

# Half-Year Report 2019

### **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 SIX Swiss Stock Exchange (ticker symbol: NWRN) and can be traded on XETRA. Newron is headquartered in Bresso near Milan, Italy, with a subsidiary in Morristown, NJ, USA.

Xadago<sup>®</sup>/safinamide has received marketing authorization for the treatment of Parkinson's disease in the European Union, Switzerland, the USA, Australia, Canada, Brazil, Colombia and the UAE, 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 2019 Highlights

#### Sarizotan - Rett syndrome

- Newron successfully completed enrollment of 129 patients in the STARS (Sarizotan Treatment of Apneas in Rett Syndrome) Phase III study; results expected in Q4 2019
- Positive results could position the Company to submit a filing for marketing authorization with the US, Canadian and European regulatory agencies, and could potentially result in the first treatment to be approved for Rett syndrome
- Newron continues to advance the International Burden of Illness study; launch of US survey to families and caregivers of Rett patients and medical professionals in October 2019
- The Company has maintained its support of the rare disease community and the annual Global Rare Disease Day

#### Xadago®/safinamide – Parkinso 殬 disease

- Following marketing authoriziation, Zambon and its regional partners have launched safinamide in Australia and Canada
- Xadago® has received marketing authorization in Brazil, Colombia and the UAE (post reporting period)
- Successful negotiations with the Italian authorities have resulted in the reimbursement cap being removed, allowing for further revenue growth
- Zambon is engaged in discussions for additional Xadago<sup>®</sup> distribution agreements in Europe, Middle East, Asia, Africa and South America
- Further dossiers for marketing authorization of Xadago<sup>®</sup> are currently under review in Japan, Mexico and Israel
- Zambon has completed discussions with the US Food and Drug Administration (FDA) on the design of a potentially pivotal efficacy study to evaluate the effects of Xadago<sup>®</sup>/safinamide in patients with levodopa induced dyskinesia (PD LID); the study is expected to start in H2 2019

#### Evenamide - Schizophrenia

- Newron continues discussions with the US FDA regarding two pivotal efficacy studies with Evenamide:
  - One study in patients with schizophrenia experiencing worsening of psychosis on atypical antipsychotics
  - Another study in ultra-treatment-resistant schizophrenia (resistant to treatment with clozapine), an orphan-like indication, which affects 20,000 to 25,000 patients in the US
- Earlier this year, Newron received a communication from the US FDA indicating concerns with findings from recently completed pre-clinical studies
  - Newron has engaged with the FDA in order to address the agency's concerns, and plans to complete additional short-term explanatory studies to address the issues raised by the FDA prior to initiation of the Phase III development program. Upon completion of the interactions in the coming weeks, Newron will update shareholders and the market

#### Corporate

- Newron received the first tranche of funding from the European Investment Bank, EUR 10 million of up to EUR 40 million, which will be used to boost the Company's R&D activities and support pivotal and post-approval CNS development programs
- In addition to its primary listing on the Swiss Stock Exchange, Newron is now also listed in Germany on the Düsseldorf Stock Exchange with trading on XETRA to facilitate greater access to Newron's shares for investors based in the EU
- Shareholders approved all resolutions at 2019 Annual General Meeting
- Cash (incl. other current financial assets) as of June 30, 2019 is EUR 39.4 million

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# **Shareholder Letter**



Dr. Ulrich Köstlin



Stefan Weber

Dear Shareholder,

We are delighted to report on Newron's progress in the first six months of 2019. Our pipeline of innovative therapies for both central and peripheral nervous system diseases has continued to advance. Notably, we formally completed patient enrollment in our STARS (Sarizotan for the Treatment of Apneas in Rett Syndrome) clinical study, with 129 Rett syndrome patients qualified and enrolled. Furthermore, our partners worldwide were successful in launching Xadago<sup>®</sup>/safinamide in Australia, followed by Canada under the brand name Onstryv<sup>®</sup>. We are pleased to report that safinamide is now available across the North American region. We expect further approvals and launches of safinamide in 2019 and 2020. With respect to our schizophrenia drug candidate Evenamide, we are working with the US Food and Drug Administration (FDA) regarding additional short-term explanatory studies that have been requested prior to initiation of our Phase III development program. We expect to be able to update the market on the outcome of these discussions in the coming weeks.

Early in July, we received the first tranche of funding from the European Investment Bank following the financing agreement signed last year, providing up to EUR 40 million.

#### Sarizotan

As previously announced, we are particularly pleased to have completed enrollment of our STARS study in patients with Rett syndrome. With 129 Rett syndrome patients randomized, we are hopeful that the results from the study will position Newron favourably to submit filings for marketing authorization with US, Canadian, and EU regulatory agencies. Results are expected in Q4 2019. More than 85% of the patients enrolled who have completed the 24-week double-blind period have continued into the long-term open-label extension. This is an indicator of the large unmet medical need in this severe indication and demonstrates the potential of a new treatment option such as sarizotan.

The study is aimed at patients suffering from Rett syndrome who present with clinically significant daytime apneas. According to our baseline data from the STARS study, apneas during awake time are seen in up to 70% of patients with at least 10% of their time spent not breathing properly. We are encouraged that, so far, treatment with sarizotan has been well tolerated with a very low rate of discontinuation.

Newron continued its support of Rare Disease Day in 2019, which is observed on February 28 each year. The objective of this event is to raise awareness for rare and orphan diseases and consequently to increase access to treatments worldwide.

As part of our commitment to the rare disease patient community, we are conducting an International Burden of Illness study. The study aims to deliver data and analytics to quantify the physical, emotional and financial challenges of Rett syndrome for patients, their families and caregivers. We believe the results will help to identify and guide improved intervention programs and services designed to complement the Rett syndrome care pathway.

#### Evenamide - Schizophrenia

Earlier this year, we received a communication from the US FDA indicating concerns with findings from recently completed pre-clinical studies of Evenamide. We discussed these issues during a conference call with investors and analysts held on May 28, 2019. Since then, Newron has engaged with the FDA in order to address the agency's concerns, and plans to complete additional short-term explanatory studies to address the issues raised by the FDA prior to initiation of the Phase III development program. Upon completion of the interactions in the coming weeks, Newron will update shareholders and the market.

