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, 2018 are not prepared, in all material respects, in conformity with the International Financial Reporting Standard applicable to interim financial reporting (IAS 34) as adopted by the European Union.

Milan, September 10, 2018

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	
		2018 (unaudited)	2017 (unaudited)
Licence income from contracts with customers	6	0	10,374
Royalties from contracts with customers	7	2,008	1,308
Other income from contracts with customers		0	5
Revenue		2,008	11,687
Research and development expenses	8	(5,029)	(4,608)
Marketing and advertising expenses		(171)	(297)
General and administrative expenses	9	(4,407)	(4,448)
Operating result		(7,599)	2,334
Financial income	10	269	200
Financial expenses	10	(225)	(950)
Result before tax		(7,555)	1,584
Income tax		(26)	(26)
Net (loss)/income		(7,581)	1,558
Earning per share			
Basic profit/(loss) per share for the period	11	(0.42)	0.10
Diluted profit per share for the period	11	N/A	0.09
Weighted average number of shares (thousands) – Basic		17,843	15,777
Weighted average number of shares (thousands) – Diluted		N/A	16,687

Interim Condensed Consolidated Statement of Comprehensive Income

(In thousand Euro)	Note	For the six months ended June 30	
		2018 (unaudited)	2017 (unaudited)
Net income/(loss) for the period		(7,581)	1,558
Other comprehensive income/(loss) to be reclassified to profit or loss in subsequent periods:			
Net income on available-for-sale assets	13/14	0	8
Exchange differences on translation of foreign operations		(68)	(103)
Net other comprehensive loss to be reclassified to profit or loss in subsequent periods		(68)	(95)
Other comprehensive income not to be reclassified to profit or loss in subsequent periods:			
Remeasurements on defined benefit plans		6	4
Net other comprehensive income not to be reclassified to profit or loss in subsequent periods		6	4
Other comprehensive loss for the period, net of tax		(62)	(91)
Total comprehensive income/(loss) for the period, net of tax		(7,643)	1,467

(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, 2018 (unaudited)	December 31, 2017 (audited)
Assets			
Non-current assets			
Property, plant and equipment		107	107
Intangible assets		34	35
Non-current receivables		83	82
		224	224
Current assets			
Inventories		5	5
Receivables and prepayments	12	14,211	12,714
Other current financial assets	13	19,368	19,439
Cash and cash equivalents	14	31,268	40,642
		64,852	72,800
Total assets		65,076	73,024
Shareholders' equity			
Share capital	15	3,569	3,567
Share premium and other reserves	16	61,330	66,539
Share option reserve	17	9,785	8,948
Retained earnings		(12,757)	(10,464)
Translation differences		(937)	(869)
Total shareholders' equity		60,990	67,721
Liabilities			
Non-current liabilities			
Employee severance indemnity		601	576
		601	576
Current liabilities			
Trade and other payables	18	3,485	4,727
		3,485	4,727
Total liabilities		4,086	5,303
Shareholders' equity and liabilities		65,076	73,024

(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, 2017		3,155	59,518	7,556	(700)	(19,782)	49,747
Net income						1,558	1,558
Other comprehensive income/(loss)					(103)	12	(91)
Total comprehensive income/(loss) for the period		0	0	0	(103)	1,570	1,467
Previous year loss allocation			(15,356)			15,356	0
Advance payment for future capital increase						19	19
Exercise of options and reclassification of reserves	15/16	8	586	(302)			292
Share option scheme	17			995			995
Balance at June 30, 2017		3,163	44,748	8,249	(803)	(2,837)	52,520
Balance at January 1, 2018		3,567	66,539	8,948	(869)	(10,464)	67,721
Net loss						(7,581)	(7,581)
Other comprehensive income/(loss)					(68)	6	(62)
Total comprehensive loss for the period		0	0	0	(68)	(7,575)	(7,643)
Previous year loss allocation			(5,282)			5,282	0
Exercise of options and reclassification of reserves	15/16	2	73	(32)			43
Share option scheme	17			869			869
Balance at June 30, 2018		3,569	61,330	9,785	(937)	(12,757)	60,990

