



**2019**

Gedeon Richter  
Annual Report



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# 1

Chairman's Letter  
to the Shareholders





**Erik Bogesch**  
Chairman

## Chairman's Letter to the Shareholders

It is with a special delight that I present this Annual Report for 2019. Notwithstanding the difficulties experienced on some of our markets we are in the position to report on a number of notable accomplishments achieved during the year under review in all the innovative strategic initiatives of Richter.

As far as the turnover is concerned, higher royalty proceeds of cariprazine marketed in the USA under the brand name VRAYLAR® together with a sales related milestone received from our USA partner, contributed the most, more than HUF 30bn (USD 98m) to our topline performance growth and increased our gross and operating profits by virtually the same amount. Such outstanding performance was also supported by the label expansion authorised by the FDA, which included bipolar depression in the range of therapeutic areas addressed by this novel atypical antipsychotic invented by Richter scientists. A series of licensing-out agreements sealed with various local champion companies has qualified cariprazine as a would-be global treatment option reaching out to more than 1.9 billion people worldwide. Market launches planned to occur in the coming years, dependant on the different regulatory requirements of the countries involved include Australia, New Zealand, a range of countries from the MENA region and from Latin America, and South Korea. Our Japanese partner, Mitsubishi Tanabe, meanwhile obtained marketing authorisation for cariprazine in Singapore and Thailand.

Women's Healthcare, the Group's core specialty segment also recorded a successful year as its turnover contributed by more than HUF 14.1bn (around EUR 434m) to sales levels reported in 2019. This segment recorded a significant growth, near half of which originated from the well-established range of oral contraceptives while BEMFOLA® also showed a more than 20 percent increase in turnover when compared to the previous year. As far as the extension of our Women's Healthcare product portfolio is concerned, we signed a series of agreements for the commercialisation and manufacture of a novel oral antifungal to treat RVVC (Recurrent Vulvovaginal Candidiasis), while the innovative oral contraceptive containing natural estrogen and drospirenone deemed to lower the risk of venous thromboembolism, was filed for European marketing authorisation in early 2020.

I am delighted that we can also report important achievements in respect of our third specialty endeavour, our biosimilar business. Our first biosimilar teriparatide, TERROSA®, developed by Richter-Helm joint venture was launched in the European Union during the reported year while our licence partner, Mochida, also launched teriparatide in Japan by the end of 2019.

Partially offsetting the excellent sales performance of our specialty portfolio, Richter's branded generic and traditional business was negatively impacted by the implementation of serialisation and by the delisting of one of its leading drug, CAVINTON in China. These regulatory measures may further impact negatively the Group's performance in Russia and in China in 2020. In addition to the above the Group's financial performance was also negatively impacted by a significant impairment loss accounted for primarily on behalf of the ESMYA intangible asset.

Altogether the Board is content with the results achieved during 2019 and I'd like to extend our appreciation for the efforts of Mr Gábor Orbán, CEO, who together with his executive staff, managed to defend the positions of Richter and successfully directed the resources leading to a sustainable increase in shareholder value.

Erik Bogesch  
Chairman

# 2

## Corporate Review



## 1. Fact Sheet

Richter Group is active in two major business segments, primarily Pharmaceuticals comprising the research and development, manufacturing, sales and marketing of pharmaceutical products, and it is also engaged in the Wholesale and Retail of these products. In addition, there is a third group ('Other') of companies comprising those members of the Group that provide auxiliary services to the former segments.

Research, development, manufacturing and marketing of pharmaceutical products are the core activities of Richter and in this endeavour the Group is supported by a number of subsidiaries, joint ventures and associated companies. Manufacturing subsidiaries of the Group, which operate in traditional markets together with a broad network of trading affiliates that ensure a strong market presence, have together created the foundation for regional leadership and a global presence in the specialty area of Women's Healthcare.

### Parent Company Data

Headquarters	1103 Budapest, Gyömrői út 19-21., Hungary
Mail address	1475 Budapest, Pf. 27., Hungary
Phone	+36 1 431 4000
Fax	+36 1 260 4891
E-mail	posta@richter.hu
Website	www.richter.hu
Established	1901
Main activity	Research, development, manufacturing and marketing of pharmaceutical products
VAT Number	10484878-2-44
EU VAT Number	HU10484878
Share capital	HUF 18,637,486,000
Number of shares issued	186,374,860
Auditor	PricewaterhouseCoopers Auditing Ltd.
Shares listed at	Budapest Stock Exchange ISIN: HU0000123096 Luxembourg Stock Exchange ISIN: US3684672054
GDRs issued by	BNY Mellon GDR / Ordinary share ratio = 1:1

### Investor Relations Department

Address	1103 Budapest, Gyömrői út 19-21., Hungary
Mail address	1475 Budapest, Pf. 10., Hungary
E-mail	investor.relations@richter.hu
Website	www.richter.hu



## 2. Financial Highlights

### Consolidated financial highlights

	2019 HUFm	2018 HUFm	Change %	2019 EURm	2018 EURm
Total revenues	507,794	445,484	14.0	1,560.7	1,398.2
Profit from operations	39,896	45,040	(11.4)	122.6	141.4
Profit for the year	48,430	36,193	33.8	148.9	113.6

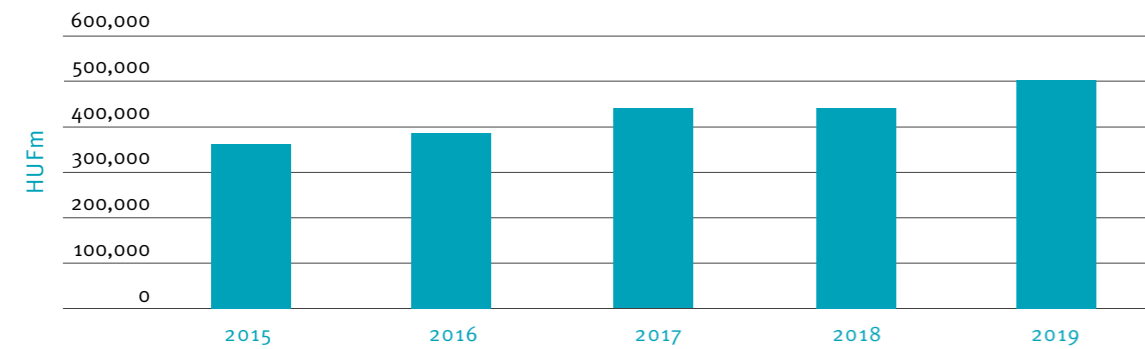
  

	2019 HUF	2018 HUF	Change %	2019 EUR	2018 EUR
Earnings per share (EPS) <sup>(1)</sup>	253	190	33.2	0.78	0.60
Dividends per ordinary shares <sup>(2)</sup>	63	100	(37.0)	0.19	0.31

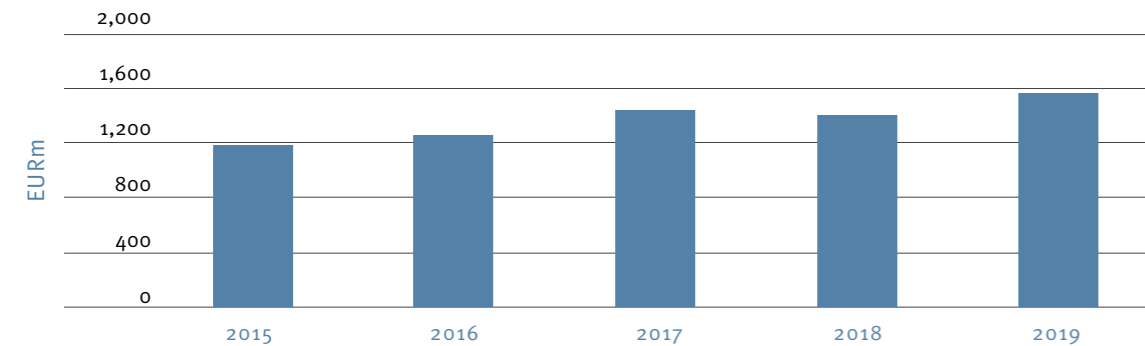
Notes: <sup>(1)</sup> Earnings per share calculations were based on the total number of shares issued.

<sup>(2)</sup> The amount of 2019 dividend per ordinary share is HUF 63 as proposed by the Board of Directors.

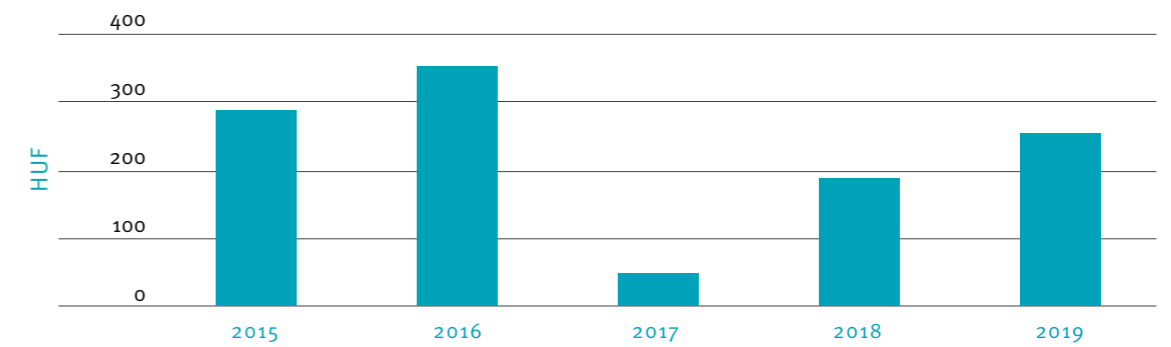
#### Revenues



#### Revenues

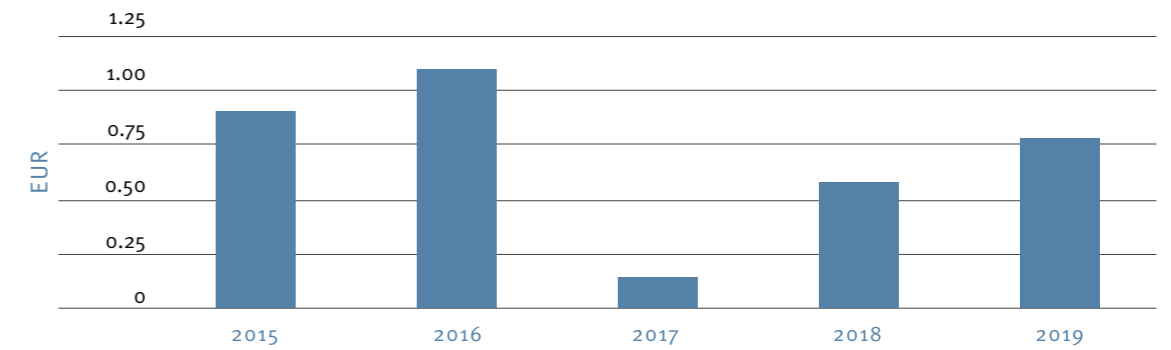


#### Earnings per share\*



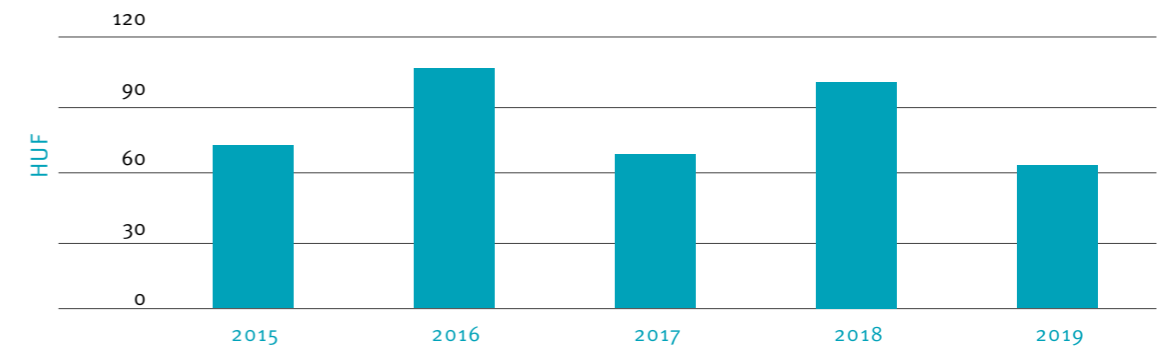
Note: \*Earnings per share calculations were based on the total number of shares issued.

#### Earnings per share\*



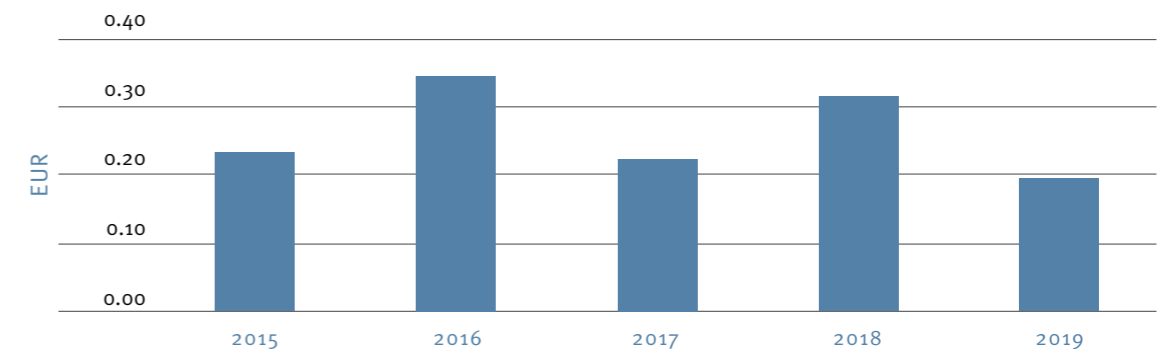
Note: \*Earnings per share calculations were based on the total number of shares issued.

#### Dividends per ordinary share\*



Note: \*The amount of 2019 dividend per ordinary share is HUF 63 as proposed by the Board of Directors.

#### Dividends per ordinary share



Note: \*The amount of 2019 dividend per ordinary share is EUR 0.19 as proposed by the Board of Directors.