Our prior experience in developing new chemical entities provides strong background for conducting explanatory studies like those the FDA is requesting. We have successfully managed similar regulatory issues in prevork. For this reason, we are confident that the FDA's comments can be addressed. Our planned development program for Evenamide currently includes two pivotal efficacy studies in patients with schizophrenia. The first study is in

Product		Phase I	Phase II	Phase III	Market	Commercial Rights
Xadago <sup>®</sup> / safinamide <sup>1</sup>	<b>EU / CH</b> Adjunctive therapy in PD					Zambon
	<b>US</b> Adjunctive therapy in PD					Zambon / US World Mede
	AUS Adjunctive therapy in PD					Seqirus
	<b>CAN</b> Adjunctive therapy in PD					Valeo
	<b>UAE</b> Adjunctive therapy in PD					Zambon
	JPN Adjunctive therapy in PD					Meiji Seika / Eisai
	BRA Adjunctive therapy in PD					Zambon
	<b>COL</b> Adjunctive therapy in PD					Zambon
	EU / US Levodopa Induced Dyskinesia(PD LID)					Zambon / US World Meds
Sarizotan <sup>2</sup>	Rett syndrome (Orphan drug status)					Newron
Evenamide <sup>1</sup>	Adjunctive therapy in Schizophrenia					Newron
	Adjunctive therapy in Clozapine-TRS					
Ralfinamide <sup>1</sup>	Orphan indication in neuropathic pain					Newron

#### **Newron's current Pipeline**

<sup>1</sup> Safinamide, Evenamide and Ralfinamide all developed from Newron's ion channel based research <sup>2</sup> Sarizotan was licensed from Merck KGaA patients experiencing worsening of psychosis on atypical antipsychotics, and the other study is in ultra-treatment-resistant schizophrenia patients not responding to clozapine. The latter represents an orphan-like indication with approximately 20,000 to 25,000 patients in the US (with similar numbers in the EU). Positive results in both studies could lead to the approval of Evenamide as a new treatment paradigm: as add-on therapy for patients with positive symptoms of schizophrenia, showing inadequate response to their current atypical medication. We plan to commercialize Evenamide ourselves in the orphan-like indication, in key territories.

#### Xadago<sup>®</sup>/safinamide – Parkinson's disease

Safinamide has now been successfully launched in 14 EU countries, Switzerland, the USA, Australia and Canada. We are very pleased that our partners worldwide were successful in the recent launches in Australia and Canada and we are hopeful of additional launches in the coming months. Zambon is engaged in discussions for additional Xadago<sup>®</sup> distribution agreements in Europe, the Middle East, Asia, Africa and South America. Most recently, Xadago<sup>®</sup> has received marketing approval in Brazil, Colombia and the United Arab Emirates (post-period). Dossiers for marketing authorization of Xadago<sup>®</sup> are currently under review in Japan, Mexico and Israel. Our income from the marketed territories increased by 11.2% over the prior year, with a promising growth rate of 44% in the US and single digit growth in the European territories. We expect further healthy growth in Europe, aided by the cap on reimbursement being removed in Italy in the second quarter of the year.

Our partner Zambon is continuing preparations towards initiating a pivotal study to evaluate the efficacy of safinamide in patients with levodopa-induced dyskinesia. The study is expected to start in H2 2019. Newron supported Zambon with the trial design and will make a fixed financial contribution to the study, in return for a greater share of royalties should the study lead to a label extension.

#### **Financial**

For the first six months of 2019, Newron reported a net loss of EUR 14.0 million, compared to EUR 7.6 million in the same period in 2018. The increase is predominantly due to the expected increased investment into the ongoing STARS pivotal study with sarizotan, for which we completed enrollment and now have the peak number of patients treated in the six-month, double-blind, placebo-controlled study phase or in the open label extension phase. Prior to the communication from the FDA detailed earlier, we had also completed the relevant preparations for our Phase III development program with Evenamide to treat patients suffering from schizophrenia, including investigator meetings in Asia and the USA.

Cash used in operating activities has increased to EUR 14.7 million from EUR 9.4 million in HI 2018. Xadago<sup>®</sup> related payments received from Zambon increased by 11.2% (EUR 2.2 million versus EUR 2.0 million in HI 2018). Newron's R&D expenses have increased to EUR 10.3 million from EUR 5.0 million in HI 2018. We have again profited from Italian R&D tax credits of EUR 2.9 million that can be offset with future tax and social contribution payments by Newron, versus EUR 2.6 million in HI 2018. G&A expenses reached EUR 5.9 million in the first six months of 2019 versus EUR 4.4 million in HI 2018, due to the assessment of potential additional listing opportunities as well as the start of market access activities in preparation

of the potential positive results from our STARS trial with sarizotan. Cash and other current financial assets at June 30, 2019 were at EUR 39.4 million, compared to EUR 43.9 million at the beginning of the year.

In order to facilitate trading and enable existing and potentially new investors from EU countries to trade Newron shares through EU brokers, we have also listed on the primary market of the Düsseldorf Stock Exchange with trading on XETRA, one of the leading electronic trading platforms in Europe. Our listing on the Swiss Stock Exchange is not affected by this initiative and remains the Company's main trading hub.

Following our financing agreement with the European Investment Bank (EIB), announced in 2018, which comprised potential funding up to EUR 40 million, Newron received its first tranche of EUR 10 million in early July 2019. This tranche will primarily be used to boost the Company's R&D activities and support pivotal and post-approval CNS development programs.

We were pleased that our shareholders approved all resolutions at our 2019 Annual General Meeting, including the approval of our financial statements as of December 31, 2018 and the appointment of statutory auditors and an audit company, both of which are under a three-year term. We were pleased to meet with so many existing and potential new investors at various conferences throughout the first half and look forward to engaging further later in the year.