(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	2018 (unaudited)	2017 (unaudited)
Profit/(Loss) before tax		(7,555)	1,584
Adjustments for:			
Depreciation and amortisation		23	23
Grants and other non monetary income		(2,093)	(1,147)
Share option expenses	17	869	995
Employee severance indemnity expense		99	25
Changes in working capital:			
Current receivables and prepayments and deferred cost (excluding grants receivable)		1,124	(496)
Trade and other payables and deferred income (excluding advances of grants)		(1,897)	(2,457)
Change in non-current receivables		(1)	(14)
Cash used in operating activities		(9,431)	(1,487)
Cash flows from investing activities			
Purchase of financial assets		0	(1'117)
Purchase of property, plant and equipment		(16)	(25)
Purchase of intangible assets		(5)	(45)
Reclassification to Other current financial assets	13	0	(15,644)
Interest received		34	28
Net cash flows from/(used in) investing activities		13	(16,803)
Cash flows from financing activities			
Repayment of borrowings		0	(182)
Proceeds from issue of shares	15/16	44	292
Advance payment for future capital increase		0	19
Net cash flows from financing activities		44	129
Net increase in cash and cash equivalents		(9,374)	(18,161)
Cash and cash equivalents at January 1,		40,642	42,948
Cash and cash equivalents at the end of the period		31,268	24,787

(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) currently inactive;
- Hunter-Fleming Limited, a fully owned biopharmaceutical company based in Brixham (United Kingdom) and focused on neurodegenerative and inflammatory disorders currently inactive;
- Newron Suisse SA, a fully owned clinical development subsidiary based in Zurich (Switzerland) currently inactive.

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 segment of the SIX Swiss Exchange, Zurich, Switzerland, under the trade name NWRN.

The Group is principally engaged in discover, develop and commercialise novel drugs to treat diseases of the Central Nervous System (CNS) and pain.

The interim condensed consolidated financial statements of Newron Group for the six months ended June 30, 2018, were authorised for issuance by the Board of Directors (“the Board”) on September 7, 2018.

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, 2018 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, 2017.

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 twelve 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, 2017, except for the adoption of new standards and interpretations effective as of January 1, 2018. The Group has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.

The Group applies, for the first time, IFRS 15 Revenue from Contracts with Customers and IFRS 9 Financial Instruments that require restatement of previous financial statements. As required by IAS 34, the nature and effect of these changes are disclosed below. Several other amendments and interpretations apply for the first time in 2018, but do not have an impact on the interim condensed consolidated financial statements of the Group.

IFRS 15 Revenue from Contracts with Customers

IFRS 15 supersedes IAS 11 Construction Contracts, IAS 18 Revenue and related Interpretations and it applies to all revenue arising from contracts with customers, unless those contracts are in the scope of other standards. The new standard establishes a five-step model to account for revenue arising from contracts with customers. Under IFRS 15, revenue is recognised at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer.

The standard requires entities to exercise judgement, taking into consideration all of the relevant facts and circumstances when applying each step of the model to contracts with their customers. The standard also specifies the accounting for the incremental costs of obtaining a contract and the costs directly related to fulfilling a contract.

The application of the new standard did not have significant impacts on both the financial statements and the relevant disclosure of the Group.

IFRS 9 Financial Instruments

IFRS 9 Financial Instruments replaces IAS 39 Financial Instruments: Recognition and Measurement for annual periods beginning on or after 1 January 2018, bringing together all three aspects of the accounting for financial instruments: classification and measurement; impairment and hedge accounting.

The Company for the new standard applied the retrospective approach: its application did not have significant impacts on both the financial statements and the relevant disclosure of the Group aside from the reclassification of Investment funds and Government bonds to the “Other current financial assets” (Please refer to note 13 and 14).

IFRS 16 Leases

IFRS 16 was issued in January 2016 and it replaces IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases-Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model like the accounting for finance leases under IAS 17.