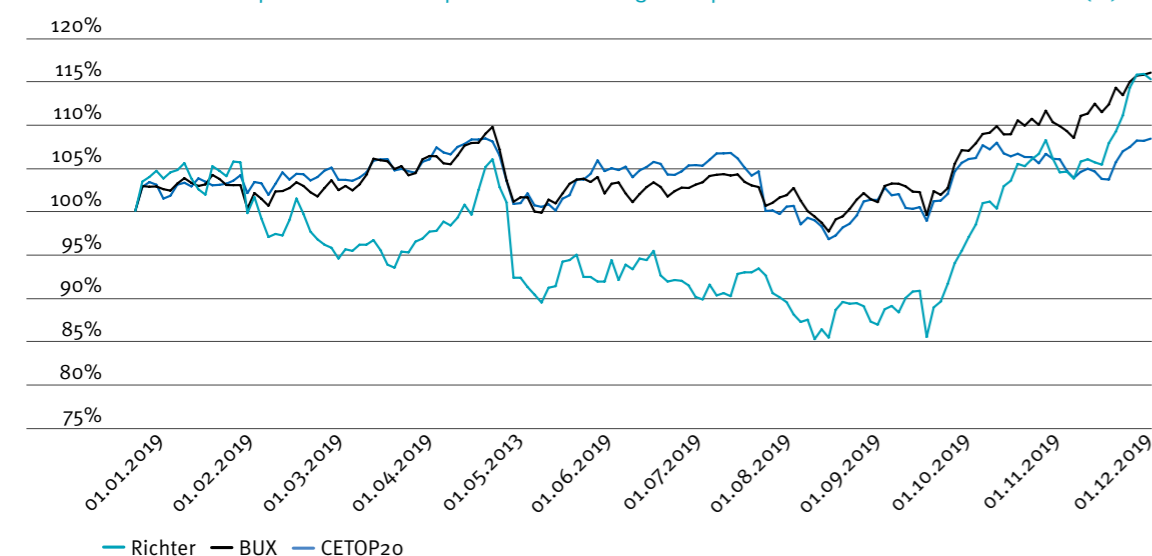
### 3. Investor Information

#### 1. Share Price and Market Capitalisation

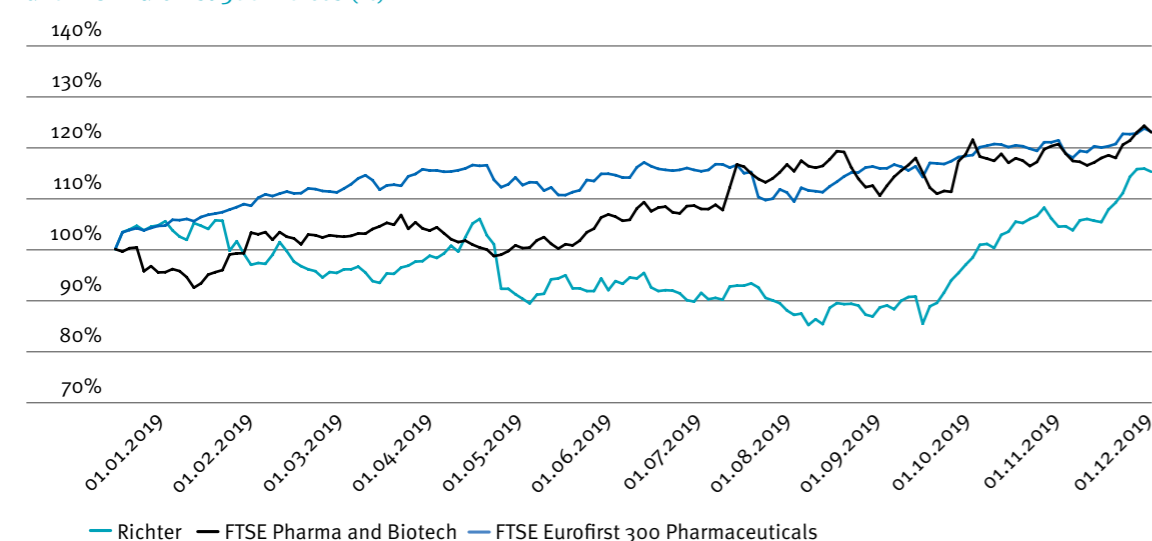
The Gedeon Richter Plc. share price on 2 January 2019 was HUF 5,560. Share price evolution was marked in the first half by mixed results announced by the Company: a better than expected expansion of royalty proceeds credited to excellent sales performance achieved by Allergan, our partner in the USA were overshadowed by the negative impact of serialization implemented in the EU together with declining Russian and Chinese sales. Following a short increase, the same negative factors impacted the share price subsequent to the release of the first half 2019 report. A slightly declining share price reached its annual minimum value, HUF 4,726 at the end of August. Improving dynamics of VRAYLAR® prescriptions in the USA led to higher investor expectations and to a ramping share price. The share price reached its annual maximum value on 23 December 2019 at HUF 6,450 value. The closing price on 30 December 2019 was HUF 6,415.

The Company's market capitalisation linked to the performance of its share price on the Budapest Stock Exchange at the end of 2019 was HUF 1,196bn reflecting an approximately 18 percent increase in HUF terms when compared to its value recorded on 28 December 2018. Market capitalisation on 30 December 2019 in Euro terms was EUR 3.62bn.

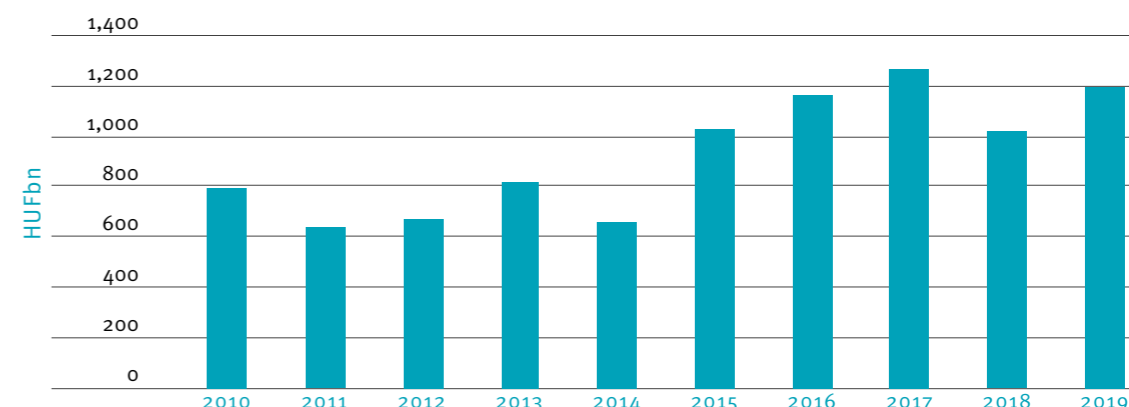
Gedeon Richter share price on the Budapest Stock Exchange compared to BUX and CETOP20 indices (%)



Gedeon Richter share price on the Budapest Stock Exchange compared to FTSE All World Pharma & Biotech and FTSE Eurofirst 300 indices (%)

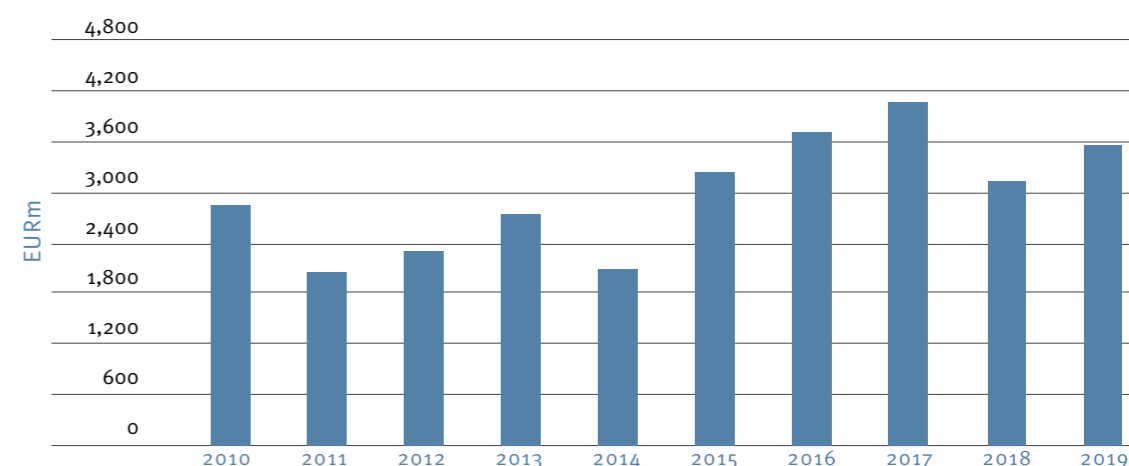


Market Capitalisation\*



Note: \*All data based on year-end prices. Calculations based on the total number of shares issued.

Market Capitalisation\*



Note: \*All data based on year-end prices. Calculations based on the total number of shares issued. Euro calculations adjusted with HUF/EUR exchange rate.

#### 2. Annual General Meeting

The Annual General Meeting is the highest decision-making body of the Company, comprising all shareholders.

Due to the situation caused by the coronavirus epidemic (Covid-19) and having regard to applicable laws (in particular Section 4 of Government Decree No. 46/2020. (III.16.)) the Company sees no possibility to hold its annual general meeting previously set to the day of April 28, 2020 in the corporate action timetable for year 2020, in person in accordance with the regulations of the Company's Statutes.

Simultaneously the Company, fulfilling its legal obligations, with respect to the statutory time limits published its announcement containing the invitation to the Company's annual general meeting in year 2020, on March 27, 2020.

The published date and venue of the AGM: **April 28, 2020 at 2.00 p.m., H-1093 Budapest Mátyás u. 8., (Budapest Music Center).**

#### 3. Dividend

In accordance with the dividend policy practised by the Company, the Board of Directors recommends the payment of 25.0 percent of Gedeon Richter Plc.'s consolidated profit attributable to owners of the parent calculated according to International Financial Reporting Standards (IFRS) for 2019.

Dividends approved by the shareholders of Gedeon Richter Plc. at the Annual General Meeting held on 24 April 2019 totalled HUF 18,637m in respect of 2018. The portion paid in relation to ordinary shares amounted to HUF 100 per share, 100 percent of the nominal share value. The Company published an official announcement regarding the dividend payment on 22 May 2019. The starting date for distributing dividend payments was 27 June 2019.



## 4. Investor Relations Activities

The Company reports formally to shareholders four times a year, simultaneously with the announcement of its quarterly non-audited results and issues audited Financial Statements whose relevant data are included in an Annual Report published, no later than the date of the Annual General Meeting. The AGM of the Company takes place in Budapest and formal notification is sent to shareholders at least 30 days in advance of the meeting. At the Meeting a business presentation is made to shareholders by the CEO and all Directors are available during the meeting to respond to questions.

Management, principally the CEO and investor relations staff, maintain a dialogue with institutional shareholders on Company performance and objectives through a programme of conferences, regular meetings, conference calls and investor roadshows. Representatives of the Investor Relations Department of Gedeon Richter Plc. participated at 3 international conferences and 3 additional investor roadshows in 2019. Gedeon Richter's management also held 19 meetings for approximately 26 fund managers and analysts at its headquarters where the Company's business progress and financial results were presented. Regular conference calls were organised during the year following publication of the quarterly reports of the Company and 21 additional conference calls were organised on request.

Driven by the intention to enhance the Company's investor relations activities, Richter's Management together with the IR Department have initiated a tradition by organizing in 2019 in Budapest an Investor Day, where the CEO, the Executive Chairman, the Research Director and the Commercial Director presented their respective areas of responsibility and answered the questions of investors and analysts.

### Conferences in 2019

BÉT	Hungarian Investor Day	Warsaw	13 June 2019
Jefferies	Healthcare Conference	London	20 November 2019
J.P. Morgan	CEE Investor Day	London	21 November 2019

### Investor Roadshows in 2019

UK - London	20-21 February 2019
UK - London	10-11 September 2019
USA - New York	13 November 2019
- Boston	14 November 2019

### Other Events - Investor Relation Day - Hungarian Fund Managers

Richter - IR Department	Investor Day	Budapest	14 October 2019
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The Company's website ([www.richter.hu](http://www.richter.hu)) includes an area which is intended to meet the specific stated needs of investors, analysts concerning information on Richter's business operations.

The Company's Investor Relations Department at its office in Budapest continues to act as a focal point for contact (Email: [investor.relations@richter.hu](mailto:investor.relations@richter.hu)) with institutional shareholders.

## 5. Analysts Providing Coverage

### Analysts Providing Regular Coverage About the Company During 2019

AEGON Asset Management	Ms Helena Naffa
Bank of America Merrill Lynch	Mr Jamie Clark, Ms Victoria Lambert
Concorde Securities Ltd.	Mr Attila Vágó
Erste Group Bank AG	Ms Vladimíra Urbánková
Jefferies International Ltd.	Mr James Vane-Tempest
J.P. Morgan	Mr Michal Kuzawinski
KBC Securities Hungarian Branch Office	Mr Norbert Cinkotai
Raiffeisen Centrobank AG	Mr Oleg Galbur
WOOD & Company Financial Services, a.s.	Mr Bram Buring
Equilor	Ms Nóra Gyöngy-Kovács

## 6. Information Regarding Richter Shares

### Shares In Issue

The total number of shares in issue at 186,374,860 as of 31 December 2019 remained unchanged from the levels reported as at 31 December 2018.

### Treasury Shares

#### Shares Held by the Company in Treasury

	Reason of purchase	Number	Nominal value (HUF)	% as of share capital	Book value (HUF)
<b>Opening balance</b>		<b>55,330</b>	<b>5,533,000</b>	<b>0.030</b>	<b>294,353,092</b>
<b>out of which owned by Parent Company</b>		<b>49,830</b>	<b>4,983,000</b>	<b>0.027</b>	<b>283,410,724</b>
Purchased	Bonus, Remuneration, programme related to employee shares bonuses	600,000	60,000,000	0.322	3,498,732,375
ESOT repurchased		326,700	32,670,000	0.175	1,876,891,500
ESOT year-end pay-off		6,998	700	0.004	43,128,674
Shares repurchased (OTC)	Bonus, Remuneration	7,752	775	0.004	40,403,424
Repurchased through a programme related to employee shares bonuses	Programme related to employee shares bonuses	13,546	1,354,600	0.007	71,949,208
<b>Total share purchased</b>		<b>954,996</b>	<b>95,499,600</b>	<b>0.512</b>	<b>5,531,105,181</b>
Professional Development Programme		15,327	1,532,700	0.008	87,748,697
ESOT shares transferred		2,260	226,000	0.001	12,938,739
Granted through a programme related to employee shares bonuses		320,534	32,053,400	0.172	1,838,899,481
<b>Total utilization</b>		<b>338,121</b>	<b>33,812,100</b>	<b>0.181</b>	<b>1,939,586,917</b>
<b>Closing balance</b>		<b>672,205</b>	<b>67,220,500</b>	<b>0.361</b>	<b>3,885,871,356</b>
<b>out of which owned by Parent Company</b>		<b>666,705</b>	<b>66,670,500</b>	<b>0.358</b>	<b>3,874,928,988</b>

The table above excludes the shares held by the Employee's Share-Ownership Trust.

The number of shares held by the Group in Treasury increased during 2019.

The Company purchased 600,000 shares on the Budapest Stock Exchange, while a further 7,752 shares were acquired on the OTC market.

In early 2018 the Management of the Company established the Richter Gedeon Plc Employee's Share-Ownership Trust ("Richter ESOT") aiming to strengthen the performance and loyalty of its officers and key employees.

The Company, in accordance with the Foundation Charter and the First Incentive Policy of the Employee's Share-Ownership Trust (ESOT), purchased 326,700 treasury shares from the ESOT in 2019, and pursuing the settlement of accounts between the Company and the ESOT 6,998 treasury shares were transferred to the Company following the conclusion of the ESOT for 2018. In accordance with the Second Incentive Policy of the ESOT the Company transferred 2,260 treasury shares to the ESOT in 2019.

Based on a decision of the Board of Directors of Gedeon Richter Plc., 15,327 shares held by the Company in Treasury were granted as bonuses during 2019 to qualified employees participating in the bonus share programme as well as to members of staff rendering outstanding performance.

In accordance with a repurchase obligation stipulated in the programme related to employee share bonuses, the Company repurchased 13,546 shares from employees who resigned from the Company during 2019.

In a programme related to employee share bonuses, the Company granted a total of 320,534 shares in respect of 4,484 of its employees for 2019. The above shares in the value of HUF 1,839m were deposited at the employees' individual securities accounts at UniCredit Bank Hungary Zrt. to be held until 2 January 2022.

The total number of Company shares at Group level held in Treasury at 31 December 2019 was 672,205, which includes 5,500 ordinary Richter shares held by the Group's subsidiaries, a holding unchanged when compared to the number reported as of 31 December 2018. ESOT owns further 2,260 shares, which are excluded from the above figures.

On 2 January 2020, following the expiry of the lock-up period the Company was able to remove all restrictions on 245,163 Richter ordinary shares granted to its employees on 19 December 2017 according to its programme related to employee share bonuses, thereby enabling these shares to be traded.

### Voting Rights

Article 13.8 of the Statutes of the Company limits the exercise of voting rights to a maximum of 25 percent both for single vote or joint vote exercised by linked interests.

### Registered Shareholders

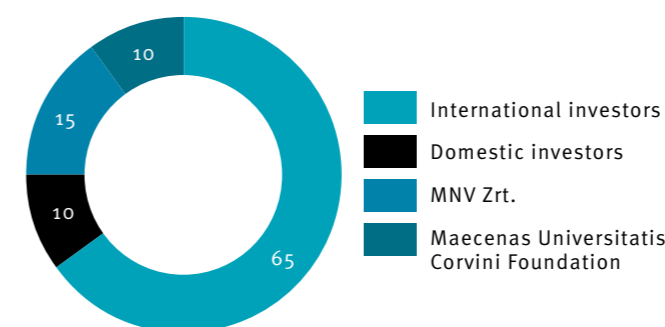
The shares held by the Hungarian State Holding Company (MNV Zrt.) declined to 15 percent as the State conceded a 10 percent stake to the Maecenas Universitatis Corvini Foundation. The proportion held by domestic investors increased to approximately 10 percent while that of international investors slightly decreased to approximately 65 percent. The proportion of treasury shares including the above mentioned holding of subsidiaries was 0.36 percent at the end of 2019.