The first half of 2019 has proven to be another productive period for Newron. We are encouraged by the continued success of our partners worldwide in the approvals and launches of safinamide and eagerly await the results of our ongoing study in sarizotan. We are confident that we can satisfactorily address the FDA's questions around Evenamide and look forward to updating you further on our innovative development pipeline and commercial success throughout the rest of the year. We reiterate our thanks to you – our shareholders – for your continued support and commitment.

Yours sincerely,

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Dr. Ulrich Köstlin Chairman

Stefan Weber Chief Executive Officer

### Interim Condensed Consolidated Financial Statements

For the six months ended June 30, 2019

## **Auditor Report**



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### 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 30 June 2019. 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 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, 2019 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 9, 2019

EY S.p.A.

Paolo Zocchi (Partner)

EY S.p.A. Sede Legale: Via Po, 32 - 00198 Roma Capitale Sociale Euro 2.525.000,001.v. Iscritta alla S.O. del Registro delle Imprese presso la C.C.I.A.A. di Roma Codice fiscale e numero di iscrizione 00434000584 - numero R.E.A. 250904 P.IVA 00891231003 Iscritta all'Albo Speciale delle società di revisione Consob al progressivo n. 2 delibera n.10831 del 16/7/1997

## Interim Condensed Consolidated Statement of Profit or Loss

(In thousand Euro, except per share information)		For the six months	ended June 30
	Note	2019 (unaudited)	2018 restated <sup>1)</sup> (unaudited)
Licence income from contracts with customers	6	56	0
Royalties from contracts with customers	7	2,176	2,008
Revenue		2,232	2,008
Research and development expenses	8	(10,298)	(5,028)
Marketing and advertising expenses		(440)	(171)
General and administrative expenses	9	(5,934)	(4,404)
Operating result		(14,440)	(7,595)
Financial income	10	452	269
Financial expenses	10	(52)	(229)
Result before tax		(14,040)	(7,555)
Income tax		(6)	(26)
Net loss		(14,046)	(7,581)
Loss per share			
Basic and diluted loss per share for the period	11	(0.79)	(0.42)
Weighted average number of shares (thousands) – Basic		17,845	17,843

### Interim Condensed Consolidated Statement of Comprehensive Income

(In thousand Euro)		For the six months	ended June 30
	Note	2019 (unaudited)	2018 restated <sup>1)</sup> (unaudited)
Net Income/(loss) for the period		(14,046)	(7,581)
Other comprehensive income/(loss) to be reclassified to profit or loss in subsequent periods:			
Net gain on other current assets	13	44	0
Exchange differences on translation of foreign operations		(5)	(68)
Net other comprehensive loss to be reclassified to profit or loss in subsequent periods		39	(68)
Other comprehensive income not to be reclassified to profit or loss in subsequent periods:			
Remeasurements on defined benefit plans		(11)	6
Net other comprehensive income not to be reclassified to profit or loss in subsequent periods		(11)	6
Other comprehensive income/(loss) for the period, net of tax		28	(62)
Total comprehensive loss for the period, net of tax		(14,019)	(7,643)

1) The Group applies, for the first time, IFRS 16 Leases that requires restatement of previous financial statements. As required by IAS 34, the nature and effect of these changes are disclosed within the notes. Please refer to Note 2 – IFRS 16 Leases – for additional information.

## Interim Condensed Consolidated Statement of Financial Position

(In thousand Euro)		As of	
	Note	June 30, 2019 (unaudited)	December 31, 2018 restated <sup>1</sup>
			(unaudited
Assets			
Non-current assets			
Property, plant and equipment		129	106
Right-of-use assets	2	190	268
Intangible assets		25	30
Non-current receivables		80	83
		424	487
Current assets			
Receivables and prepayments	12	20,007	15,659
Other current financial assets	13	27,167	16,230
Cash and cash equivalents	14	12,241	27,623
		59,415	59,512
Total assets		59,839	59,999
Shareholders' equity			
Share capital	15	3,569	3,569
Share premium and other reserves	16	46,306	61,341
Share option reserve	17	12,171	11,018
Retained earnings		(19,165)	(20,203)
Translation differences		(894)	(889)
Total shareholders' equity		41,987	54,836
Liabilities			
Non-current liabilities			
Interest-bearing loan	18	9,348	C
Cash-settled share-based liabilities	19	657	С
Non-current lease liabilities	2/20	58	125
Employee severance indemnity		618	606
		10,681	73
Current liabilities			
Current lease liabilities	2/20	138	151
Trade and other payables	21	7,033	4,281
		7,171	4,432
Total liabilities		17,852	5,163
Shareholders' equity and liabilities		59,839	59,999

1) The Group applies, for the first time, IFRS 16 Leases that requires restatement of previous financial statements. As required by IAS 34, the nature and effect of these changes are disclosed within the notes. Please refer to Note 2 – IFRS 16 Leases – for additional information.

## 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, 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	16		(5,282)			5,282	0
Exercise of options and reclassification of reserves	15/17	2	73	(32)			43
Share option scheme	17			869			869
Adoption of IFRS 16						(8)	(8)
Restated <sup>1)</sup> balance at June 30, 2018		3,569	61,330	9,785	(937)	(12,765)	60,982
Balance at January 1, 2019		3,569	61,341	11,018	(889)	(20,203)	54,836
Net loss						(14,046)	(14,046)
Other comprehensive income/(loss)					(5)	33	28
Total comprehensive loss for the period		0	0	0	(5)	(14,014)	(14,019)
Previous year loss allocation	16		(15,035)			(15,035)	0
Fair value reserve release						17	17
Share option scheme	17			1,153			1,153
Balance at June 30, 2019		3,569	46,306	12,171	(894)	(19,165)	41,987

1) The Group applies, for the first time, IFRS 16 Leases that requires restatement of previous financial statements. As required by IAS 34, the nature and effect of these changes are disclosed within the notes. Please refer to Note 2 – IFRS 16 Leases – for additional information.