Lessor accounting under IFRS 16 is substantially unchanged from today’s accounting under IAS 17. Lessors will continue to classify all leases using the same classification principle as in IAS 17 and distinguish between two types of leases: operating and finance leases. IFRS 16 also requires lessees and lessors to make more extensive disclosures than under IAS 17.

IFRS 16 is effective for annual periods beginning on or after January 1, 2019. Early application is permitted, but not before an entity applies IFRS 15. A lessee can choose to apply the standard using either a full retrospective or a modified retrospective approach. The standard’s transition provisions permit certain reliefs.

The Group is evaluating the implementation and effect of adopting the new standard, currently not expected to have material impacts.

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

IFRIC Interpretation 22 Foreign Currency Transactions and Advance Considerations

The Interpretation clarifies that, in determining the spot exchange rate to use on initial recognition of the related asset, expense or income (or part of it) on the derecognition of a non-monetary asset or non-monetary liability relating to advance consideration, the date of the transaction is the date on which an entity initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, then the entity must determine a date of the transactions for each payment or receipt of advance consideration.

Amendments to IAS 40 Transfers of Investment Property

The amendments clarify when an entity should transfer property, including property under construction or development into, or out of investment property. The amendments state that a change in use occurs when the property meets, or ceases to meet, the definition of investment property and there is evidence of the change in use. A mere change in management's intentions for the use of a property does not provide evidence of a change in use.

Amendments to IFRS 2 Classification and Measurement of Share-based Payment Transactions

The IASB issued amendments to IFRS 2 Share-based Payment that address three main areas: the effects of vesting conditions on the measurement of a cash-settled share-based payment transaction; the classification of a share-based payment transaction with net settlement features for withholding tax obligations; and accounting where a modification to the terms and conditions of a share-based payment transaction changes its classification from cash settled to equity settled. On adoption, entities are required to apply the amendments without restating prior periods, but retrospective application is permitted if elected for all three amendments and other criteria are met. The Group has neither cash-settled share-based payments nor share-based payment transaction with net settlement features for withholding tax obligations and had not made any modifications to the terms and conditions of its share-based payment transaction.

Amendments to IFRS 4 Applying IFRS 9 Financial Instruments with IFRS 4 Insurance Contracts

The amendments address concerns arising from implementing the new financial instruments standard, IFRS 9, before implementing IFRS 17 Insurance Contracts, which replaces IFRS 4. The amendments introduce two options for entities issuing insurance contracts: a temporary exemption from applying IFRS 9 and an overlay approach.

Amendments to IAS 28 Investments in Associates and Joint Ventures – Clarification that measuring investees at fair value through profit or loss is an investment-by-investment choice

The amendments clarify that an entity that is a venture capital organisation, or other qualifying entity, may elect, at initial recognition on an investment-by-investment basis, to measure its investments in associates and joint ventures at fair value through profit or loss. If an entity, that is not itself an investment entity, has an interest in an associate or joint venture that is an investment entity, the entity may, when applying the equity method, elect to retain the fair value measurement applied by that investment entity associate or joint venture to the investment entity associate's or joint venture's interests in subsidiaries. This election is made separately.

3 Segment reporting

The Company operates in a single business segment, which is research and development of pharmaceutical drugs. Geographically the research and development activities are performed in Italy and in USA. 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

Functional 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 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 exchange rates

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)	
	2018	2017	June 30, 2018	Year-end 2017
CHF 1	0.85492	0.92882	0.86438	0.85455
GBP 1	1.13662	1.16199	1.12860	1.12714
SEK 1	0.09851	0.10420	0.09567	0.10159
USD 1	0.82617	0.92334	0.85778	0.83382

6 Licence income from contracts with customers

Licence income from contracts with customers amounted to nil as of June 30, 2018 (2017: EUR 10,374). Licence income in 2017 was related to the non-refundable milestone payments cashed-in from Zambon S.p.A. upon the approval – obtained from Food and Drug Administration (FDA) – of the use of Xadago® (safinamide) for the treatment of Parkinson's disease as add-on therapy to levodopa/carbidopa and the identification of the Australian (Seqirus) and Canadian (Valeo Pharma) commercial partners. Licence income in 2017 were shown net of the amount transferred to Merck KGaA.