Data in the table below was compiled based on the share registry adjusted for information provided by KELER Zrt. as clearing company, global custodians and nominees.

Ownership Structure on 31 December 2019			
Ownership	Ordinary shares	Voting rights %	Share capital %
Domestic ownership	64,010,047	34.47	34.34
State ownership total	47,052,641	25.34	25.24
out of which MNV Zrt.	28,415,029	15.30	15.24
out of which Maecenas Universitatis Corvini Foundation	18,637,486	10.04	10.00
out of which Municipality	126	0.00	0.00
Institutional investors	8,411,253	4.53	4.51
Retail investors	8,546,153	4.60	4.59
International ownership	121,677,349	65.52	65.29
Institutional investors	121,381,988	65.36	65.13
Retail investors	295,361	0.16	0.16
Treasury shares*	674,465	0.00	0.36
Undisclosed ownership	12,999	0.01	0.01
<b>Share capital</b>	<b>186,374,860</b>	<b>100.00</b>	<b>100.00</b>

Note: \*Treasury shares include the combined ownership of the parent company, the subsidiaries and the Employee's Share-Ownership Trust.

Detailed ownership structure as of 31 December 2019 (%)



### Ordinary Shareholdings by the Members of the Company's Boards

	31 December 2019 Number of ordinary shares	31 December 2018 Number of ordinary shares
Board of Directors	51,599	51,599
Supervisory Committee	1,967	2,313
Executive Board	4,727	24,119
<b>Total</b>	<b>58,293</b>	<b>78,031</b>

Membership of the Company's Boards is shown on pages 21-24 of the Annual Report.

## 4. Corporate Governance

Corporate Governance principles and practice implemented by the Company are in accordance both with the guidelines set by the Budapest Stock Exchange and the directives of the capital market.

Gedeon Richter's key principles of Corporate Governance are to create and maintain satisfactory dialogue with shareholders so as to enhance shareholder value, to differentiate the roles and responsibilities of the Board of Directors, the Executive Board and the Supervisory Board, and to operate the Group's business in compliance with legal and regulatory requirements and to maintain the highest ethical standards.

The Annual General Meeting ranks as the highest decision making body of the Company, and comprises all shareholders. The Annual General Meeting decides on the adoption of the annual financial statements and the appropriation of profit, the election or removal of members of the Board of Directors, Supervisory Board and Audit Board, the appointment of the statutory auditor, amendments to the Statutes, changes in the Company's share capital and other issues in its competence. With the exception of cases where the presence of a larger number of shareholders is required in order to constitute a quorum, a quorum of the General Meeting exists if shareholders, personally or through their representatives, representing over half of the votes embodied by voting shares are present at the General Meeting and have duly evidenced their shareholder representative status. If the General Meeting has no quorum, the General Meeting is required to be reconvened. With the exception of cases where under given circumstances the presence of a larger number of shareholders is required in order to constitute a quorum, the reconvened General Meeting shall have a quorum for the purpose of considering items on the agenda of the original General Meeting if shareholders representing more than 20 percent of the votes relating to the voting shares issued by the Company are present personally or via proxy at the reconvened General Meeting and their shareholding or representation right has been duly evidenced.

The Board of Directors is the ultimate decision making body of the Company except with respect to those matters reserved for shareholders. A majority of Directors of the Board are Non-Executive Directors. All the non-executive directors are independent of management and free from any business or other relationship that could materially interfere with the exercise of their independent judgment. The Board meets regularly, throughout the year. According to the Statutes, it has a formal schedule of matters reserved to it for decisions. The Board works to an agreed agenda in reviewing the key activities of the business and the Company's long-term strategy. The Company Secretary is responsible to the Board and is available to individual Directors in respect of Board procedures. Board members are elected and re-elected at the AGM for a maximum term of 5 years. Since 2004 two subcommittees of the Board exist which prepare and submit proposals contributing to the Board's decision making process. The subcommittees each consist of at least three members the majority of whom are non-executive independent Board directors.

The Corporate Governance and Nomination Subcommittee is responsible for considering and making recommendations to the Board concerning the appropriate size, functions and needs of the Board. This responsibility includes establishing the criteria for Board membership; conducting appropriate inquiries into the background and qualifications of possible candidates; considering matters of corporate governance and reviewing periodically our Corporate Governance Principles.

The Compensation Subcommittee is responsible for establishing annual and long-term performance goals and objectives for elected officers. This responsibility includes preparing a proposal for the compensation of the Chief Executive Officer.

The Executive Board is responsible for the executive management of the Company's business. The Executive Board is chaired by the Chief Executive Officer.

Overseeing the management of the Company is the Supervisory Board. It meets regularly during the year in accordance with legal requirements and at other times when necessary to consider details of the Company's operating activities. It submits proposals to the Board of Directors and discusses the Company's strategy, financial results, investment policy and systems of internal audit and control. The Supervisory Board is provided with regular and detailed information about the management of the Company. The Chairman of the Supervisory Board may attend meetings of the Board of Directors as an advisor. The members of the Supervisory Board are elected or re-elected from time to time at the AGM for a maximum term of 3 years.

The Audit Board is responsible for the oversight of the Company's internal accounting standards. The Board consists of three independent members of the Supervisory Board who are elected by the AGM. Furthermore, among others, observing the enforcement of the professional, conflict of interest and independency requirements applicable to the statutory auditor and monitoring of other services provided by the statutory auditor to the Company or the companies controlled by the Company, besides the auditing of consolidated and individual annual reports, belong in the scope of competences and tasks of the Audit Board.

## 5. Company's Boards

### Board of Directors

#### Lifetime Honorary Chairman

##### Mr William de Gelsey (1921)

Senior adviser to CA IB Corporate Finance Limited, Member of UniCredit Markets & Investment Banking Division Vienna, London and Budapest. More than 50 years of international investment banking experience. Has significant banking experience in Hungary. A graduate of Trinity College, Cambridge. Member of the Board of Directors from 1995 to April, 2017. Chairman of the Board between 1999 and 2016. Lifetime Honorary Chairman of the Company since January 2017.

##### Mr Erik Bogsch (1947)

Chemical engineer, qualified economic engineer. With Richter since 1970, initially in a number of Research and Development management positions. Medimpex director in Mexico from 1977 to 1983. Managing Director of Medimpex UK from 1988 to 1992. Member of the Board of MAGYOSZ, Chairman between 2006 and 2016. Managing Director of Gedeon Richter from 1992 to November 2017. Member of the Board of Directors from 1992. Chairman of the Company's Board of Directors. Executive Director responsible for Commercial, for Legal and Global Operations, for PR and Government Relations of the Company, since 1 November 2017.

##### Dr György Bagdy (1955)

Professor of pharmacology and toxicology, Pharm. D., PhD at Semmelweis University, DSc at the Hungarian Academy of Sciences (MTA). Fogarty Visiting Fellow at the Section on Clinical Neuropharmacology, Laboratory of Clinical Science, National Institute of Mental Health (NIMH – Bethesda, USA) between 1986 and 1989. From 1991 to 2001 fellow of the National Institute of Psychiatry and Neurology, Hungary, from 2002 to 2007 its scientific director. Head of Department of Pharmacodynamics at the Faculty of Pharmacy, Semmelweis University since 2008. Vice rector for scientific affairs at Semmelweis University between 2015 and 2018. In 2012 he received the Academy award of the Hungarian Academy of Sciences and in 2014 he was granted the Issekutz Award. Joined the Board in 2019.

##### Dr Gábor Gulácsi (1958)

Appointed Deputy Managing Director upon joining the Company in 2000. Responsible for Finance. Economist, University doctorate in Economic Sciences. He began his professional career in 1981 as a fellow researcher at the Institute for Economic Planning. He joined in 1988 the team for strategic analyses of the Ministry of Transport and Telecommunication and in 1990 he became Deputy Secretary of State in the Ministry of Industry and Trade and its legal successors. Between 1996 and 1998 he was a member of the management team of Pénzüntézet Központ Rt. and later of Pannonplast Rt. He served as a Secretary of State in the Ministry of Economic Affairs between 1998 and 2000. He joined the Board in 2010.

##### Dr Ilona Hardy (1956)

Lawyer, securities specialist. Began her professional career at Hungarian State Development Bank. Between 1988 and 1990 Head of Securities Trading Secretariat. Between 1990 and 1992 founder CEO of the Budapest Stock Exchange and member of its Board. From 1992 to 1994 Board Member of Hungarian State Property Agency, Privatization Agencies (ÁVÜ, ÁPV). Currently Chairperson of the Board „Aranykor” Voluntary Pension Fund, member of the Budapest Stock Exchange Advisory Committee, Chair of the Supervisory Board of BOM, deputy chair of the Hungarian Atlantic Council, Board member of National Association of Voluntary Funds. Member of the Company's Board of Directors since April 2017.

##### Mr Csaba Lantos (1962)

Economist and sociologist. Employee of Budapest Bank from 1987, later employee of Creditanstalt Group. At the end of the 1990's leader of CA-IB, then from 2000 to 2007 deputy CEO and member of the Board of Directors of OTP Bank Nyrt. Currently member, Chairman of the Board of Directors and of the Supervisory Board of several Hungarian and international companies. Joined the Board in 2010.

### Mr Gábor Orbán (1979)

Began his professional career as an economist for the National Bank of Hungary and the European Central Bank. He later joined Aegon Asset Management where he worked as a fund manager and the Head of the fixed income desk. He served as the State Secretary in charge of taxation and the financial sector at the Ministry for National Economy for two and half years, followed by a year spent at Banque Rothschild where he worked as a consultant. He earned his MA degree at the Budapest University of Economics and studied also in the United States. Richter's Director of Corporate Strategy since September 2016, Chief Operating Officer since 1 January 2017. Member of the Company's Board of Directors from April 2017. Appointed Chief Executive Officer from 1 November 2017.

### Dr Anett Pandurics (1973)

Economist, from 1998 to 2001 consultant at IFUA Horváth & Partner Ltd. From 2001 to 2005 Strategic Coordination Director at Magyar Posta Rt. From 2005 Chief Executive Officer and Chairman of the Board of Directors of Hungarian Post Insurance Co. (Magyar Posta Biztosító Zrt.) and Hungarian Post Life Insurance Co. (Magyar Posta Életbiztosító Zrt.). Since 2009 Executive Board Member of the Association of Hungarian Insurance Companies, from 2013 its President. Member of the Board of Directors since April, 2018.

### Mr Bálint Szécsényi (1974)

Economist, graduated at the Budapest University of Economics. Employed by Equilor Investment Ltd. since 2000, Corporate Finance Director from 2002 to 2004, Managing Director between 2005 and 2009. Since 2010 Chief Executive Officer at Equilor Investment Ltd. Chairman of the Supervisory Board at Equilor Asset Management Ltd. and Chief Executive Officer of Central-Eastern European Private Equity and Venture Capital Management Ltd. Vice-president of Budapest Stock Exchange between 2011 and 2015. Member of the Board of Directors since April, 2018.

### Prof. Dr Szilveszter E. Vizi (1936)

Medical doctor, academician. Graduated from Semmelweis University of Medicine. From 1989 to 2002 Director of the Institute of Experimental Medicine (IEM) of the Hungarian Academy of Sciences. President of the Hungarian Academy of Sciences between 2002 and 2008. Currently a researcher at the IEM. Joined the Board in 2008.

### Dr Kriszta Zolnay (1966)

MSc in Pharmacy, Doctor of Pharmacy, international marketing expert. From 1992 to 2002 worked at Roche Magyarország Kft. as a medical representative and coordinated clinical trials as a biotechnological product specialist. From 2002 to July 2015 Managing Director of one of Hungary's largest pharmacies, Szeged's Kígyó Pharmacy. From July 2015 to June 2019 Managing Director of Gedeon Richter UK Ltd. and Medimpex UK Ltd. headquartered in London. Joined the Board of Directors in 2014.

## Executive Board

### Mr Gábor Orbán (1979)

Began his professional career as an economist for the National Bank of Hungary and the European Central Bank. He later joined Aegon Asset Management where he worked as a fund manager and the Head of the fixed income desk. He served as the State Secretary in charge of taxation and the financial sector at the Ministry for National Economy for two and half years, followed by a year spent at Banque Rothschild where he worked as a consultant. He earned his MA degree at the Budapest University of Economics and studied also in the United States. Richter's Director of Corporate Strategy since September 2016, Chief Operating Officer since 1 January 2017. Member of the Company's Board of Directors from April 2017. Appointed Chief Executive Officer from 1 November 2017.

### Mr Erik Bogesch (1947)

Chemical engineer, qualified economic engineer. With Richter since 1970, initially in a number of Research and Development management positions. Medimpex director in Mexico from 1977 to 1983. Managing Director of Medimpex UK from 1988 to 1992. Member of the Board of MAGYOSZ, Chairman between 2006 and 2016. Managing Director of Gedeon Richter from 1992 to November 2017. Member of the Board of Directors from 1992. Chairman of the Company's Board of Directors. Executive Director responsible for Commercial, for Legal and Global Operations, for PR and Government Relations of the Company, since 1 November 2017.

### Dr István Greiner (1960)

Appointed Research Director in 2014. Chemical engineer (M.Sc), a qualified patent attorney, has a PhD and an MBA degree (Open University, UK). Joined Richter in 1984 and has held a number of management positions including Head of Chemical R&D, Head of the Patent Department between 1996 and 1999. In 2001 he was appointed Deputy to the Research Director and from 2006 he also became responsible for the new recombinant biotechnological activity of the Company.

### Dr Gábor Gulácsi (1958)

Appointed Deputy Managing Director upon joining the Company in 2000. Responsible for Finance. Economist, dr. univ. in Economic Sciences. He began his professional career in 1981 as a fellow researcher at the Institute for Economic Planning. He joined in 1988 the team for strategic analyses of the Ministry of Transport and Telecommunication and in 1990 he became Deputy Secretary of State in the Ministry of Industry and Trade and its legal successors. Between 1996 and 1998 he was a member of the management team of Pénzüntézet Központ Rt. and later of Pannonplast Rt. He served as a Secretary of State in the Ministry of Economic Affairs between 1998 and 2000. He joined the Board in 2010.

### Mr Tibor Horváth (1974)

Appointed Commercial Director since August, 2017. Has an MSc in Biology and Chemistry and an MBA in Marketing and International Commerce. Joined Richter in 1999 as a market analyst then worked as a licensing manager. In 2005 he was appointed Managing Director of Richter's German subsidiary Gedeon Richter Pharma GmbH, where he worked until August 2017.

### Dr György Thaler (1959)

Appointed Development Director in 1993. Chemical engineer, University doctorate in Chemical Sciences. With Richter since 1983 in a number of management positions. Member since 2001 of the Executive Committee and of the Board of Medicines for Europe (former European Generics Medicines Association, EGA) and Chairman of the Legal Affairs Committee of the same organization since its establishment.

## Supervisory Board

### Dr Attila Chikán (1944)

Professor of the Corvinus University of Budapest, Business Economics Department. Manager of the Competitiveness Research Centre, doctor of the Hungarian Academy of Sciences. Between 2000 and 2003 Rector of the Budapest University of Economics and Public Administration. From 1998 to 1999 Minister of Economy. Chairman of the Supervisory Board since 2000. Member, Chairman of Audit Board.

### Prof. Dr Jonathán Róbert Bedros (1961)

Physician, health economist, honorary associate professor. Graduate of Semmelweis Medical University. Head physician and General Director of the Ministry of Interior's Central Hospital and Institutions from 1999 to 2005, and of Pest County Flór Ferenc Hospital from 2006 to 2011. Currently Head Physician and General Director of Szent Imre Hospital. Joined the Supervisory Board in 2012. Member of the Audit Board.