## Interim Condensed Consolidated Statement of Cash Flow

(In thousand Euro)		For the six months	-
	Note	2019 (unaudited)	2018 restated <sup>1)</sup> (unaudited)
Loss before tax		(14,040)	(7,555)
Adjustments for:			
Depreciation and amortisation		103	93
Other non monetary income	8	(3,309)	(2,088)
Share option expenses	17	1,153	869
Employee severance indemnity expense		89	99
Changes in working capital:			
Current receivables and prepayments and deferred cost	12	(1,450)	1,124
Trade and other payables and deferred income		2,746	(1,897)
Change in non-current receivables		3	(1)
Cash used in operating activities		(14,729)	(9,356)
Cash flows from investing activities			
Purchase of financial assets	13	(1,079)	0
Disposal of financial assets	13	528	0
Purchase of property, plant and equipment		(48)	(16)
Purchase of intangible assets		0	(5)
Interest received	10	29	34
Net cash flows from/(used in) investing activities		(570)	13
Cash flows from financing activities			
Proceeds from issue of shares		0	44
Lease liabilities	20	(83)	(75)
Net cash flows from financing activities		(83)	(31)
Net increase in cash and cash equivalents		(15,382)	(9,374)
Cash and cash equivalents at January 1,		27,623	40,642
Cash and cash equivalents at the end of the period		12,241	31,268

1) The Group applies, for the first time, IFRS 16 Leases that requires restatement of previous financial statements. As required by IAS 34, the nature and effect of these changes are disclosed within the notes. Please refer to Note 2 – IFRS 16 Leases – for additional information.

## 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 and, since June 26, 2019, is also listed at the Dusseldorf Stock Exchange and traded on the XETRA electronic trading platform under the trade name NP5.

The Group is principally engaged in development and commercialization of 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, 2019, were authorised for issuance by the Board of Directors ("the Board") on September 5, 2019.

### 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, 2019 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, 2018.

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 3I, 20I8, except for the adoption of new standards and interpretations effective as of January I, 20I9. 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 16 Leases that requires 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 2019, but do not have an impact on the interim condensed consolidated financial statements of the Group.

#### IFRS 16 Leases

IFRS 16 supersedes 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. The standard sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for most leases under a single on-balance sheet model.

The Group adopted IFRS 16 using the full retrospective method of adoption with the date of initial application of January 1, 2019. The Group elected to use the transition practical expedient allowing the standard to be applied only to contracts that were previously identified as leases applying IAS 17 and IFRIC 4 at the date of initial application. The Group also elected to use the recognition exemptions for lease contracts that, at the commencement date, have a lease term of 12 months or less and do not contain a purchase option ("short-term leases"), and lease contracts for which the underlying asset is of low value ("low-value assets").

The effect of adoption IFRS 16 is as follows:

### Net impact on the statement of financial position as at December 31, 2018:

Assets	
Right-of-use	268
Liabilities	
Interest-bearing loan	276
Equity	
Retained earnings	(8)

Impact on the statement of profit or loss for the six-months period ended June 30, 2018:

Research and Development expenses	
Lease costs	(26)
Depreciation and amortization expense	25
	(1)
General and administrative expenses	
Lease costs	(49)
Depreciation and amortization expense	46
	(3)
Financial expenses	
Interest expenses	4
Effect on Profit and Loss	0

Impact on the statement of cash flows for the six-months period ended June 30, 2018:

Adjustments for:	
Cash used in operating activities	75
Net cash from financing activities	(75)

a) Nature of the effect of adoption of IFRS 16

The Group has lease contracts mainly related to offices, archiving spaces and vehicles. Before the adoption of IFRS 16, the Group classified each of its leases (as lessee) at the inception date as operating leases. In an operating lease, the leased property was not capitalized, and the lease payments were recognised as rent expense in the statement of profit or loss on a straight-line basis over the lease term. Any prepaid rent and accrued rent were recognised under Prepayments and Trade and other payables, respectively.

Upon adoption of IFRS 16, the Group applied a single recognition and measurement approach for all leases that it is the lessee, except for short-term leases and leases of low-value assets. The Group recognised lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets. In accordance with the full retrospective method of adoption, the Group applied IFRS 16 at the date of initial application as if it had already been effective at the commencement date of existing lease contracts. Accordingly, the comparative information as of December 31, 2018, has been restated. As at December 31, 2018:

- Net Right-of-use assets of EUR 268 were recognised and presented separately in the statement of financial position
- Additional lease liabilities of EUR 276 were recognised and included under Interest bearing loans and borrowings
- The net effect of these adjustments equal to EUR 8 had been adjusted to Retained earnings

For the six-months period ended June 30, 2018:

- Depreciation expense increased by EUR 70 relating to the depreciation of additional assets recognised (i.e., increase in right-of-use assets)
- Rent expense and Travel expenses decreased by EUR 75 relating to previous operating leases
- Finance costs increased by EUR 4 relating to the interest expense on additional lease liabilities recognised

b) Summary of new accounting policies

Set out below are the new accounting policies of the Group upon adoption of IFRS 16:

#### Right-of-use assets

The Group recognises right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognised right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of-use assets are subject to impairment.

#### Lease liabilities

At the commencement date of the lease, the Group recognises lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees.

In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is re-measured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

Short-term leases and leases of low-value assets The Group applies the short-term lease recognition exemption to its short-term leases (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value (i.e., below EUR 5,000). Lease payments on short-term leases and leases of low-value assets are recognised as expense on a straight-line basis over the lease term.

### Significant judgement in determining the lease term of contracts with renewal options

The Group determines the lease term as the noncancellable term of the lease, together with any periods covered by an option to extend the lease if it is reasonably certain to be exercised, or any periods covered by an option to terminate the lease, if it is reasonably certain not to be exercised. The Group applies judgement in evaluating whether it is reasonably certain to exercise the option to renew. That is, it considers all relevant factors that create an economic incentive for it to exercise the renewal. After the commencement date, the Group reassesses the lease term if there is a significant event or change in circumstances that is within its control and affects its ability to exercise (or not to exercise) the option to renew (e.g., a change in business strategy).