7 Royalties from contracts with customers

(In thousand Euro)	For the six months ended June 30,	
	2018	2017
Royalties	2,008	1,308

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 several European countries among which Germany, Italy, Spain and United Kingdom and, after the Swissmedic approval, Switzerland. Moreover, on July 11, 2017, after the FDA approval, US WorldMeds, Zambon commercial partner, has launched Xadago® also in the U.S. market. Royalties payable to Newron according to the agreement in place with Zambon, have been communicated to Newron by its partner.

In the first six months of 2018, royalties from contracts with customers increased by 54% in comparison with the corresponding period of the previous year mainly because of: i) the growing sales in European countries; ii) the increased number of markets in which Xadago® is commercialised and iii) the positive effect related to the launch of Xadago® in the US market.

On February 2016, Italian Medicines Agency (AIFA) approved Xadago® selling price and imposed a ceiling on sales. As a matter of attention, it should be noted that AIFA has set a ceiling covering the period – March 1, 2018 to February 28, 2019. Royalties of the period have been accounted for taking into consideration the ceiling.

8 Research and development expenses net of grants and other reimbursements

(In thousand Euro)	For the six months ended June 30,	
	2018	2017
Services received from subcontractors	1,943	1,077
Staff costs	1,414	1,497
Consultancy fees	453	547
Material and consumable used	771	876
Operating lease cost	35	208
Travel expenses	216	356
Other research and development costs	197	47
	5,029	4,608

The increase in Services received from subcontractors is in line with the activities developed by the Group in the first half of the year: the phase III double blind, placebo-controlled study the Company performed to evaluate the efficacy of Sarizotan in Rett Syndrome patients is almost at the end of the enrolment phase and, consequently, also the expenses increased.

Staff costs amount to EUR 1,414 (2017: 1,497). The variance compared to prior period is related to the reduction of option costs and the decrease of accrued social contribution costs on vested options (as required by local companies, law in certain countries).

Decrease in Consultancy fees and Material and consumable used is mainly due to the reduced activities performed by consultants in preparing documentation to be filled with the regulatory authorities (mainly for Evenamide) and product manufacturing related to the Sarizotan clinical trial.

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 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. Accordingly, research and development expenses are presented net of reimbursements amounting to EUR 8 (2017: 223).

As stated by art. 1, paragraph 35 of the Italian Law 190/2014 – the so called “2015 Stability Law” – and clarified, by the Italian Tax Authority in the Official Memorandum 5/E dated 23 March 2016, companies investing in research and development activities are allowed to recognize an R&D tax credit in the period 2015–2020 that can be used to offset certain taxes and contributions. According to the application guidelines issued by the Tax Authority, R&D tax credit for a specified year is recognized to the extent of a defined percentage (50%) of the difference between certain R&D expenses incurred in the year and the average of the same expenses incurred in the three-year period 2012–2014. As clarified by Tax Authority in the Official Memorandum 19/E dated February 14, 2017, the R&D tax credit will last until 2020 and the yearly ceiling has been set at EUR 20 million per year.

Expenses incurred by the Company in the first half of 2018, granted an estimated total R&D tax credit of EUR 2,635 (2017: 2,081). Therefore, Staff Costs, Services received from sub-contractors, Consultancy fees and Material and consumable used have been reduced respectively by EUR 365 (2017: 395), EUR 1,414 (2017: 739), EUR 272 (2017: 356) and EUR 585 (2017: 591). The overall effect is detailed in the following table.