### Dr Zsolt Harmath (1975)

Economist, certified accountant. In 2005 he graduated in law as a second degree. From 1999 to 2010 employed by Magyar Posta Zrt. in different financial positions. From 2003 to 2004 Deputy Manager of Finance; from 2005 responsible for the Company's SAP System. From 2010 Director of Controlling, CPA and Property appraisal at Hungarian National Asset Management Inc. Since 2014 Director responsible for Finance at Hungarian National Asset Management Inc. He is a member of the Board of Directors of National Business Services Ltd. and HM ARMCOM Zrt. Chairman of the Supervisory Board of FHB Mortgage Bank Co. Plc. and BMSK Zrt. Member of the Supervisory Board of RÁBA Nyrt. and Magyar Közlöny Lap- és Könyvkiadó Korlátolt Felelősségű Társaság. Joined the Supervisory Board and Audit Board in April, 2018.

#### Mrs Klára Kovácsné Csikós (1954)

Employee representative. Chemical technician, general manager of advanced level. With Richter since 1972. Formerly laboratory technician, official in charge of innovation, then technologist. Currently manager assistant at the Department of Technical services. Member of the Works Council since 2007. Chairman of the Works Council since 2010. Joined the Supervisory Board in 2015.

#### Dr Éva Kovácsné Kozsda (1962)

Employee representative. Chemical engineer, quality management auditor, MBA. With Richter since 2003. Formerly product manager at the Department of Technician services. Currently project official in charge of active ingredients at Department of Chemistry. Joined the Supervisory Board in 2015.

## Changes to Boards during 2019

At the Annual General Meeting held on 24 April 2019  
Dr György Bagdy

was appointed to the Board of Directors for a 3 (three) year period until the 2022 AGM.

At the Annual General Meeting the following were reappointed to the Board of Directors for a 3 (three) year period until the 2022 AGM  
Mr Csaba Lantos  
Dr Gábor Gulácsi.

The membership of Dr. Norbert Szivek in the Board of Directors expired on the date of the AGM 2019.

With effect from 31 August 2019, Mr János Csák resigned from his membership in the Board of Directors of Gedeon Richter Plc.

## 6. Employees in Leadership Position Directly Supporting the Activities of the Executive Board

The finetuning of strategic targets executed during 2019 was followed by a certain reorganisation of the Company's executive tasks.

The Executive Board is directly supported in its activities by the directors of the following functional areas: HR, manufacturing, regulatory science and quality control.

#### Katalin Erdei (1974)

After graduating at the University of Szeged from the Faculty of Arts, Katalin Erdei has gained 18 years of experience in the field of human resource management. She worked in various positions at companies such as Győri Keksz Kft, Ferrero Hungary and then Mars Hungary and Global. From 2012, she was a member of the management board at Mars' Hungarian subsidiary and from 2015, she worked as a Regional HR Manager at the European headquarters of Mars Inc, in Germany. She has joined Richter in 2018 to drive the global HR agenda of our Company.

#### Dr Imre Péter (1960)

Pharmacist, specialist pharmacist, university doctor of pharmacy. He graduated from Semmelweis Medical University. He started his career at Richter in 1984, initially as an analyst in quality control. He has been the Director of Quality Management since 1999, supervising Quality Assurance and Quality Control.

#### Attila Szénási (1984)

Director of Pharmaceutical manufacturing, joined the Company at the beginning of 2019. Responsible for the production of Budapest and abroad manufacturing sites. Chemical engineer with a degree in organizational management. Gained experience at well known multinational companies in chemical and pharmaceutical industries and in global environment before entering to the Company.

#### Tamás Szolyák (1966)

Joined to the company in September, 2018 as Head of Regulatory Science. He began his carrier as medical representative in 1992. Worked for Novartis and its predecessor companies for 21 year. He filled various position in sales and marketing. Between 2007 and 2013 he was the General Manager of the Hungarian affiliate of Novartis. Within this period he was the President of AIPM, the local association of innovative companies. From 2013 he focused on healthcare projects, covering development scenarios for the Hungarian primary care system. Joined to the Hungarian National Authority of Pharmacy, where he was responsible for regulatory and patient safety matters.

## 7. Risk Management

Richter is committed to long term value creation for all its stakeholders, including its customers, investors, employees, and to society at large. In order to succeed in this endeavour Richter operates a risk management system which abides by the highest international standards and best industry practices. Richter views Risk Management as one of the tools for effective Corporate Governance. Management attempts to identify, to understand and to evaluate in due time emerging risks and to initiate such successful corporate responses that ensure both a stable and sustainable operation of the Company and the implementation of its corporate strategy.

### Elements of the comprehensive Risk Management model

at the Company are as follows:

- the Board of Directors is responsible for the supervision and management of risk management procedures;
- Directors responsible for each strategic pillar are in charge with the mitigation of strategic risks;
- Leaders of corporate functional units are responsible for the mitigation of emerging risks within their scope of activity, while Quality Management and Regulatory Affairs mitigate various cross-functional risks;
- Sales related compliance risks are mitigated through a centralised, separate functional unit;
- Financial risks are mitigated in a centralised manner by the Financial Directorate;
- The adequacy of internal risk management procedures are monitored by the Audit Department in accordance with an approved annual plan and reports on the efficiency of the internal controls in place are delivered at least once a year to the Supervisory Board and the Audit Committee.

Most important risk factors of Richter Group are shown on the next pages of the Report.

Regarding changes of risks during 2019 increasing ▲, decreasing ▼, or unchanging risks ► are also displayed on the following pages.

### Strategic risks

Risk area	Description of risks	Major risk management actions taken	Impact changes in 2019
<ul style="list-style-type: none"> <li>• Outstanding contribution of Cariprazine to the turnover and profits of the Company</li> </ul>	<ul style="list-style-type: none"> <li>• The contribution of Cariprazine depends crucially by the turnover recorded by our USA licence partner and the longterm prevalence of the pricing environment rewarding the introduction of innovative products.</li> </ul>	<ul style="list-style-type: none"> <li>• Trials aiming to expand the indication and PASS trials co-managed with our USA based partner and geographic expansion of the coverage area by making licensing-out agreements with new partners.</li> </ul>	►
<ul style="list-style-type: none"> <li>• Higher risks associated with CNS research projects advancing into higher phases</li> </ul>	<ul style="list-style-type: none"> <li>• A number of CNS research projects step into clinical development phase associated with significantly increasing costs and with a maintained high failure rate.</li> </ul>	<ul style="list-style-type: none"> <li>• Regular overview of the projects based on strict evaluation criteria (go/no go type of decision) and a search to partnering for development and marketing licence as soon as the proof of concept is met.</li> </ul>	▲
<ul style="list-style-type: none"> <li>• Development and marketing of WHC and biosimilar specialty products using own and licence partners' resources</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical trials associated with higher costs and risks are required and special regulatory requirements are needed for the marketing approval when compared to generic developments while limited R&amp;D resources are at the disposal of the Company.</li> </ul>	<ul style="list-style-type: none"> <li>• Reorganisation of medical and regulatory activities, strict monitoring of clinical studies and CROs.</li> <li>• Concluding complex agreements of co-operation aiming at the development and licensing-out of WHC specialty and biosimilar products.</li> </ul>	►
<ul style="list-style-type: none"> <li>• Maintaining the turnover proceeding from branded generic products</li> </ul>	<ul style="list-style-type: none"> <li>• Main markets of branded generic products are impacted by government interventions aiming at price reduction, sharp competition, price erosion and a short product life.</li> </ul>	<ul style="list-style-type: none"> <li>• Well chosen new generic products and first market introductions on our main geographies.</li> </ul>	►
<ul style="list-style-type: none"> <li>• Protection of our traditional product portfolio in a worsening market environment</li> </ul>	<ul style="list-style-type: none"> <li>• Narrowing of indication or market ban subsequent to potential reporting of adverse events or failure to completely meet all the regulatory requirements cumulated over time.</li> </ul>	<ul style="list-style-type: none"> <li>• Higher attention to PV issues, active regulatory-related dialogue with Authorities, carrying out development projects to maintain validation.</li> </ul>	▲

## Pharmaceutical industry related price reimbursement, operational and compliance risks

Risk area	Description of risks	Major risk management actions taken	Impact changes in 2019
<ul style="list-style-type: none"> <li>Negative changes in pricing and reimbursement system in the CEE region, in Russia and in China, clawback liabilities in the European countries</li> </ul>	<ul style="list-style-type: none"> <li>Price reduction and number restriction of reimbursed products in the CEE region, in Russia and in China, claw back-related liabilities.</li> </ul>	<ul style="list-style-type: none"> <li>New product launches, focusing the promotion to the least exposed product portfolio;</li> </ul>	▲
<ul style="list-style-type: none"> <li>Difficulties in accessing qualified staff in the Central and East European companies of the Group</li> </ul>	<ul style="list-style-type: none"> <li>It is increasingly difficult to hire qualified staff for pharmaceutical manufacturing on the Hungarian, the Romanian and the Polish labour market.</li> </ul>	<ul style="list-style-type: none"> <li>Wage increases and methods aiming at longterm commitment to company are being employed;</li> <li>Exceptional wage rise was applied in the manufacturing companies during 2019; launch of in-house qualification programmes;</li> <li>Relocation of the manufacturing to Russia;</li> <li>University training co-operations.</li> </ul>	▶
<ul style="list-style-type: none"> <li>Lower output and higher costs associated with the implementation of EU serialisation and with the preparation for the serialisation in Russia</li> </ul>	<ul style="list-style-type: none"> <li>Unique identification tags printed on boxes and the transfer of such tags through the IT system requires massive investment, negatively impacts the output and causes market shortages.</li> </ul>	<ul style="list-style-type: none"> <li>Additional staff employed, introduction of weekend shifts, acquisition of additional packaging lines.</li> </ul>	▶
<ul style="list-style-type: none"> <li>Drug development and manufacturing has to meet quality requirements which may be extremely high in certain cases, monitoring of potential adverse events and product liability through the entire lifespan of the product</li> </ul>	<ul style="list-style-type: none"> <li>Non-compliance with GMP, GLP, GCP, GDP, IT GXP, PV may result in the revocation of activity licences;</li> <li>Quality defects, delays, uncompetitive cost levels, loss of reputation due to supplier deficiencies;</li> <li>New side effects, contamination, manufacturing fault, intentional damage, counterfeiting;</li> <li>Use of unique identification tags („serialisation”) on drug boxes becomes a condition for market entry and for ongoing market presence since 2019.</li> </ul>	<ul style="list-style-type: none"> <li>Production based on Market Authorisation, Quality Assurance;</li> <li>Application of quality assurance systems, SOP controlled operation;</li> <li>Development of own API in the case of key products;</li> <li>Applying a supplier rating system seeking to register alternative suppliers;</li> <li>Product liability insurance, general liability insurance, compensation.</li> </ul>	▶
<ul style="list-style-type: none"> <li>Selling practices that comply with ethical standards in the industry, high level of data protection</li> </ul>	<ul style="list-style-type: none"> <li>Employee behavior that violates the ethical and advertising rules of drug promotion;</li> <li>Non-compliance with GDPR requirements due to unauthorised use of personal data or inadequate data protection.</li> </ul>	<ul style="list-style-type: none"> <li>Compliance programme approved by the Board of Directors;</li> <li>By-laws on GDPR and getting ready to comply;</li> <li>IT security development.</li> </ul>	▶

<ul style="list-style-type: none"> <li>Ensuring high availability of pharmaceutical equipment and IT systems</li> </ul>	<ul style="list-style-type: none"> <li>API manufacturing is a dangerous operation, risk of fire and explosion;</li> <li>Product shortages subsequent to unexpected plant shutdown;</li> <li>Individual machine failure leading to lowering output, inspection risk due to obsolescence;</li> <li>IT server failure, scarcity of data transfer capacities, unauthorised access, data theft.</li> </ul>	<ul style="list-style-type: none"> <li>Production safety measures, insurance on property and on downtime as recommended by the Risk Survey;</li> <li>Adequate level of capacity maintenance, maintenance and troubleshooting;</li> <li>Investments in IT and measures to improve availability and security.</li> </ul>	▶
<ul style="list-style-type: none"> <li>Maintaining a high standard workplace safety and health system;</li> <li>Applying procedures to reduce environmental load to limit values</li> </ul>	<ul style="list-style-type: none"> <li>API exposure, workplace accidents, labour loss, compensation;</li> <li>Stringent environmental load limits (noise, dust, sewage) must be adhered to, expensive waste disposal must be carried out.</li> </ul>	<ul style="list-style-type: none"> <li>Application and certification of MEBIR system;</li> <li>Comprehensive life and accident insurance;</li> <li>Operating corporate environmental organisation, Environmental Management System (EMS), monitoring qualification, investments.</li> </ul>	▶

## Financial risks

Risk area	Description of risks	Major risk management actions taken	Impact changes in 2019
<ul style="list-style-type: none"> <li>Currency risk</li> </ul>	<ul style="list-style-type: none"> <li>The Group is highly exposed to RUB and USD on the revenue side, exchange rate fluctuations may distort all income in HUF and EUR.</li> </ul>	<ul style="list-style-type: none"> <li>Natural hedge to some extent by cost items occurring in the same currency;</li> <li>Financial hedging operation on the basis of authorization granted by the Board of Directors.</li> </ul>	▶
<ul style="list-style-type: none"> <li>Buyer credit risk</li> </ul>	<ul style="list-style-type: none"> <li>Certain markets in the Richter Group (CIS and Other markets) and some affiliated companies (Romanian wholesale company) face increased buyer credit risk.</li> </ul>	<ul style="list-style-type: none"> <li>Extended MEHIB trade credit insurance for CIS markets and for the Rest of the World region of the Richter Group;</li> <li>Current COFACE insurance for Romanian Pharmafarm customers</li> </ul>	▼
<ul style="list-style-type: none"> <li>Risk of investing in free funds</li> </ul>	<ul style="list-style-type: none"> <li>At the parent company a secured reinvestment scheme for temporary free cash must be achieved;</li> <li>At subsidiaries, a secured management of occasionally significant amounts of free funds is sometimes required.</li> </ul>	<ul style="list-style-type: none"> <li>Parent company: Adoption, strict adherence to, and control of financial regulations at board level;</li> <li>Centralized control of excess funds at subsidiaries.</li> </ul>	▶
<ul style="list-style-type: none"> <li>Taxation related risks</li> </ul>	<ul style="list-style-type: none"> <li>Parent company: certification of eligibility for tax benefits on basis of R&amp;D and royalty;</li> <li>Group: certification of transfer pricing between affiliated companies.</li> </ul>	<ul style="list-style-type: none"> <li>Procedure for the settlement royalty-linked tax allowances negotiated with Tax Authority, the accumulation of tax loss carrying forward (TLCF) opportunities resulting from the Parent Company's annual negative tax base;</li> <li>Group transfer price: Masterfile based on established rates, local transfer pricing documentation.</li> </ul>	▼

## 8. Recent Litigation

On 20 December 2019, subsidiaries of the Company and Gedeon Richter Plc. brought an action for infringement of U.S. Patent Nos. 7,737,142 ("the '142 patent"), and 7,943,621 ("the '621 patent") in the United States District Court for the District of Delaware against Aurobindo Pharma Limited és Aurobindo Pharma USA, Inc. (collectively, "Aurobindo"), Sun Pharmaceutical Industries Limited and Sun Pharma Global FZE (collectively, "Sun"), and Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Limited d/b/a Zydus Cadila (collectively, "Zydus") in connection with abbreviated new drug applications, respectively filed with the FDA by Aurobindo, Sun and Zydus, seeking approval to market generic versions of VRAYLAR® and challenging said patents. The '142 patent expires in September 2029, and the '621 patent expires in December 2028. No trial date or case schedule has been set.





# 3

Chief Executive  
Officer's Review





**Gábor Orbán**  
Chief Executive Officer

I am pleased with the significant progress that we achieved in 2019 in shifting the composition of our turnover towards specialty products. Turnover proceeds from these products increased to around 50 percent of total pharma sales, which I consider to be an important step in executing our strategy.

In order to accelerate the implementation of the strategy and to cope with the challenges we are facing, our management team initiated during the year a thorough review of our corporate strategy. We now follow a redefined, more specific list of strategic initiatives with related KPIs and action plans.