The renewal options for leases of motor vehicles were not included as part of the lease term because the Group has a policy of leasing motor vehicles for not more than four years and hence not exercising any renewal options.

c) Amounts recognised in the statement of financial position and profit or loss

Set out below, are the carrying amounts of the Group's right-of-use assets and lease liabilities and the movements during the period:

	Righ			
	Offices	Motor vehicles	Total	Lease liabilities
Right-of-use asset, gross	502	223	725	
Cumulated depreciation	(337)	(120)	(457)	
As at December 31, 2018	165	103	268	276
Depreciation	(46)	(32)	(78)	0
Interest			0	3
Payments			0	(83)
As at June 30, 2019	119	71	190	196

IFRIC Interpretation 23 Uncertainty over Income Tax Treatment

The Interpretation addresses the accounting for income taxes when tax treatments involve uncertainty that affects the application of IAS 12 Income Taxes. It does not apply to taxes or levies outside the scope of IAS 12, nor does it specifically include requirements relating to interest and penalties associated with uncertain tax treatments. The Interpretation specifically addresses the following:

- Whether an entity considers uncertain tax treatments separately
- The assumptions an entity makes about the examination of tax treatments by taxation authorities
- How an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates
- How an entity considers changes in facts and circumstances

An entity has to determine whether to consider each uncertain tax treatment separately or together with one or more other uncertain tax treatments. The approach that better predicts the resolution of the uncertainty needs to be followed.

The Group applies significant judgement in identifying uncertainties over income tax treatments. Since the Group operates in a complex multinational environment, it assessed whether the Interpretation had an impact on its consolidated financial statements. Upon adoption of the Interpretation, the Group considered whether it has any uncertain tax positions.

The interpretation had no impact on the consolidated financial statements of the Group.

Amendments to IFRS 9: Prepayment Features with Negative Compensation

Under IFRS 9, a debt instrument can be measured at amortised cost or at fair value through other comprehensive income, provided that the contractual cash flows are "solely payments of principal and interest on the principal amount outstanding" (the SPPI criterion) and the instrument is held within the appropriate business model for that classification. The amendments to IFRS 9 clarify that a financial asset passes the SPPI criterion regardless of an event or circumstance that causes the early termination of the contract and irrespective of which party pays or receives reasonable compensation for the early termination of the contract.

These amendments had no impact on the consolidated financial statements of the Group.

Amendments to IAS 19: Plan Amendment, Curtailment or Settlement

The amendments to IAS 19 address the accounting when a plan amendment, curtailment or settlement occurs during a reporting period. The amendments specify that when a plan amendment, curtailment or settlement occurs during the annual reporting period, an entity is required to determine the current service cost for the remainder of the period after the plan amendment, curtailment or settlement, using the actuarial assumptions used to remeasure the net defined benefit liability (asset) reflecting the benefits offered under the plan and the plan assets after that event. An entity is also required to determine the net interest for the remainder of the period after the plan amendment, curtailment or settlement using the net defined benefit liability (asset) reflecting the benefits offered under the plan and the plan assets after that event, and the discount rate used to remeasure that net defined benefit liability (asset).

These amendments had no impact on the consolidated financial statements of the Group as it did not have any plan amendments, curtailments, or settlements during the period.

#### Annual Improvements 2015 – 2017 Cycle IAS 12 Income Taxes

The amendments clarify that the income tax consequences of dividends are linked more directly to past transactions or events that generated distributable profits than to distributions to owners. There-fore, an entity recognises the income tax consequences of dividends in profit or loss, other comprehensive income or equity according to where it originally recognised those past transactions or events.

An entity applies the amendments for annual reporting periods beginning on or after January 1, 2019, with early application permitted. When the entity first applies those amendments, it applies them to the income tax consequences of dividends recognised on or after the beginning of the earliest comparative period.

Since the Group's current practice is in line with these amendments, they had no impact on the consolidated financial statements of the Group.

#### IAS 23 Borrowing Costs

The amendments clarify that an entity treats as part of general borrowings any borrowing originally made to develop a qualifying asset when substantially all of the activities necessary to prepare that as-set for its intended use or sale are complete.

The entity applies the amendments to borrowing costs incurred on or after the beginning of the annual reporting period in which the entity first applies those amendments. An entity applies those amendments for annual reporting periods beginning on or after January I, 2019, with early application permitted.

Since the Group's current practice is in line with these amendments, they had no impact on the consolidated financial statements of the Group.

#### **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 (rates as of)		
	2019	2018	June 30, 2019	Year-end 2018	
CHF1	0.88538	0.85492	0.90050	0.88739	
GBP 1	1.14465	1.13662	1.11539	1.11791	
SEK 1	0.09507	0.09851	0.09467	0.09752	
USD 1	0.88512	0.82617	0.87873	0.87336	

#### 6 Licence income from contracts with customers

Licence income from contracts with customers amounted to EUR 56 as of June 30, 2019 (2018: nil). Licence income is related to a non-refundable milestone payment cashed in by Zambon S.p.A upon launch of Xadago<sup>®</sup> (safinamide) for the treatment of fluctuating idiopathic Parkinson's disease, as add-on therapy to a regimen that includes levodopa, into the Australian market by its partner Seqirus. Licence income in 2019 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,	
	2019	2018 restated
Royalties from contracts with customers	2,176	2,008

Following the European Commission approval of the use of Xadago<sup>®</sup> (safinamide) for the treatment of idiopathic Parkinson's disease, starting by May 15, 2015, Zambon has launched Xadago® in 14 European union countries among which Germany, Italy, Spain and United Kingdom and, after the Swissmedic approval, Switzerland. On July 11, 2017, after Food and Drug Administration (FDA) approval, US WorldMeds, Zambon's commercial partner, has launched Xadago® also in the U.S. market. In 2019, after approval by the Therapeutic Goods Administration of the Australian Government Department of Health, Xadago has been launched also in Australia and New Zealand. 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 2019, royalties from contracts with customers increased by 8.4% in comparison with the corresponding period of the previous year mainly because of the growing sales in both the European and USA markets and the positive effect related to the launch of Xadago<sup>®</sup> in Australia.