The table below summarizes the impact of abovementioned reductions and reimbursements on gross R&D expenses:

(In thousand Euro)	For the six months ended June 30,	
	2018	2017
Research and development expenses, gross	7,672	6,912
R&D Tax Credit	(2,635)	(2,081)
Reimbursed by Zambon	(8)	(223)
	5,029	4,608

Since inception, no development costs have been capitalised except for 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,	
	2018	2017
Staff costs	2,004	2,015
Consultancy and other professional services	1,416	1,502
Intellectual properties	476	351
Travel expenses	155	165
Operating lease cost	198	207
Depreciation and amortisation expense	23	23
Other expenses	135	185
	4,407	4,448

Staff costs for the six-months ended June 30, 2018 are in line with 2017, as a consequence of the increase in headcounts, compensated by the decrease in stock options' cost related to social contributions expenses, as also explained in the previous note.

In the six-months period ending June 30, 2017, the Company asked for the collaboration of external providers in order to identify in/out licencing opportunities: those expenses have not been incurred also in 2018 thus, expenses related to Consultancy and other professional services decreased.

The increase in Intellectual properties expenses is related to the fees incurred by the Company during the European validation's process of two Newron, patents (each patent granted by the European authority must be validated in all EU countries).

10 Financial result, net

(In thousand Euro)	For the six months ended June 30,	
	2018	2017
Interest income	51	35
Foreign exchange gains	218	149
Other income	0	16
	269	200

The Company's costs structure is exposed to exchange rate fluctuations, mainly with the US Dollars: for this reason, starting from December 2016, the Board and management have decided to cover a nine to twelve month rolling period of US Dollar expenses. At the end of the six-months period, exchange gains are mainly related to a positive fluctuation of the US Dollar, partially recovering 2017 losses as per table below.

(In thousand Euro)	For the six months ended June 30,	
	2018	2017
Interest expenses	(17)	(7)
Foreign exchange losses	(83)	(906)
Other costs	(125)	(37)
	(225)	(950)

11 Earnings per share

The basic earnings 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,	
	2018	2017
Net profit/(loss) attributable to shareholders	(7,581)	1,558
Weighted average number of shares (thousands) – Basic	17,843	15,777
Profit/(loss) per share – basic (in Euro)	(0.42)	0.10
Weighted average number of shares (thousands) – Diluted	N/A	16,687
Profit per share – diluted (in Euro)	N/A	0.09

The only category of potential ordinary shares that have dilutive effect are the stock options; at the end of the six-months period, Newron has granted a total of n. 1,218,291 (see also Note 17) to certain employees, directors and consultants. As of June 30, 2018, these are antidilutive, as their conversion would decrease the loss per share. Thus, the values of basic and diluted loss per share as of June 30, 2018, coincided. Finally, on July 5, 2018, the Board of Directors granted a total of n. 344,812 options to all Newron, employees and directors plus certain consultant at a strike price of 11.63 CHF (EUR 10.06 as translated at the exchange rate on July 4, 2018). Please refer to Note 22 “Events after the balance sheet date” for further details.

12 Receivables and prepayments

(In thousand Euro)	As of	
	June 30, 2018	December 31, 2017
	unaudited	audited
Receivables	2,159	1,066
Government grants receivable	0	14
Prepayments	694	1,476
VAT receivable	183	499
R&D tax credit	11,087	9,570
Other receivables	88	89
	14,211	12,714

Receivables are almost entirely represented by the invoices and accruals related to the royalties on net sales performed by Zambon Group in Europe, Switzerland and United States of America. After closing date, the receivable was partially cashed in for approximately EUR 1 million.

At the end of the six months period, R&D tax credit that, was equal to EUR 11,087 (December 31, 2017: 9,570). The net increase by EUR 1,517 is due to the combined effect of the estimated six-months period accruals equal to EUR 2,635 and its use to offset certain taxes and contributions during the six-month period ended June 30, 2018, for a total of EUR 1,118. For additional information, please refer to note 8. According to the expected development plan detailed in the Group business plan, the amount of R&D tax credit recognized as of June 30, 2018, will be recovered through the offset of the expenses of the upcoming years.

13 Other current financial assets

(In thousand Euro)	As of	
	June 30, 2018	December 31, 2017
	unaudited	audited
Government bonds	503	603
Listed bonds	3,870	3,795
Investment funds	14,995	15,041
	19,368	19,439

Gain and losses arising from the adjustment to the fair value of bonds and funds were recognized respectively in the comprehensive income and in the income statement. All acquired securities are in line with the Group's investment policy.