VRAYLAR® continued to be the fastest-growing atypical antipsychotic brand in the US, physician and patient experience and satisfaction with this product remained at very high levels. Allergan continued to support VRAYLAR® with a market-leading peer-to-peer promotional program and direct-to-consumer advertising. The FDA approval published in May 2019, authorising the extended use to include bipolar depression to the label, significantly boosted the number of prescriptions and in turn the sales of VRAYLAR®. In the meantime Allergan and AbbVie Inc. entered into a transaction agreement under which AbbVie initiated the acquisition of Allergan. Should the deal be approved we are looking forward to cooperating with AbbVie in the future to further exploit the maximum potential of VRAYLAR®.

Following the initial launch of cariprazine in the USA and its introduction to the EU and CIS markets over the past few years, we succeeded through several bilateral agreements towards a global presence for cariprazine. As a result of our successful partnering activity we have signed a series of agreements with companies to commercialise the product in Australia, New-Zealand, Latin America, the MENA region and in South Korea. Richter's Japanese license partner, Mitsubishi Tanabe obtained marketing authorisation for cariprazine in Singapore and Thailand during the reported year.

I can also report on significant progress achieved by our other specialty initiative, i.e. the biosimilar business where we have successfully launched our first own developed biosimilar, TERROSA® (teriparatide). I am pleased in particular that we were first to hit the market in geographical Europe. In addition, our license partner, Mochida, launched the product in November 2019 on the Japanese market.

Our key specialty area remains Women's Healthcare, where we provide one of the broadest range of products available to women of all age groups. In order to pursue these objectives, in October 2019 we have entered into a license and development and technology transfer agreement with Mycovia Pharmaceuticals, Inc. to commercialise and manufacture the product codenamed VT-1161, currently in Phase III clinical trials for the treatment of Recurrent Vulvovaginal Candidiasis. This is an unmet need in the women's healthcare therapeutic field with currently available treatment options addressing this condition only on a temporary basis. VT-1161 is designed to have greater selectivity, fewer side effects and improved efficacy.

In March 2020 the Pharmacovigilance Risk Assessment Committee has started a new review procedure following a recent case of liver injury in a patient taking ESMYA® and sales activities of the product were temporarily suspended. Patient safety is paramount for Richter and we continue to support regulatory authorities in this matter.

The developments outlined above were complemented by an overall favourable FX environment, which contributed to our good sales results reported in 2019 by close to HUF 15bn.

The challenges facing branded generic markets worldwide affected also our business rather negatively during 2019. Our production capacities were impaired by the implementation of measures connected to serialization and this had a negative impact on our sales figures in H1 last year. These measures commanded high capital expenditure levels linked to the commission of packaging hardware and monitoring software, which in turn has led to increasing costs of operation together with higher levels of headcount and wages. In addition to the above, certain price cuts were implemented by the Russian authorities during 2019. Prices of drugs included in the Essential Drug List are expected to be reviewed again during 2020, and therefore we expect those downward pressures to be sustained in this market. A further negative impact occurred in the second half of 2019 in China, where local authorities announced the exclusion of CAVINTON from the reimbursement list. Though the changes came into force with effect from 1 January 2020, distributors acted in anticipation by restricting orders as early as 2019. A defensive strategy is being pursued in this business segment in order to offset these factors as much as possible. Investing in our operations selectively with the aim of enhancing their resilience and cost-effectiveness supports our endeavor to achieve this goal.

Accelerating our portfolio renewal requires additional funding of our R&D activities. The healthy progress of our ongoing research projects requires higher levels of spending. By providing the additional funding, we demonstrate our commitment to creating a sustainable product pipeline.

Our operating and net profit levels were hit by impairment losses accounted for primarily in respect of the ESMYA® intangible asset during the reported year. A first write-off became necessary in the third quarter 2019 because twelve months passed since Allergan received a Complete Response Letter from the FDA and no satisfactory conclusion was reached in the regulatory submission process of ulipristal acetate in the USA. An additional impairment loss had to be accounted for in respect of the ESMYA® intangible asset in the last quarter 2019 with the termination of European data exclusivity in mind. This will occur with effect from May 2020.

Our Group reported HUF 507,794m consolidated sales in 2019, representing a 14 percent increase when compared with 2018.

Cariprazine related revenues amounted to HUF 57,686m, which includes a HUF 47,565m royalty component and a one-off sales related milestone payment in the amount of HUF 7,072m.

Profit for the year was HUF 48,430m in 2019, representing a HUF 12,237m year-on-year increase.

The Group delivered a strong performance in 2019 and we started 2020 in a good position. Looking ahead to 2020 and beyond, I am optimistic for the future of Richter. Whilst market conditions are likely to remain challenging, we have demonstrated the resilience of our businesses. I believe we have set ourselves the right strategic objectives and have a strong leadership team in place to deliver sustainable growth over the long term. Finally, I would like to thank my colleagues across Richter Group for their hard work and dedication, and our shareholders for their continued support.



Gábor Orbán  
Chief Executive Officer



# 4

## Strategic Initiatives



An in-depth review of Richter's operations has led the Management Team to refocus the Company's strategy thus and realign corporate resources to changing environmental challenges.

Aiming to maximise shareholder value the Management Team has identified the following strategic targets:

- building a high added value portfolio
- achieving sustainable growth while maintaining margin levels
- successfully carrying out high entry barrier activities
- keeping and whenever possible improving the importance of brands
- establish a healthy balance between long term value creation and short life-cycle generic drugs

Consequently the following strategic initiatives have been defined:

## 1. Cariprazine

Cariprazine was discovered by Richter scientists in the early 2000s and co-developed with Forest Laboratories until its launch in 2016 in the USA with two indications: schizophrenia and bipolar mania. Cariprazine was also approved by the EMA in 2017 for the schizophrenia indication. In 2019 bipolar depression was added by the FDA to the product label in the USA. This strategic pillar aims towards maximizing cariprazine's market potential by extending the range of existing formulations, by widening the therapeutic scope and by extending its geographical availability.

## 2. Original Research – Focus on CNS

Research of new chemical entities has always been of paramount importance to our corporate strategy. In 2014 as a consequence of increasing pressure to improve cost efficiency, a thorough review of our CNS portfolio resulted in a number of projects being either terminated or suspended. Notwithstanding, building on the scientific and commercial success of cariprazine, our research team continues to focus on central nervous system related disorders.

An adjustment in the research concept occurred in 2019 when symptomatic research criteria replaced the previous indication based approach. Symptoms are grouped into three clusters, such as cognitive, negative and positive, which can be traced back to a number of indications. This strategic initiative aims towards submitting for registration within a strategic time horizon a new target molecule by managing in a cost effective way a healthy project pipeline with the involvement of new development partners.

## 3. Women's Healthcare

One of Richter's most important niche areas is its Women's Healthcare business with unique and long-term experience in this therapeutic field. The Company has consistently utilised its pharmaceutical manufacturing facilities to undertake the required complex and lengthy development processes which result in high quality gynaecological products. The strategic aim of this initiative is to reach a leading position in geographical Europe by entering into novel WHC areas with unmet need, by offering a trendsetting portfolio and by pursuing partnering opportunities. These targets can be achieved by acquiring innovative products or late stage projects in any of the following subsegments: female fertility, uterine fibroids / endometriosis, female contraception, infectious diseases in female healthcare and HRT.

## 4. Biosimilar Business

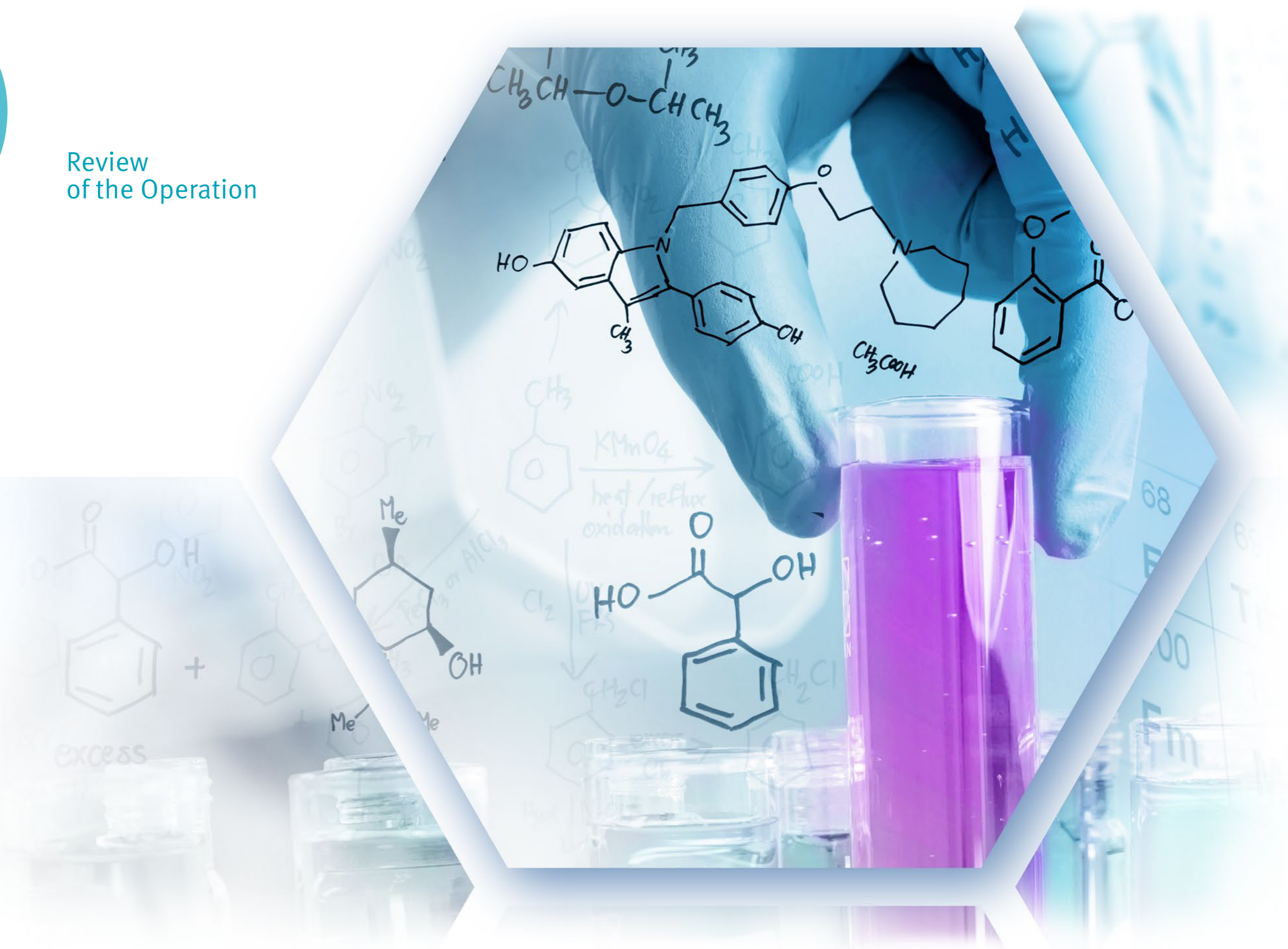
Biopharmaceuticals (often referred to as 'biologics') have taken a significant share of the global pharmaceutical market in the last two decades. Based on our almost 50 years of experience in the area of classical fermentation, combined with molecular biology knowledge, a strategic decision was made by management in 2006 to commence recombinant biotechnological activities at the Company. An acquisition of a German development and manufacturing company in 2007 was complemented by the construction of a greenfield pilot plant, an attached laboratory and a manufacturing unit in Hungary. This strategic initiative aims towards a steady contribution to the Group's sales revenues. New business and in-licensing opportunities together with contract manufacturing / contract developing and manufacturing projects, partnering for ongoing developments and the geographic expansion of the teriparatide coverage all support us in this endeavour. The therapeutic focus targeted for developments is rheumatology and oncology.

## 5. Branded Generic and Traditional Products

Contributing to around one half of Richter's pharma revenues, our traditional and branded generic portfolio remains an important cornerstone of our business. We capitalise on our vertically integrated business model, which comprises in-house development and manufacturing of finished form products as well as most of the APIs. This is complemented by the sales and marketing of the entire portfolio. Nonetheless, a highly competitive market environment combined with tightening regulatory standards, price regulations and increasing patient awareness going hand in hand with cost pressures on energy and wages keeps our performance under pressure in this part of the business. We aim towards maintaining our existing market positions in our traditional geographies building on strong corporate and product brands.

# 5

## Review of the Operation





**Dr István Greiner**  
Research Director

**Dr György Thaler**  
Development Director

## 1. Research and Development

Innovation and the research of original drug molecules have been key elements in the Company's strategy since its foundation in 1901. With more than 1,200 employees in the field of research and development Richter today is the most significant pharmaceutical research base in the Central and Eastern European region. Pharmaceutical R&D embraces four strategic areas, notably recombinant biotechnological activities, research and development of new chemical entities (NCEs), late stage women's healthcare projects and generic products.

In order to adjust our original research activities to the recently reshuffled strategic initiatives we have reviewed the potential focus areas of the disorders of the Central Nervous System that we aim to pursue. In this process the experiences gained during the successful development of cariprazine were also exploited. As a result of the review procedure, which was supported by external consultants, three major areas of NCE research within the CNS therapeutic field were outlined as symptom clusters, namely negative, positive and cognitive. There are a number of different indications related to the above mentioned symptom clusters, which provide a wide range of targets to pursue. Preclinical and clinical research activities have been restructured in line with this new approach.

A new investment carried out in the field of original research resulted in the implementation of artificial intelligence (AI) based software in order to support the synthesis and to assess the structure of new molecules. This measure is expected to further improve efficiency.

Cariprazine related activities remained a meaningful part of the everyday work of individual departments within the Research Directorate, notably the execution of cariprazine related post approval commitments, including preclinical and clinical studies together with the execution in co-operation with Allergan of important pediatric studies. The management of both Richter and Allergan remain determined to further develop cariprazine by conducting Phase III clinical trials in the treatment of major depression as adjunctive therapy.

In May 2019 the FDA approved the supplemental New Drug Application (sNDA) in the treatment of bipolar depression.

At the end of 2019, in addition to cariprazine the Company had a research portfolio of 15 ongoing original research projects, two of which are in their early clinical phase with the remainder in preclinical research and development phase.

Support activity to the development programme of estetrol (E4) and drospirenone (DRSP) containing novel OC was carried out during the reported year. The lidocaine containing intrauterine gel is under registration in the EU. A similar version of Organon's NUVARING®, co-developed with Evestra, is also under registration. In addition two other rings are being developed for various Women's Health indications.

Phase II/b clinical study of the novel, combined oral contraceptive licensed-in from Pantarhei is under preparation.

Based on our almost 50 years of experience in the area of classical fermentation, and combined with molecular biology knowledge, a strategic decision was made by management in 2006 to start recombinant biotechnological activities at the Company. The Hamburg based Richter-Helm Biologics, established jointly with Helm AG carries out development and manufacturing of microbial proteins. In addition, a biotechnology laboratory and pilot plant became operational in 2009 complemented by a greenfield investment, targeting the production of the most complex mammalian cell products, was inaugurated and became operational in 2012 in Hungary.

In February 2019 we withdrew our Application for a Marketing Authorisation (MAA) from the European Medicines Agency (EMA) for EFGRATIN, a biosimilar pegfilgrastim. The Company's Management decided to continue its development for the European market.

The development of denosumab containing biosimilar product (Amgen's Prolia® and Xgeva®), arrived in a late pre-clinical stage. The development is designed in a way that it complies with both European and USA regulatory requirements.

Development of trastuzumab was discontinued during the reported year.