On February 2016, Italian Medicines Agency (AIFA) approved Xadago<sup>®</sup> selling price and imposed a ceiling on sales. As a matter of attention, it should be noted that AIFA has removed the ceiling effective from March 1, 2019. Royalties cashed in until end of February 2019, 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,	
	2019	2018 restated
Services received from subcontractors	7,259	1,943
Staff costs	1,296	1,414
Consultancy fees	557	453
Material and consumable used	677	771
Operating lease cost	146	16
Travel expenses	270	209
Depreciation and amortization expense	26	25
Other research and development costs	67	197
	10,298	5,028

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 is performing to evaluate the efficacy of sarizotan in Rett Syndrome patients, has completed enrolment and is treating the last patients enrolled. Moreover, the Company was in the preliminary stage of two Phase III double blind placebo-controlled studies to evaluate the efficacy of evenamide, either in patients with schizophrenia experiencing worsening of psychosis or in treatmentresistant schizophrenia patients not responding adequately to clozapine, when it was asked by FDA to delay the initiation of those studies prior to completing additional short term explanatory studies aimed at addressing the concerns raised by the authority. As of June 30, 2019, Newron booked for all costs required to put the above studies on hold.

Staff costs amount to EUR 1,296 (2018: 1,414). The variance compared to prior period is mainly related to the following effects: a) decrease in accrued social contribution costs on vested options (as required by local law in certain countries where the Group operates through its subsidiaries); b) higher R&D Tax Credit reimbursement partially compensated by c) an increased number of employees.

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 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 markup. Accordingly, research and development expenses are presented net of reimbursements amounting to EUR 25 (2018: EUR 8).

As stated by art. I, 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 March 23, 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 a yearly ceiling has

been set at EUR 20 million per year. The "2019 Stability Law" has partially amended the existing rules: a) from January 1, 2019 onward, the defined percentage of 50% will be reduced to 25% for all R&D expenses except Staff costs and expenses incurred with certain Italian subcontractors like Universities and Small Innovative Companies and b) the yearly ceiling has been reduced to EUR 10 million per year.

Expenses incurred by the Company in the first half of 2019, granted an estimated total R&D tax credit of EUR 2,898 (2018: 2,635). Therefore, Staff Costs, Services received from sub-contractors, Consultancy fees and Material and consumable used have been reduced respectively by EUR 393 (2018: 365), EUR 2,155 (2018: 1.414), EUR 142 (2018: 272) and EUR 208 (2018: 585).

The overall effect is detailed in the following table.

(In thousand Euro)	For the six months ended June 30,	
	2019	2018 restated
Research and development expenses, gross	13,221	7,671
R&D Tax Credit	(2,898)	(2,635)
Reimbursed by Zambon	(25)	(8)
	10,298	5,028

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: both have been completely written off in previous years.

#### 9 General and administrative expenses

(In thousand Euro)	For the six months ended June 30,	
	2019	2018 restated
Staff costs	2,624	2,004
Consultancy and other professional services	2,478	1,416
Intellectual properties	423	476
Travel expenses	168	135
Operating lease cost	48	169
Depreciation and amortization expense	77	69
Other expenses	116	135
	5,934	4,404

Staff costs for the six months ended June 30, 2019 are higher than the 2018 balance mainly due to the increase in stock options cost.

In the six-months period ending June 2019, Consultancy and other professional services increased mainly for the following reasons: a) increase in Legal and Administrative consultancies mainly related to the assessment of potential dual listing opportunities and the expenses incurred by the Company to have its shares traded, since June 26, 2019, on the primary market of the Düsseldorf Stock Exchange as well as XETRA and b) the start of market access activities in preparation of the potential positive data on sarizotan trial.

#### **10 Financial results**

(In thousand Euro)	For the six months ended June 30,	
	2019	2018 restated
Interest income	46	51
Foreign exchange gains	97	218
Otherincome	309	0
	452	269

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.

Other income reflects the increase in the fair value of Group Financial assets recognized at fair value through profit or loss, recovering losses booked in 2018.

(In thousand Euro)	For the six months ended June 30,	
	2019	2018 restated
Interest expenses	(25)	(21)
Foreign exchange losses	(27)	(83)
Other costs	0	(125)
	(52)	(229)

The adoption of IFRS 16 has increased Interest expenses by EUR 3 (2018: EUR 4).

#### 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,	
	2019	2018 restated
Net loss attributable to shareholders	(14,046)	(7,581)
Weighted average number of shares (thousands) – Basic	17,845	17,843
Losses per share – basic and diluted (in Euro)	(0.79)	(0.42)

The categories of potential ordinary shares that have dilutive effect are the stock options and warrants. At the end of the six-months period, Newron has granted a total of n. 1,549,080 (see also Note 17 for additional information) stock options to certain employees, directors and consultants and a total of n. 201,793 warrants to EIB (please refer to Note 19 for additional information). As of June 30, 2019, 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, 2019, coincided.

#### **12 Receivables and prepayments**

(In thousand Euro)	As of	
	June 30, 2019	December 31, 2018 restated
	unaudited	unaudited
Receivables	1,545	1,242
Prepayments	1,720	224
VAT receivable	1,213	420
R&D tax credit	15,404	13,625
Other receivables	125	148
	20,007	15,659

Receivables are almost entirely represented by the invoices and accruals related to the royalties on net sales performed by Zambon Group and its commercial partners in Europe, Switzerland, United States of America and Australia. At the end of the six-months period, R&D tax credit was equal to EUR 15,404 (December 31, 2018: 13,625). The net increase by EUR 1,779 is due to the combined effect of the estimated six-months period accruals equal to EUR 2,898 and its use to offset certain taxes and contributions during the six-months period ended June 30, 2019, for a total of EUR 1.119 (2018: 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, 2019, 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, 2019	December 31, 2018 restated
	unaudited	unaudited
Government bonds	508	1,030
Listed bonds	4,208	3,099
Investment funds	12,451	12,101
Short term financial receivables	10,000	0
	27,167	16,230

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.