14 Cash and cash equivalents

(In thousand Euro)	As of	
	June 30, 2018	December 31, 2017
	unaudited	audited
Cash at bank and in hand	31,268	40,642
	31,268	40,642

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

Group's liquidity (Other current financial assets plus Cash and cash equivalent) amounts approximately to EUR 51 million (EUR 60 million as at December 31, 2017). Expenses of the period have been partially financed by royalties and by existing cash.

15 Share capital

As of December 31, 2017, the subscribed share capital was equal to EUR 3,567,469.00, divided into 17,837,345 ordinary shares with par value equal to EUR 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, 2016 – Newron Group	3,154,633.60
– issue of ordinary share (Stock options exercise)	12,835.40
– issue of ordinary share (Capital Increase)	400,000.00
As of December 31, 2017 – Newron Group	3,567,469.00
– issue of ordinary share (Stock options exercise)	1,400.00
As of June 30, 2018 – Newron Group	3,568,869.00

On March 22, 2016, the extraordinary shareholders' meeting resolved, among other items, to increase the Company's share capital of an amount of up to EUR 711,177.20, corresponding to up to 3,555,886 newly issued Newron, ordinary shares with a par value of EUR 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 and to grant to the Board of Directors of the powers to issue either shares or convertible bonds. On September 26, 2017, the Company announced the completion of a private placement of new 2,000,000 shares (nominal value of EUR 0.20), corresponding to an increase in share capital equal to EUR 400,000 through an accelerated book building procedure: shares have been subscribed by institutional investors.

On March 27, 2018, the extraordinary shareholders' meeting resolved, among other items, to increase the Company's share capital of an amount of up to EUR 1,426,987.60, corresponding to up to 7,134,938 newly issued Newron, ordinary shares with a par value of EUR 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 and to grant to the Board of Directors of the powers to issue either shares, convertible bonds and warrants.

During the six-month period ended June 30, 2018, certain stock option holders have exercised their right: accordingly, the Company issued a total of 7,000 new ordinary shares (par value equal to EUR 0.20 each).

As of June 30, 2018, the subscribed share capital is equal to EUR 3,568,869.00 divided into 17,844,345, ordinary shares with a par value equal to EUR 0.20 each. There is no authorised share capital.

16 Share premium

(In thousand Euro)	As of	
	June 30, 2018	December 31, 2017
	unaudited	audited
At the beginning of the year	66,539	59,518
Loss allocation	(5,282)	(15,237)
Issue of shares	0	22,960
Issue of shares (exercise of options)	41	430
Reclassification from share option reserve	32	347
Share capital issue costs	0	(1,479)
At the end of the period	61,330	66,539

As a consequence of the exercise of options, the cost accrued into the Share options reserve through-out 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 among which ESOP 2011, ESOP 2013; ESOP 2014; ESOP 2015 and ESOP 2017 are still valid. All options have been awarded free of charge.

The table below shows a summary of the granted options:

	Employee Share Option Plans					
	2011	2013	2014	2015	2017	Total
At January 1, 2017	55,451	387,737	185,548	314,456	0	943,192
Granted	0	0	0	113,999	260,732	374,731
Waived	0	0	0	(28,455)	0	(28,455)
Exercised	0	(59,563)	(4,614)	0	0	(64,177)
At December 31, 2017	55,451	328,174	180,934	400,000	260,732	1,225,291
Exercised	0	(7,000)	0	0	0	(7,000)
At June 30, 2018	55,451	321,174	180,934	400,000	260,732	1,218,291

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 EUR 837 and it's related to the following opposite effects: a) additional costs of the period equal to EUR 869 (out of which EUR 561 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 EUR 32.

As of June 30, 2018, 734,420 options were vested; additional 35,484 options will vest within year end.

On July 5, 2018, the Board of Directors granted a total of n. 344,812 options to all Newron, employees and directors plus certain consultant at a strike price of 11.63 CHF (EUR 10.06 as translated at the exchange rate on July 4, 2018). Please refer to Note 22 ("Events after the balance sheet date") for further details.