The Company considers it essential to establish partnerships to facilitate the development and marketing of new molecules. We join forces with academic and university institutions in the early phase of our research activities, while we make efforts to establish cooperation with other pharmaceutical companies when it comes to the development

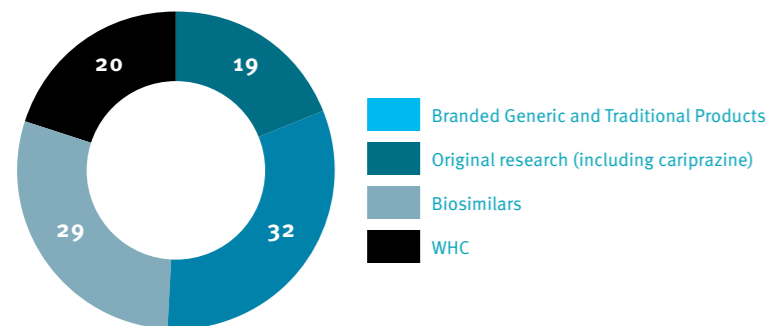
of molecules in clinical phases. In 2013 Richter has further expanded its partnership base in the field of original research activities by entering into a collaboration agreement for the discovery and development of new chemical entities in the field of cognitive disorders with Orion Corporation. According to the agreement the partnership provides an opportunity whereby the two companies jointly select and bring forward up to three discovery phase candidates and share all the development related expenses on an equal basis.

In its endeavour to support biosimilar business Richter signed a license and collaboration agreement in 2010 with Mochida Pharmaceutical Co. Ltd. to develop and market Richter's biosimilar product portfolio. In addition we established and later expanded partnership with STADA to include the commercialisation of Richter's biosimilar teriparatide and pegfilgrastim by the means of a non-exclusive license and distribution agreement in Europe (excluding Russia).

Generic development work in several therapeutic areas continued in 2019. Due to the decline in the number of global patent expiries, generic product development opportunities are also decreasing, a trend which is expected to prevail in the medium-term. Richter responded to these challenges by increasing the proportion of more complex, high added value development programmes and by initiating a number of lifecycle management projects over the past few years. All these changes are linked to our strong commitment to reshape substantially our business by focusing more on innovative, high added value areas. Process development activities and bioequivalence studies on several active pharmaceutical ingredients and on finished products continued during the year while our licensing-in activity contributed to the development of the Group's product portfolio.

The Group reported 2019 spending of HUF 48,860m (EUR 150.2m) on research and development, representing a year on year increase 20.5 percent in HUF terms and 9.6 percent of 2019 consolidated sales.

#### Split of R&D spending (%)



The table below highlights all products which were either developed in-house, acquired or licensed-in during 2019.

#### New Products Launched in Hungary During 2019

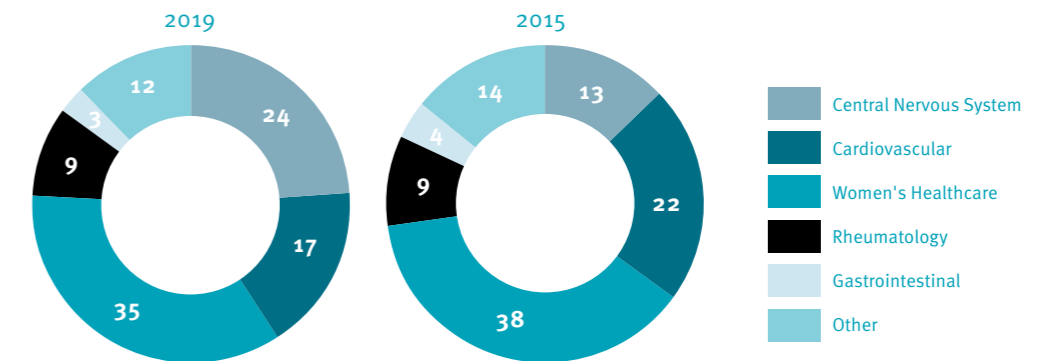
Brand name	Active ingredient	Therapeutic area	Launch date
ASSIMIL*	agomelatin	Central nervous system, antidepressant	Q1 2019
BEWIM	prasugrel	Cardiovascular, platelet aggregation inhibitor	Q1 2019
PAPILOCARE*	natural ingredients	Women's Healthcare, HPV	Q1 2019
BELSANOR*	solifenacin	Urology	Q2 2019
CO-XETER	ezetimibe+rosuvastatin	Cardiovascular, lipid-lowering	Q3 2019
CYCLOGEST*	progesterone	Women's Healthcare, fertility treatment	Q3 2019
TERROSA®	teriparatide	Osteoporosis	Q3 2019

Note: \*Licenced-in product.

## 2. Products

Richter's business model is supported by a portfolio divided between two major product groups. Around 50 percent of our turnover realised during 2019 originated from sales of high added value specialty products, while the other half was generated by branded generic and traditional drugs.

#### Products by therapeutic groups (%)



#### TOP 10 Products

Brand name	Active ingredient	Therapeutic area	2019 HUFm	2018 HUFm	Change HUFm	Change %
Oral contraceptives	hormones	Women's Healthcare, oral contraceptives	95,097	90,047	5,050	5.6
VRAYLAR® / REAGILA®	cariprazine	Central nervous system, antipsychotic	57,686	25,127	32,559	129.6
CAVINTON	vinpocetine	Central nervous system, nootropic	24,529	31,791	(7,262)	(22.8)
MYDETON	tolperisone	Muscle relaxant	19,811	18,913	898	4.7
BEMFOLA®	follitropin alfa	Women's Healthcare, fertility	16,127	13,348	2,779	20.8
PANANGIN	asparaginates	Cardiovascular, cardiac therapy	15,115	15,106	9	0.1
VEROSPIRON	spironolactone	Cardiovascular, diuretic	13,542	12,189	1,353	11.1
AFLAMIN*	aceclofenac	Non-steroid antiinflammatory	10,759	9,931	828	8.3
ESMYA®	ulipristal acetate	Women's Healthcare, uterine myoma	9,432	8,241	1,191	14.5
LISOPRESS	lisinopril	Cardiovascular, antihypertensive	8,385	9,087	(702)	(7.7)
<b>Subtotal</b>			<b>270,483</b>	<b>233,780</b>	<b>36,703</b>	<b>15.7</b>
Other			136,859	130,951	5,908	4.5
<b>Total</b>			<b>407,342</b>	<b>364,731</b>	<b>42,611</b>	<b>11.7</b>
<b>Share of the TOP 10 products</b>			<b>66.4%</b>	<b>64.1%</b>		

Note: \*Licenced-in product.



## 1. Specialty Products

### Cariprazine

#### Overview

Cariprazine is an oral, once daily atypical antipsychotic approved for the acute treatment of adult patients with manic or mixed episodes associated with bipolar I disorder, with a recommended dose range of 3 to 6 mg/day and for the treatment of schizophrenia in adults, with a recommended dose range of 1.5 to 6 mg/day. The safety and efficacy of cariprazine was studied in a clinical trial program of more than 2,700 patients with these conditions.

While the mechanism of action of cariprazine in schizophrenia and bipolar I disorder is unknown, the efficacy of cariprazine could be mediated through a combination of partial agonist activity at the dopamine D<sub>3</sub> and D<sub>2</sub> receptors with high binding affinity and at the serotonin 5-HT<sub>1A</sub> receptors and an antagonist activity at 5-HT<sub>2B</sub> and 5-HT<sub>2A</sub> receptors with high and moderate binding affinity as well as its binding to the histamine H<sub>1</sub> receptors. Cariprazine shows lower binding affinity to the serotonin 5-HT<sub>2C</sub> and α<sub>1A</sub>-adrenergic receptors and has no appreciable affinity for cholinergic muscarinic receptors.

Cariprazine is currently being investigated in clinical trials as adjunctive treatment for major depressive disorder in adults.

#### Cariprazine Sales

	2019 HUFm	2018 HUFm	Change HUFm	Change %	2019 EURm	2018 EURm
<b>Cariprazine*</b>	<b>57,355</b>	<b>25,079</b>	<b>32,276</b>	<b>128.7</b>	<b>176.3</b>	<b>78.7</b>
VRAYLAR®	47,565	24,173	23,392	96.8	146.2	75.9
VRAYLAR® milestone	7,072	-	7,072	-	21.7	-
REAGILA®	2,718	906	1,812	200.0	8.4	2.8

Note \* The above cariprazine turnover does not include API sales proceeds.

#### Recent developments

In May 2019 FDA has approved a supplemental New Drug Application (sNDA) for VRAYLAR® (cariprazine) for expanded use to treat bipolar depression in adults. VRAYLAR® has been already approved in the U.S. to treat schizophrenia and bipolar mania in adults. There are nearly 11 million adults in the U.S. living with bipolar disorder, a condition that causes extreme shifts in mood, energy, and activity levels. This label extension has added significant momentum to US sales in the second half of 2019.

In our endeavour to exploit additional medical and commercial potential of the product the Management of both Richter and Allergan have decided to advance with Phase III clinical trials for the treatment of Major depressive disorder (MDD) as an adjunctive therapy. Therefore we jointly run two Phase III clinical trials in this respect.

Following the initial launch of cariprazine in the USA and its introduction to the EU and CIS markets over the past few years, Richter succeeded through several bilateral agreements to ensure cariprazine's near global presence.

The list of international co-operations was opened in May 2019 when an exclusive licence agreement was sealed with Australia based Seqirus Pty Ltd to commercialise cariprazine in this country and in New Zealand. Further down the road Richter agreed with its partner Allergan to expand the geographic scope of their licence agreement to include major markets in Latin America. In addition to the above Richter announced in July 2019 that it had signed an exclusive licence agreement with Hikma Pharmaceuticals to commercialise the product in certain Middle East and North African (MENA) markets. Mitsubishi Tanabe Pharma Corporation's subsidiaries in Singapore and Thailand obtained in August the regulatory approval of cariprazine. After the closing of the reported period Richter signed a licence and supply agreement with WhanIn Pharm. Co., Ltd. for the commercialisation of cariprazine in the South Korean market.

### WHC

#### Overview

One of Richter's most important niche areas is its Women's Healthcare business. The Company has unique and long-term experience in this field dating back to when its founder, Mr Gedeon Richter, a pharmacist, started to conduct research into steroids.

Our Women's Healthcare franchise traditionally has had a strong presence in Central and Eastern Europe and in the CIS region. Our USA business reinforced in the mid 90's was scaled up by signing a strategic agreement with Duramed Inc. on oral contraceptives, which was extended both in scope and in duration with Barr Inc. Subsequent mergers and acquisitions did not interfere with our long-term partnerships, which over time have enabled our US organisation to become a renowned Women's Healthcare API supplier.

In accordance with the Company's strategy, two acquisitions were concluded during 2010, in order to reinforce the Women's Healthcare portfolio and to set foot on Western European markets. The acquisition of PregLem enabled Richter to enhance its portfolio with ESMYA®. The other acquisition brought direct access to Grünenthal's well-established oral contraceptive franchise.

In addition to this portfolio a promising product has been added in June 2016 with the acquisition of Finox Holding focused on the development and commercialisation of innovative and cost effective products addressing female fertility. This acquisition allowed Richter to establish its presence in the female fertility therapeutic area – a major growth market.

As part of our strategy to rebalance our regional presence, and at the same time to expand the Women's Healthcare franchise on a global scale, we also strengthened our position in regions like China, Latin America and Australia. Beyond the geographical expansion, it is an important objective for us to broaden and strengthen our Women's Healthcare product portfolio via establishing collaboration agreements with companies possessing promising products or development projects.

### Female fertility

#### Overview

Up to 25 percent of all couples may experience problems in conceiving a child, a figure that appears to be rising partly due to the trend to delay pregnancy. The World Health Organization estimates that there are about 60 to 80 million cases of infertility around the world. Being a responsible player in the pharmaceutical universe we are aware of the importance of productiveness of the female population and we are committed to addressing women's needs.

#### Products

Focusing on the meaningful widening of our core Women's Healthcare portfolio Richter acquired the global rights of the innovative biosimilar product BEMFOLA®.

BEMFOLA®, a recombinant-human Follicle Stimulating Hormone (r-hFSH) was developed by Finox as a biosimilar to GONAL-f®, an established reference product. BEMFOLA® was the first biosimilar r-hFSH launched in Europe.

Sales of BEMFOLA® recorded during 2019 amounted to HUF 16,127m (EUR 49.6m) increasing by 20.8 percent in HUF terms over the amounts recorded in 2018.

Further expanding the fertility portfolio we have agreed with L.D. Collins & Co. Limited, a UK based company, to commercialise its 400 mg progesterone containing assisted reproduction technology (ART) product, CYCLOGEST®. Beside the regulation of ovulation and menstruation, progesterone is essential in establishing and maintaining early pregnancy. CYCLOGEST® pessaries contain 400mg of progesterone, a naturally occurring progestogen. CYCLOGEST® prepares the lining of the uterus (endometrium) to be as receptive as possible to the embryo and therefore it is critical to support the luteal phase as part of ART (Assisted Reproductive Technology).

The product was launched in the following European countries by the end of 2019: Hungary, Denmark and Portugal.

New delivery technologies are well received by lifestyle driven patient groups as younger generations require new, non-oral approaches to contraception. Digitalization in healthcare creates an opportunity to make faster progress in the area of personalized healthcare. The analysis of real-world data – anonymised patient data collected from visits to doctors, medical records and other sources – will give a major boost to innovation in the medium to long term.

Pursuing the above mentioned trends we signed in 2017 an exclusive licence and distribution agreement with Prima-Temp, a US based company, to commercialise its innovative medical device, AYOLA globally, except for the USA and Canada.

AYOLA is a smart, self-inserted vaginal ring that continuously measures a woman's core body temperature to detect subtle changes that occur prior to ovulation as an aid in detecting the fertile window. An alert is sent to her smart phone when she is most fertile through the accompanying AYOLA app. By continuously and passively measuring core body temperature, Prima-Temp's smart technology powered by its proprietary algorithm provides a convenient and precise means for identifying the fertile window. The ring does not contain any active ingredient but a temperature measurement sensor.

## Uterine fibroids / endometriosis

### Overview

Uterine fibroids are the most common benign, solid tumours of the female genital tract, affecting between 20 and 25 percent of women of reproductive age. The condition is characterised by excessive uterine bleeding, anaemia, pain, frequent urination or incontinence and infertility.

### ESMYA®

ESMYA® 5 mg tablet containing ulipristal acetate is a first-in-class, orally active, selective progesterone receptor modulator. It reversibly blocks the progesterone receptors in target tissues. The 3 months once-a-day oral therapy is effective to stop uterine bleeding, correct anaemia and shrink fibroid volume thus improving quality of life.

The European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) commenced a review of drug induced liver injury potentially related to ESMYA® in late 2017. In July 2018 the European Commission (EC) decision opened the way for the relaunch of this product with a restricted use.

In August 2018 Allergan received a Complete Response Letter from the FDA in respect of the New Drug Application (NDA) filing for ulipristal acetate. As no material development occurred in the next 12 months in August 2019 Richter has accounted for an impairment loss in respect of Esmya USA Intangible asset. For additional details please consult the Financial Review.

ESMYA® reported total sales of HUF 9,432m (EUR 29.0m) in 2019, representing a 14.5 percent growth in HUF terms over a very low base period performance.

Following the end of the reported year, in March 2020 the Pharmacovigilance Risk Assessment Committee (PRAC) of European Medicines Agency (EMA) subsequent to its meeting held on 09 -12 March 2020 initiated a review procedure following a recent case of liver injury which led to liver transplantation in a patient taking ESMYA®. Ongoing treatments were stopped and new treatments are not allowed to be commenced prior to the announcement of the final decision taken by the European Committee.

## Female Contraception

### Overview

We offer a broad range of contraceptive options to assist women to shape their lives according to their wishes. When it comes to the choice of contraceptive methods, reliability, safety, ease of use and convenience all play a major role. Step by step we have built up a product portfolio, which contains a number of first, second, third and fourth generation oral contraceptives and emergency contraceptives, providing a broad range for the female population to choose those products which fit most with their personal needs.

### Products

Extending our Women's Healthcare franchise, a levonorgestrel releasing Intrauterine System (IUS), LEVOSERT® was launched in Central Europe and further licensed-in from Allergan for Western and Northern European countries in 2017 and in 2019 for Latin American countries.

Total turnover achieved by this product in 2019 amounted to HUF 1,932m (EUR 5.9m).