Short-term financial receivables are related to the financing agreement that the Group has signed with the European Investment Bank (EIB) on October 29, 2018 granting Newron with up to EUR 40 million term loan facility over the coming years, subject to achieving a set of agreed performance criteria. Following Newron, request – dated Friday, June 28, 2019 – EIB approved, on the same day, to transfer to Newron the Trance 1 of the term loan facility, amounting to EUR 10 million. The funds were made available on Company's account on Monday July 1, 2019. Please refer to Note 18 for additional information.

#### 14 Cash and cash equivalents

(In thousand Euro)	As of	
	June 30, 2019	December 31, 2018 restated
	unaudited	unaudited
Cash at bank and in hand	11,360	27,623
Short-term investments	881	0
	12,241	27,623

Management monitors the Group's cash position on rolling forecasts based on expected cash flows 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 (Other current financial assets plus Cash and cash equivalents) amounts approximately to EUR 39 million (EUR 44 million as at December 31, 2018). Expenses of the period have been partially financed by royalties and existing cash.

#### 15 Share capital

As of December 31, 2018, the subscribed share capital was equal to EUR 3,569,069.00, divided into 17,845,345 ordinary shares with par value equal to EUR 0.20 each. There was 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, 2017 – Newron Group	3,567,469.00
– issue of ordinary share (Stock options exercise)	1,600.00
As of December 31, 2018 – Newron Group	3,569,069.00
As of June 30, 2019 – Newron Group	3,569,069.00

As of June 30, 2019, the subscribed share capital was equal to EUR 3,569,069.00, divided into 17,845,345 ordinary shares with par value equal to EUR 0.20 each. There is no authorised share capital.

#### 16 Share premium

(In thousand Euro)	As of	
	June 30, 2019	December 31, 2018 restated
_	unaudited	unaudited
At the beginning of the year	61,341	66,539
Loss allocation	(15,035)	(5,282)
Issue of shares (exercise of options)	0	48
Reclassification from share option reserve	0	36
At the end of the period	46,306	61,341

In 2018, as a consequence of the exercise of options, the cost accrued into the Share options reserve throughout the vesting period has been reclassified into the share premium reserve.

#### **17 Share option reserve**

(In thousand Euro)	As of			
	June 30, 2019	December 31, 2018 restated		
	unaudited	unaudited		
At the beginning of the year	11,018	8,948		
Reclassification to Share Premium	0	(36)		
Share option scheme	1,153	2,106		
At the end of the period	12,171	11,018		

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; ESOP 2017 and ESOP 2018 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	2018	Total
At Janaury 1, 2018	55,451	328,174	180,934	400,000	260,732	0	1,225,291
Granted	0	0	0	0	0	398,874	398,874
Waived	0	0	0	(7,309)	(13,948)	(13,046)	(34,303)
Exercised	0	(8,000)	0	0	0	0	(8,000)
At December 31, 2018	55,451	320,174	180,934	392,691	246,784	385,828	1,581,862
Waived	0	0	0	(7,551)	(6,974)	(18,257)	(32,782)
At June 30, 2019	55,451	320,174	180,934	385,140	239,810	367,571	1,549,080

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 1,153 and it is related to the following opposite effects: a) additional costs of the period equal to EUR 1,278 (out of which EUR 202 refers to G&A employees and the remaining EUR 1,076 to R&D ones) and b) the write-off of accrued cost related to options waived by two employees that left the Company.

As of June 30, 2019, 840,992 options were vested; additional 164,561 options will vest within year end.

The following table shows additional information regarding options granted as of June 30, 2019:

Plan's name	Exercise price (in Euro)	Number out- standing	Weighted- average remaining contractual life (years)	Number exer- cisable
ESOP 2011	5.29	55,451	0.75	55,451
ESOP 2013	6.32	312,924	3.75	312,924
ESOP 2013	6.66	7,250	3.75	7,250
ESOP 2014	13.88	76,494	3.75	76,494
ESOP 2014	13.94	104,440	3.75	104,440
ESOP 2015	28.14	225,391	5.75	225,391
ESOP 2015	24.90	14,938	5.75	14,938
ESOP 2015	25.41	28,455	5.75	21,341
ESOP 2015	15.22	8,537	5.75	4,268
ESOP 2015	21.87	36,992	5.75	18,495
ESOP 2015	15.97	70,827	5.75	0
ESOP 2017	15.97	239,810	8.16	0
ESOP 2018	10.06	322,042	9.01	0
ESOP 2018	7.27	45,529	9.01	0
		1,549,080		840,992

#### 18 Interest-bearing loan

On October 29, 2018, the Group entered into a financing agreement with EIB granting Newron with up to EUR 40 million term loan facility over the coming years, subject to achieving a set of agreed performance criteria. The loan may be drawn in five tranches within a 36-month period from signing. The facility has a fiveyear term from the date of drawdown for each tranche. Group's obligations under the EIB agreement are secured by a security interest in certain cash accounts for the benefit of EIB.

Following Newron's request, dated Friday, June 28, 2019, EIB approved, on the same day, to transfer to Newron Tranche 1 of the term loan facility, amounting to EUR 10 million. The loan is accounted for amortized cost. The Tranche 1 has an interest rate of 3% to be paid on an annual basis in arrears. A further annual fixed rate of 6.75% is payable together with the outstanding principal amount on expiry of the facility. Furthermore, according to the agreement between the parties, Newron has granted EIB with n. 201,793 warrants to purchase Newron, ordinary shares (for additional information, please refer to Note 19).