18 Trade and other payables

(In thousand Euro)	As of	
	June 30, 2018	December 31, 2017
	unaudited	audited
Trade payables	1,258	2,223
Accrued expenses	1,060	971
Pension contribution payable	277	300
Social security	271	334
Other payables	619	899
	3,485	4,727

Decrease in Trade payables is mainly related to the development activities performed by the Group: 2017 balance should be analysed in comparison with the Prepayments (please refer to note 12 for additional info).

Decrease in Other payables is almost related to the accruals of personnel-related expenses.

19 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, 2018, and December 31, 2017 respectively.

	Cash, loans and receivables	Other current financial assets	Other financial liabilities at amortized cost
As of June 30, 2018			
Assets			
Non Current receivables	83	-	-
Other current financial assets	-	19,368	-
Cash and cash equivalents	31,268	-	-
Trade and other receivables	2,853	-	-
Total	34,204	19,368	-
Liabilities			
Trade and other payables	-	-	1'877
Total	-	-	1'877
As of December 31, 2017			
Assets			
Non Current receivables	82	-	-
Other current financial assets	-	19,439	-
Cash and cash equivalents	40,642	-	-
Trade and other receivables	2,556	-	-
Total	43,280	19,439	-
Liabilities			
Trade and other payables	-	-	3,122
Total	-	-	3,122

There were no transfers between Level 1 and Level 2 during the six-month period ending on June 30, 2018 and the whole year 2017.

20 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, 2018 and June 30, 2017, as well as balances with related parties outstanding as of June 30, 2018 and June 30, 2017:

As of June 30, 2018	Sales to / Cost reim- bursed by related parties	Royalties	Purchases from related parties	Amounts owed by related parties, net
Zambon (whole group)	8	2,008	83	967
As of June 30, 2017				
Zambon (whole group)	11,750	1,484	82	1,210

As detailed above, sales to Zambon are mainly related to: a) the non-refundable milestone payments cashed-in from Zambon S.p.A. upon approval – obtained from the Food and Drug Administration – of the use of Xadago® (safinamide) for the treatment of Parkinson’s disease as add-on therapy to levodopa/carbidopa; b) the identification of the Canadian and Australian partners 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 the U.S. Royalties have started in May 2015 after the launch of Xadago in Germany and, since then, in twelve other EU countries as well as Switzerland. Purchases from Zambon are related to the leasing of the premises located in Bresso and additional archiving space.

21 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 EUR 7.5 million. The Company shall not incur material penalty fees for the closure of any of its contracts.

Contingent liabilities

According to the agreements signed with Zambon S.p.A. and 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.

22 Events after the balance sheet date

On July 5, 2018, Newron’ Board of Directors – partially executing the power granted by the Company’s shareholders’ meeting held on 27 March 2018 – resolved to increase, with exclusion of options rights pursuant to article 2443 and 2441, parts 5, 6 and/or 8 of the Italian Civil Code, Newron’ share capital up to EUR 82.051,80 corresponding to up to n. 410,259 ordinary shares to be dedicated to a new stock option plan (ESOP 2018) approved during the same meeting. ESOP 2018 characteristics are in line with the ones of the existing plans. During the meeting, the Board of Directors granted a total of n. 344,812 options to all Newron’ employees and directors plus certain consultant at a strike price of 11.63 CHF (EUR 10.06 as translated at the exchange rate on July 4, 2018). The Group’s Board of Directors can grant further options under ESOP 2018.

Bresso, September 7, 2018

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, 2018	17,844,345
52-week high (in CHF)	21.80
52-week low (in CHF)	8.07
June 30, 2018 closing share price	11.84
Loss per share (in EUR)	0.42
Cash and cash equivalents, other short-term financial assets as at June 30, 2018 (in EUR 1,000)	50,635
Market capitalization as at June 30, 2018 (in CHF)	211,277,045

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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 diseases of the central and peripheral nervous system; (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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