To further diversify the range of contraceptives to women in 2018 we signed an agreement with Mithra Pharmaceuticals to commercialise a combined oral contraceptive, containing estetrol and drospirenone. The product is considered a novel oral contraceptive with natural, native estrogen acting selectively in tissues. The geographic scope of the agreement covers Europe and Russia. Following the closing of the reported year, in February 2020 EMA started the evaluation of Richter's marketing authorisation application.

An API releasing vaginal ring, similar to Organon's NUVARING® dubbed EVE-112, which was developed in co-operation with Evestra Inc. is currently under registration in the EU. Initial co-operation agreement was signed between Richter and Evestra Inc. in 2015 and was later extended with different financial arrangements in 2017 and 2019.

A contract has been signed with Pantarhei Bioscience BV in 2019 according to which we are going to commercialise Pantarhei's combined oral contraceptive, containing ethynil estradiol, levonorgestrel and dehydroepiandrosterone (DHEA). The product, currently under development has successfully completed Phase II trials and is ready for further clinical studies. The geographic scope of the agreement covers Europe, Russia, Latin America and Australia.

ARC (Androgen Restored Contraception) is a novel concept of oral contraception developed and patent protected by Pantarhei with the aim to restore sexual function with a special focus on sexual desire and arousal and to prevent mood disturbances. This is achieved by adding DHEA to the contraceptive pill. DHEA is a natural human adrenal androgen that is metabolised partially to testosterone after oral intake, which hormone level is suppressed when fertile women use a contraceptive pill. By adding DHEA to the pill, the testosterone levels are normalised.

## Infections

### Overview

Recurrent Vulvovaginal Candidiasis is a debilitating, chronic infectious condition that affects millions of women. Primary symptoms include vaginal itching, burning, irritation and inflammation. Some women may experience abnormal vaginal discharge and painful sexual intercourse or urination, causing variable but often severe discomfort and pain. RVVC impacts quality of life, to a degree comparable to asthma and worse than diseases such as headache and migraine. In Europe, the standard of care treatment for RVVC has many drawbacks including limited effectiveness, safety concerns with chronic dosing, and inadequate ability to provide long-term protection.

### Products

In 2019 Richter and Mycovia Pharmaceuticals, Inc. have entered into an exclusive license and development and technology transfer agreement to commercialise and manufacture VT 1161 for the treatment of RVVC. The geographic scope of the licence agreement covers Europe, Russia, the other CIS countries, Latin America and Australia.

VT-1161 is an orally available inhibitor of fungal CYP51 infection being developed by Mycovia for the treatment of RVVC and onychomycosis. The product candidate currently in Phase III clinical trials is designed to be highly selective and have improved efficacy, and it may avoid side effects that limit the use of current antifungals in the treatment of RVVC.

The above mentioned Phase III clinical trials are currently running in USA and EU based clinical trial centres. Richter is seeking the opportunity to also include Russian sites.

## Hormone Replacement Therapy

### Overview

The menopause is a period of natural transition that every woman eventually experiences. The decline in oestrogen production that characterises this transition period can have short and long-term implications. It is no secret that the menopause might have a negative influence on quality of life. Furthermore, oestrogen loss is closely associated with the development of osteoporosis and bone fractures. Our aim is to maintain women's health and quality of life over the long-term.

### Products

According to an established cooperation with Acrux, an Australian drug delivery company, Richter commercialises Acrux's estradiol transdermal spray therapy for female menopause symptoms in all markets outside the United States.

Turnover of LENZETTO® during 2019 amounted to HUF 1,935m (EUR 5.8m).

### Other WHC products

An agreement signed in 2017 with the Sweden based company, Pharmanest enabled Richter to further broaden of its WHC portfolio.

SHACT is a novel delivery technology that provides pain relief on mucosal tissue. In a clinical study conducted in Sweden, SHACT treatment was associated with significant reduction of pain and discomfort in women undergoing gynaecological interventions without causing bothersome side effects.

The agreement covers Europe, Latin America and certain other markets. The registration dossier has been submitted to the EMA in the last quarter of 2018.

## Women's Healthcare Products of Richter Group

Brand name	Active ingredients	Product type	Regions where launched <sup>(1)</sup>
<b>Oral contraceptives (OC)</b>			
VOLINA / MIDIANA / ARANKA / MAITALON 30 / ROSINA	DRP + 30 mcg EE	Fourth generation	Hungary; EU; CIS; RoW; Latin America
SYMICIA / DAYLETTE / VOLINA MITE / REZIA / MAITALON 20 / DARYLIA / DIMIA / LILADROS / ARANKELLE	DRP + 20 mcg EE	Fourth generation	Hungary; EU; CIS; RoW; Latin America
REGULON / DESORELLE / DESMIN 30	DSG + 30 mcg EE	Third generation	Hungary; EU; CIS; RoW; Latin America
NOVYNETTE / DESMIN 20 / FEMINA	DSG + 20 mcg EE	Third generation	Hungary; EU; CIS; RoW; Latin America; China
AZALIA / LACTINETTE	DSG	Third generation	Hungary; EU; CIS; RoW; Latin America
LINDYNETTE 20 / KARISSA	GST + 20 mcg EE	Third generation	Hungary; EU; CIS; RoW; Latin America
LINDYNETTE 30	GST + 30 mcg EE	Third generation	Hungary; EU; CIS; RoW
MILLIGEST / TRISTIN / PERLEAN	GST + 30/40 mcg EE	Third generation	Hungary; EU
VIOLETTA / VARIANTA	GST + 15 mcg EE	Third generation	EU; CIS
KLEODINA	LVG + 30 mcg EE	Second generation	EU
RIGEVIDON / MICROFEMIN	LVG + 30 mcg EE	Second generation	Hungary; EU; CIS; RoW; Latin America; China
TRI-REGOL	LVG + 30/40 mcg EE	Second generation	Hungary; EU; CIS; RoW; China
BELARA / CHARIVA / LYBELLA / BALANCA	CLM + 30 mcg EE		Hungary; EU; CIS; RoW; Latin America
BELARINA / EVAFEM	CLM + 20 mcg EE		Latin America; EU; RoW
NEO-EUNOMIN	BCLM + 50 mcg EE		EU
EVE 20	norethisterone + 20 mcg EE	First generation	EU
SILUETTE / MISTRAL / MISTRA / SIBILLA	dienogest + 30 mcg EE	Fourth generation	Hungary; EU; CIS; Latin America
<b>Emergency contraceptives (EC)</b>			
POSTINOR / RIGESOFT / LEVONELLE-2 / PLAN B	LVG (2x)		Hungary; EU; CIS; USA; RoW; China; Latin America
ESCAPELLE / LEVONELLE ONE-STEP / POSTINOR 1 / PLAN B ONE-STEP / EVITTA	LVG (1x)		Hungary; EU; CIS; USA; RoW; Latin America; China
<b>Contraceptive device (CD)</b>			
GOLDLILY / SILVERLILY	Au + Cu, Ag + Cu	IUD	Hungary; EU; CIS; RoW
LEVOSERT® <sup>(2)</sup>	levonorgestrel	IUD	Hungary; EU; RoW
<b>Menopausal care</b>			
TULITA / MINIVEL	norethisterone + estradiol	Hormone replacement therapy	Hungary
TRIAKLIM	norethisterone + estradiol	Hormone replacement therapy	Hungary
PAUSOGEST	norethisterone + estradiol	Hormone replacement therapy	Hungary
GOLDAR / SHYLA / MARYSA <sup>(2)</sup>	tibolone	Hormone replacement therapy	EU
ESTRIMAX	estradiol	Hormone replacement therapy	Hungary; EU

## Women's Healthcare Products of Richter Group

Brand name	Active ingredients	Product type	Regions where launched <sup>(1)</sup>
LENZETTO <sup>®(2)</sup>	estradiol	Hormone replacement therapy (spray)	Hungary; EU; CIS; Latin America
OSSICA	ibandronate	Osteoporosis	Hungary; EU
SEDRON / OSTALON / BEENOS	alendronate	Osteoporosis	Hungary; EU; CIS; RoW
CALCI-SEDRON-D / OSTALON CALCI D	alendronate + Ca, vitamin D	Osteoporosis	Hungary; CIS
<b>Pregnancy care and Obstetrics</b>			
GRAVIDA, GRAVIDA OPTIMA <sup>(2)</sup>	vitamins	Pregnancy care	Hungary
OXYTOCIN	oxytocine	Labour induction (injection)	Hungary; EU; CIS; RoW; Latin America
BROMOCRIPTIN	bromocriptin mesilate	Prolactin inhibitor	Hungary; EU; CIS; RoW; China
GLOBIFER / RICHTER FERROBIO <sup>(2)</sup>	iron supplement	Pregnancy care	EU
GYNOSITOL / RICHTER CYCLEBALANCE <sup>(2)</sup>	myoinositol	Pregnancy care	Hungary; EU
<b>Fertility</b>			
BEMFOLA <sup>®</sup>	follitropin alfa	Fertility treatment	Hungary; EU; RoW
CYCLOGEST <sup>®(2)</sup>	progesterone	Fertility treatment	Hungary; EU; RoW
<b>Gynaecological infections</b>			
MYCOSYST / MYCOSYST GYNO / FLUCON	fluconazole	Antifungal	Hungary; EU; CIS; RoW; Latin America
GYNO FEMIDAZOL	miconazole nitrate	Antifungal	EU
GYNOFORT / GYNAZOL <sup>(2)</sup>	butoconazole nitrate	Antifungal (cream)	Hungary; EU; CIS; RoW
KLION D	metronidazole + miconazole	Antifungal	Hungary; EU; CIS; RoW; Latin America
FLUOMIZIN <sup>(2)</sup>	dequalinium chloride	Anti-infectiv, antiseptic	EU; CIS
GYNOFLOR <sup>(2)</sup>	estriol + lactobacillus	Women's Healthcare, restoration of vaginal flora and atrophic vaginitis	EU
<b>Other Gynaecological conditions</b>			
ESMYA <sup>®</sup>	ulipristal acetate	Uterine myoma	Hungary; EU; CIS; RoW; Latin-Amerika
LEVOSERT <sup>®(2)</sup>	levonorgestrel	Menorrhagia	Hungary; EU; CIS; RoW
NORCOLUT	norethisterone	Premenstruation syndrome, mastodynia, dysfunctional uterine bleeding, endometriosis	Hungary; CIS; RoW; China; Latin America
ZAFRILLA / SAWIS	dienogest	Endometriosis	EU
PAPILOCARE <sup>®(2)</sup>		HPV-induced cervical lesions	Hungary; EU
<b>Bulk products</b>		<b>Oral contraception</b>	<b>EU; USA; RoW; Latin America</b>

Abbreviations used in the table:

LVG: Levonorgestrel	DRP: Drospirenone
EE: Ethynil estradiol	GST: Gestodene
CLM: Chlormadinone	DSG: Desogestrel
	BCLM: Biphasic-chlormadinone

Notes: (1) Products are launched in certain countries of the given region.  
(2) Licenced-in products.

## Biosimilar Business

### Overview

A biosimilar medicine is a biological medicine that is developed to be highly similar to an already authorised biological medicine (the 'reference medicine'). The biosimilar medicines do not have any significant differences from the reference medicine in terms of quality, safety or efficacy.

By competing with original biologics across a growing range of therapy areas, biosimilars enable stakeholders – including payers, physicians and patients – to benefit from greater choice when it comes to treatment options. A large and diverse group of around 180 manufacturers globally are investing in the development and commercialisation of biosimilars, bringing with this investment the promise of high-quality biologic therapies at a lower cost.

Richter identified a number of years ago, the potential growing importance of biological drugs over the medium to long-term and in 2006 took the strategic decision to enter this novel, high added intellectual value field. In doing so Richter's management was confident that its decades long expertise in fermentation, a most sensitive procedure used both in the manufacturing process of biological drugs and in that of steroids, would create a competitive edge over many of its peers.

Initially, Richter acquired in 2007 a family owned R&D and manufacturing site headquartered in Hamburg, Germany, establishing with Helm AG a joint venture business with Richter as the majority shareholder. Richter Helm Biologics comprises a plant able to perform the manufacturing of bacterial and yeast cell based proteins, a pilot plant and a linked analytical and R&D laboratory unit.

A much larger scale investment followed with the construction in Budapest of a pilot plant and a laboratory to enable the development of biologics based on mammalian cell expression. This was complemented with a totally new manufacturing unit built in the industrial park of Debrecen in Eastern Hungary. These assets enable development in Budapest and manufacture in Debrecen of biological drugs based on mammalian cells fermentation.

When selecting candidate products Richter proceeded very carefully, focusing on certain therapeutic areas, notably Rheumatology/Osteoporosis and Oncology. These areas are considered to be among the highest growth rate therapeutic segments.

As is customary when it comes to relatively higher risk or significantly larger investments, Richter identified strategic alliances with companies similarly interested in biosimilars in order to share both risks and costs. In this endeavour Richter has concluded such agreements, one with Mochida for the Japanese market, one with STADA based in Germany. Further partners are sought with the aim of establishing joint product development activities.

### Products

Teriparatide has been developed by Richter-Helm BioTec GmbH & Co. KG. The product has been launched under the label TERRISA<sup>®</sup> by Richter via its affiliates in Europe immediately following the patent expiry of the reference product in August 2019.

Teriparatide is biosimilar to the biologically active fragment of the human parathyroid hormone, it replaces the natural hormone and stimulates bone formation. The product is approved in adults for the same indications as Eli Lilly's FORSTEO<sup>®</sup>, i.e. used for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture and treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non vertebral fractures but not hip fractures has been demonstrated.

Mochida Pharmaceutical Co., Ltd., Richter's licence partner launched biosimilar teriparatide in Japan in the fourth quarter 2019. The product was developed for Japan by Mochida based on a licence and collaboration agreement signed in 2010 with Richter.

Turnover of teriparatide reported by the end of 2019 amounted to HUF 2,851m (EUR 8.8m).

In our endeavour to pursue with the rheumatology indication we are going forward by developing further biosimilar molecules. One such candidate is denosumab, which is approved in two indications: oncology and rheumatology. The originator is Amgen and its patent expires both in Western Europe and in the USA in 2025. We expect to manufacture this product in our reliable, state-of-the-art, 21<sup>st</sup> century Debrecen facility.

## 2. Branded Generic and Traditional Products

In spite of the steady increase of our specialty portfolio, branded generic and traditional products still contribute about 50 percent to the Group's pharmaceutical turnover.

Richter's business model is supported by its vertically integrated research, development, manufacturing and distribution capacities complemented by selective licensing agreements. Licensing-in has become an important route for the Group to renew its product portfolio.

### Main Licencing-in Partners of Richter

Company	Country	Product	Therapeutic area
Acrux	Australia	LENZETTO®	Women's Healthcare, hormone replacement therapy (spray)
Allergan	Ireland	several products	Gastrointestinal, Urology, Women's Healthcare, Central nervous system
Almirall Prodesfarma	Spain	AFLAMIN	Non-steroid antiinflammatory
Astellas	Japan	SUPRAX	Antibiotic
Evestra	USA	EVE-112, EVE-116, EVE-120	Women's healthcare, contraceptive (ring), incontinence (ring)
Helm AG	Germany	FENTANYL patch, VAGIFEM vaginal tablet, Estradiol vaginal tablet (Vagisoft), BELSANOR (solifenacin) tablet, ASSIMIL (agomelatin) tablet, COSIM (lacosamid) tablet	Oncology, Women's Healthcare, Urology, Central nervous system, antipsychotic, antiepileptic
Janssen	Belgium	several products	Central nervous system, Antifungal, Antibacterial
L.D. Collins	United Kingdom	CYCLOGEST®	Women's healthcare, fertility
Medinova	Switzerland	FLUOMIZIN, GYNOFLOR	Women's healthcare, gynaecological infections
Mithra	Belgium	ESTELLE®, TIBOLONE	Women's healthcare, oral contraceptive, hormone replacement
Pantarhei	Netherlands	combined ARC oral contraceptive	Women's healthcare, oral contraceptive
Pharmanest AB	Sweden	SHACT	Women's healthcare, topical analgesic (gel)
Prima Temp	USA	PriyaRing	Women's healthcare, infertility
ProStrakan, Kyowa Kirin	United Kingdom	LUNALDIN	Oncology
Recordati S.p.A	Italy	REAGILA®	Central nervous system, antipsychotic
Sanofi-Aventis	France	TARIVID	Antibiotic
Teva / Medis	Iceland	ATORVOX, NEBIBETA, TANYDON HCTZ, SILDEREC	Cardiovascular, Urology
Procure Health	Spain	PAPILOCARE	Women's healthcare, HPV
Mycovia Pharmaceuticals	USA	Oteseconazole	Women's healthcare, vaginal infections

This product group consists of two major categories: a range of well established, matured, traditional products which are complemented by a list of more recent products either developed in-house or licensed-in. Sales of these products are focused primarily on Central and Eastern European and CIS markets. Most important therapeutic areas covered by these products are Cardiovasculars and CNS.