#### 19 Cash-settled share-based liability

As a consideration for Tranche I, on June 28, 2019 the Company awarded, free of charge, EIB with n. 201,793 warrants, representing 1.04% of the fully-diluted (i.e. taking into consideration not only the issued share capital but also the outstanding stock options – please refer to Notes 15 and 17) share capital as of the granting date. EIB will be entitled to receive one newly issued Newron, share per each warrant at an exercise price equal to EUR 9.25. If no triggering events as defined in the contract with EIB will occur, issued warrants can't be exercised before March 15, 2024. The agreement includes a cash-settlement option. Warrants will expire on November 28, 2028.

Warrants Fair Value has been calculated according with the binomial model assuming no arbitrage, a riskneutral framework, a volatility equal to 62,62% and no issuance of dividends. As of June 30, 2019, warrants' fair value, calculated using the Suisse Interest Rate Swap curve, was equal to EUR 657.

#### **20** Lease liabilities

(In thousand Euro)	As o	of	
	June 30, 2019	December 31, 2018 restated	
_	unaudited	unaudited	
At the beginning of the year	276	369	
Increase of the period	0	52	
Interest	3	8	
Payments	(83)	(153)	
At the end of the period	196	276	
Non-current	58	125	
Current	138	151	

The Group adopted IFRS 16 using the full retrospective method of adoption with the date of initial application of January 1, 2019. The Group elected to use the transition practical expedient allowing the standard to be applied only to contracts that were previously identified as leases applying IAS 17 and IFRIC 4 at the date of initial application. The Group also elected to use the recognition exemptions for lease contracts that, at the commencement date, have a lease term of 12 months or less and do not contain a purchase option ("short-term leases"), and lease contracts for which the underlying asset is of low value ("low-value assets").

#### 21 Trade and other payables

(In thousand Euro)	As o	As of			
	June 30, 2019	December 31, 2018 restated			
	unaudited	unaudited			
Trade payables	1,713	1,149			
Accrued expenses	4,090	1,942			
Pension contribution payable	297	291			
Social security	275	182			
Other payables	658	717			
	7,033	4,281			

Increase in Trade payables and Accrued expenses is mainly related to the development activities performed by the Group during the first half of 2019 (please refer also to Note 8 and 9 for additional information).

#### 22 Financial instruments by category

d The following tables present the breakdown of
d financial assets and liabilities, evaluated at fair value,
9 by category as of June 30, 2019, and December 31, 2018
2 respectively.

#### Fair Value hierarchy

Level I — Quoted (unadjusted) market prices in active markets for identical assets or liabilities Level 2 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable Level 3 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

As of June 30, 2019	Level	Financial assets at fair value through OCI with reclassification	Financial assets at fair value through profit and loss	Liabilities at fair value through profit or loss	Other financial liabilities at amortized cost
Assets					
Other current financial assets	1	4,716	12,451	_	_
Total		4,716	12,451	-	-
Liabilities					
Interest-bearing loan	2	-	-	_	9,348
Non-current lease liabilities	3	-	-	_	58
Current lease liabilities	3	-			138
Cash-settled share-based liabilities	2			657	_
Total		-	-	657	11,915

As of December 31, 2018	Level	Financial assets at fair value through OCI with reclassification	Financial assets at fair value through profit and loss	Liabilities at fair value through profit or loss	Other financial liabilities at amortized cost
Assets					
Other current financial assets	1	4,129	12,101	_	_
Total		4,129	12,101	-	-
Liabilities					
Trade and other payables	1	-	-	-	1,866
Non-current lease liabilities	3	-	-	-	125
Current lease liabilities	3	-			151
Total		-	-	-	2,142

There were no transfers between Levels during the six-month period ending on June 30, 2019 and the whole year 2018.

#### 23 Related party transactions

The following tables provide the total amount of transactions that have been entered into with related parties during the six-months period ending June 30, 2019 and June 30, 2018, as well as balances with related parties outstanding as of June 30, 2019 and June 30, 2018:

As of June 30, 2019	Sales to/Cost reimbursed by related parties	Royalties	Purchases from related parties	Amounts owed by related parties, net	Amounts owed to related parties
Zambon (whole group)	87	2,176	106	169	0
As of June 30, 2018					
Zambon (whole group)	8	2,008	83	967	0

#### 24 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 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 KGaA, the achievement of future results related to the development of certain Newron compounds will trigger the payment of milestone 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.

#### 25 Events after the balance sheet date

On July 10 the Group reported that its partner, Zambon S.p.A, together with Valeo Pharma Inc. announced the launch of Onstryv<sup>®</sup> (safinamide) for the treatment of Parkinson's disease in Canada.

Bresso, September 5, 2019

Stefar Weber

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, 2019	17,845,345
52-week high (in CHF)	13.78
52-week low (in CHF)	5.33
June 30, 2019 closing share price	6.30
Loss per share (in EUR)	0.79
Cash and cash equivalents, other short-term financial assets as at June 30, 2019 (in EUR 1,000)	39,408
Market capitalization as at June 30, 2019 (in CHF)	112,425,673

#### Contact

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#### Imprint

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

**Concept** FTI Consulting, London, U.K. IRF Communications AG, Zurich, Switzerland

Graphic design, production and prepress TGG Hafen Senn Stieger, St.Gallen, Switzerland

Photos Marco Moscadelli, Studio Fotografico Moscadelli, Milan, Italy

#### **Important Notices**

This document contains forward-looking statements, including (without limitation) about (I) 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.

Newron may not actually achieve the plans, intentions or expectations disclosed in forward-looking statements and assumptions underlying any such statements may prove wrong. Investors should therefore not place undue reliance on them. There can be no assurance that actual results of Newron's research programmes, development activities, commercialization plans, collaborations and operations will not differ materially from the expectations set out in such forward-looking statements or underlying assumptions.

Newron does not undertake any obligation to publicly update or revise forward-looking statements except as may be required by applicable regulations of the SIX Swiss Exchange where the shares of Newron are listed.

This document does not contain or constitute an offer or invitation to purchase or subscribe for any securities of Newron and no part of it shall form the basis of or be relied upon in connection with any contract or commitment whatsoever.

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