Cardiovascular drugs showed a 1.2 percent sales increase in 2019, accounting for 17 percent of total pharmaceutical sales. The cardiac therapy PANANGIN (asparaginates), the leading product in this therapeutic area, remained virtually unchanged (0.1 percent increase) in 2019 as higher turnover recorded in Russia could entirely offset by

decline occurred in China. Sales of VEROSPIRON (spironolactone) increased by 11.1 percent in the reported year due to higher sales levels achieved in Russia and in Ukraine. The turnover of LISOPRESS declined (by 7.7 percent) during the reported year.

Central Nervous System related drugs contributed altogether 11 percent of total pharmaceutical sales. The above figure does not include royalty income and sales related milestone received in respect of our specialty product, VRAYLAR®. Turnover of CAVINTON (vinpocetine), our other major original CNS drug decreased by 22.8 percent compared with the previous year primarily due to significantly lower sales levels in China and in Russia, the two main markets of the product. In China the Authority announced the delisting of CAVINTON from the reimbursement list with effect from 1 January 2020, which negatively impacted the turnover in the second half of 2019. Additionally, a substantial price cut was implemented by the Russian authorities for the product in late August, which also impacted adversely the sales performance of CAVINTON in the reported year.

A new category in Richter's therapeutic listing was created by merging previous muscle relaxants, osteoporosis and anti-inflammatory areas into Rheumatology. This area also includes specialty biosimilar TERROSA®. In addition the following products also belong to this area: muscle relaxant drugs, MYDETON / MYDOCALM and ARDUAN; non-steroid anti-inflammatory, AFLAMIN / AIRTAL / BIOFENAC; osteoporosis drugs, OSSICA and SEDRON / OSTALON / BEENOS and other anti-inflammatory products. Rheumatology amounted to 9 percent of total pharmaceutical revenue of the Group in 2019. Sales of the original product MYDETON / MYDOCALM (tolperisone) increased by 4.7 percent in the reported year primarily due to higher sales levels achieved in the Other CIS countries and in Ukraine.



### 3. Capital Expenditure

Capital expenditure for the Group, including payments for intangible assets, totaled HUF 58,085m in 2019.

Some of the most important projects carried out during the reported year comprise the following:

The Budapest located API manufacturing plant of the Group was fitted during the reported year with a conical vacuum dryer and a top-loader packaging line for injectable products was also installed. This line is also able to carry out the packaging of BEMFOLA®. Our biosimilar manufacturing capacities were reinforced by the completion of a second production line put into operation at Richter's site in Debrecen.

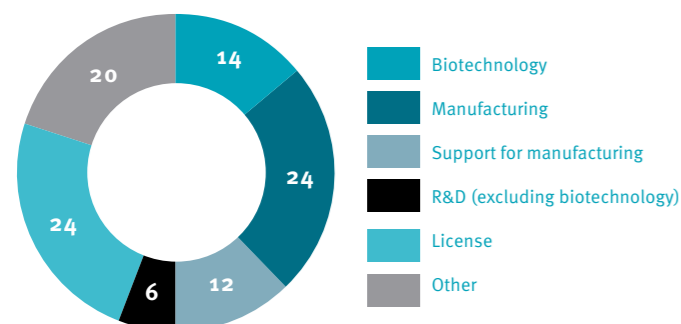
A new packaging line was added to the existing capacities to address the increased demand subsequent to serialization measures implemented at the beginning of the year. These measures also required additional resources to be directed towards IT development to complement the above mentioned packaging facility expansion.

At our Budapest site the construction of a central archive building was completed and it is expected to become operational during the first quarter of 2020.

We commenced during the reported year the construction of a new packaging building at our Russian plant, while at our Romanian subsidiary we carried out certain capacity expansion and maintenance investments. The R&D area was in focus in our Polish subsidiary to provide, among others, technical background for nanotechnology developments. The execution of a complex three-year program aiming at the modernization of our API production unit in India, started in 2018 continued in 2019.

A number of small scale investments have been carried out supporting procurement of necessary equipment, capital expenditure pertaining to auxiliary plants and infrastructure, environmental protection and improvement of workplace health and safety both at our Hungarian sites and at our subsidiaries abroad.

Capital expenditure analysed by function in 2019 (%)



### 4. Manufacturing and Supply

#### Our focus

During 2019, Richter's management paid special attention to offering a reliable and up-to-date product range at affordable prices in response to changing market needs. Flexibility of supply and the optimization of expenditures were achieved by continuously improving the cost-effectiveness of products and technologies, and by the targeted operation of a supply system with successful integration of its subsidiaries. Operated in conformity with a volatile market environment the production and supply chain ensured supply.

In 2019 we have continued to drive operational excellence and make adjustments to our operational base so as to maximize the efficiency of our supply chain whilst maintaining the highest standards of quality and security of supply. During the reported year we focused on continuously improving our supply systems as part of a sustained cost saving and efficiency enhancing programme.

During 2019 serialization represented the most important challenge in the area of manufacturing of finished drugs. As part of the fight against drug counterfeiting, a unique identifier and a tamper-proof closure must be used on the packaging of prescription drugs for human use on the basis of European Union rules. The scope of this regulation has been extended, as of February 2019, to all pharmaceutical companies operating in the EU. It impacted not only the capital expenditures, but also resulted in an increased cost of goods because of the higher number of employees required to run our equipment and also because of the lower yield and lower productivity. Implementing serialization temporarily adversely impacted our topline. In the past, the Company has made every effort to maintain capacity utilization at relatively high levels to make sure that unit costs are kept as low as possible. This resulted in limited capacity reserve compare to other European manufacturers. Additionally, the product portfolio of the Company is more diverse than the average, which means that the number of changeovers is significantly higher. During the year initial difficulties have been resolved. The capacity constraints have been addressed by hiring extra staff, we have normalized our production by installing new production lines and our inventory level are also back to normal. We estimate the lost revenue to be around EUR 13m in the CIS and CEE region as a consequence of this shortage of capacity in 2019.

#### Production

Manufactured volumes of finished products (number of boxes as packaging units) at Group level increased by 2.2 percent in 2019, while API production declined by 10.5 percent compared with levels achieved a year ago. Volumes of finished products manufactured at the parent company declined substantially in early 2019 due to the implementation of the required new technology linked to serialization. From the beginning of the fourth quarter 2019 we could return to earlier manufacturing levels. In respect of our manufacturing subsidiaries the volume of finished drugs produced in Russia increased by 32.8 percent, in Romania by 7.9 percent and in Poland by 1.7 percent when compared to the previous year.

With regard to our API production in Hungary steroid API volumes decreased by 11.8 percent. In line with the workload allocations the contribution of the facility in Dorog to the total API production of the parent company remained unchanged, representing still approximately 70 percent.

## 5. Quality Management

Richter's management has always believed that it is pivotal for the company to comply with all relevant national and international pharmaceutical legislations, including the rules and guidelines issued by public institutions and agencies such as the European Commission, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

The Company rigorously follows Hungarian and international regulations and guidance in its scope of activities (active ingredient research, product development, animal experiments, clinical trials, manufacturing etc.). Gedeon Richter Plc. has developed, implemented and is running a comprehensively designed, fully documented and regularly monitored Quality Management System, intended to give appropriate support to all its pharmaceutical activities. Such a system has been designed and implemented to ensure that all the human, technical and administrative factors which affect quality are under continuous and proper control. It covers all the critical system-elements and requires active involvement of both the management and personnel.

During 2018 we outlined a digital vision for the Quality Management System, including expectations over a 5 year term for Quality Management foresight: "Effective Quality Management" within a framework of automated and paperless processes with value-creating colleagues. The strategy is based on:

- coordination of Quality Management IT development and supply with long-term Quality Management priorities
- harmonization of Quality Management within a framework of a joint digital strategy including subsidiaries (Romania, Russia, Poland)
- decreasing Quality Management lead time to issue certificates of compliance
- more effective usage of workforce with automatization of non-value creating activities
- considering resources and human needs during implementation of Quality Management IT systems

To help us achieve our strategic goals, all employees are involved in the quality assurance process, participate in the design, implementation and control of GMP related activities within the company. In order to ensure their awareness of corporate regulations and expectations, Richter employees are periodically informed and trained and their working conditions aligned with quality requirements.

### Inspections and audits

It is very important for us to maintain a good relationship with our partners, and first of all to preserve the honourable confidence of patients and doctors in our products. Therefore, we place great emphasis on investigating every remark and complaint received and preventing the reoccurrence of problems of a similar nature.

An outstanding result of our quality assurance activity is that the Company has received no significant warnings during the quality inspections conducted by Hungarian and international professional authorities over the last 10 years.

In 2019 audits at our Budapest site totalled 35 days, notably the National Institute of Pharmacy and Nutrition, Belarus, Russia ISO 9001, Turkish Authority and Saudi Arabian Authority. At our Dorog site the National Institute of Pharmacy and Nutrition and the Russian Authority spent 10 days.

Audits conducted by our partners took 26 days at our Budapest, Dorog and Debrecen sites.

At our Polish subsidiary 5 regulatory inspections were passed while the Parent Company conducted 2 internal audits during the reported period. Additionally, we completed customer audits conducted by 19 partners. The Russian subsidiary successfully passed the ISO 9001-2015 audit, which is crucial for marketing authorisations and renewals. The Authority extended our GMP certificate and expanded the manufacturing licence for hormones. Our Romanian subsidiary successfully completed 2 inspections (Russian and Peruvian Authority) and a customer audit in 2019.

We received no significant observations, except some proposals during the inspections and audits.

### Other activities

Operating the Quality Management System entails multi-faceted and extremely complex regulatory adherence by the Total Quality Management Directorate. Our aim is to carry out the inspection of the Quality Management System with a reinforcing IT support. Accordingly, we organized several comprehensive projects during 2019.

In the Industry 4.0 competition the Quality Management Directorate takes part with two projects. One of them is linked to supporting a product release process (Dashboard) with a planned IT system which improves effectiveness by collecting batches from different database, scheduling tasks, analyzing them and making quick interventions. The other project is about an even higher level of automation, making manufacturing documents replacing manual document writing, multiple posting and approval with a manual signature.



**Tibor Horváth**  
Commercial and  
Marketing Director

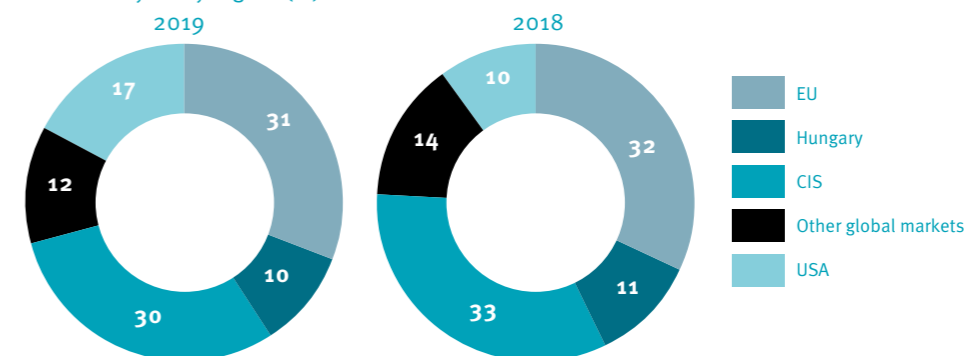
## 6. Pharmaceutical Sales by Geographies

### Sales by Region

	2019 HUFm	2018 HUFm	Change HUFm	Change %	2019 EURm	2018 EURm
<b>Hungary</b>	<b>39,809</b>	<b>38,736</b>	<b>1,073</b>	<b>2.8</b>	<b>122.4</b>	<b>121.6</b>
<b>EU<sup>(*)</sup></b>	<b>125,982</b>	<b>116,887</b>	<b>9,095</b>	<b>7.8</b>	<b>387.2</b>	<b>366.8</b>
EU12	60,458	58,789	1,669	2.8	185.8	184.5
Poland	23,428	24,204	(776)	(3.2)	72.0	76.0
Romania	11,173	10,517	656	6.2	34.3	33.0
EU 15	65,524	58,098	7,426	12.8	201.4	182.3
<b>CIS</b>	<b>123,969</b>	<b>121,661</b>	<b>2,308</b>	<b>1.9</b>	<b>381.0</b>	<b>381.8</b>
Russia	86,911	92,404	(5,493)	(5.9)	267.1	290.0
Ukraine	11,470	8,320	3,150	37.9	35.3	26.1
Other CIS republics	25,588	20,937	4,651	22.2	78.6	65.7
<b>USA</b>	<b>71,101</b>	<b>35,985</b>	<b>35,116</b>	<b>97.6</b>	<b>218.5</b>	<b>113.0</b>
<b>China</b>	<b>18,975</b>	<b>26,384</b>	<b>(7,409)</b>	<b>(28.1)</b>	<b>58.3</b>	<b>82.8</b>
<b>Latin America</b>	<b>7,210</b>	<b>5,779</b>	<b>1,431</b>	<b>24.8</b>	<b>22.2</b>	<b>18.2</b>
<b>Rest of the World</b>	<b>20,296</b>	<b>19,299</b>	<b>997</b>	<b>5.2</b>	<b>62.4</b>	<b>60.6</b>
<b>Total</b>	<b>407,342</b>	<b>364,731</b>	<b>42,611</b>	<b>11.7</b>	<b>1,252.0</b>	<b>1,144.8</b>

Note: <sup>(\*)</sup> All Member States of the European Union, except for Hungary.

Sales analysis by region (%)





## Hungary

The underlying market experienced a high growth rate of 9.6 percent and retail sales of Richter products achieved an increase of 9.0 percent according to the latest available IQVIA (successor of IMS) data. The Company is now ranked No. 5 amongst players in the Hungarian pharmaceutical market with a market share of 5.0 percent. Taking into account the prescription drugs retail market alone, Richter qualifies for second place with a market share of 7.7 percent.

### New Products Launched in Hungary During 2019

Brand name	Active ingredient	Therapeutic area	Launch date
ASSIMIL*	agomelatin	Central nervous system, antidepressant	Q1 2019
BEWIM	prasugrel	Cardiovascular, platelet aggregation inhibitor	Q1 2019
PAPILOCARE*	natural ingredients	Women's Healthcare, HPV	Q1 2019
BELSANOR*	solifenacin	Urology	Q2 2019
CO-XETER	ezetimibe+rosuvastatin	Cardiovascular, lipid-lowering	Q3 2019
CYCLOGEST*	progesterone	Women's Healthcare, fertility treatment	Q3 2019
TERROSA®	teriparatide	Osteoporosis	Q3 2019

Note: \* Licenced-in product.

### TOP 10 Products in Hungary

Brand name	Active ingredient	Therapeutic area	2019 HUFm	2018 HUFm	Change HUFm	Change %
Oral contraceptives	hormones	Women's Healthcare, oral contraceptive	2,658	2,947	(289)	(9.8)
TANYDON	telmisartan + hydrochlorothiazide	Cardiovascular, antihypertensive	2,257	1,772	485	27.4
QUAMATEL	famotidine	Gastrointestinal, antiulcer	1,879	1,891	(12)	(0.6)
CAVINTON	vinpocetine	Central nervous system, nootropic	1,777	2,054	(277)	(13.5)
XETER	rosuvastatin	Cardiovascular, cholesterol-lowering	1,642	1,709	(67)	(3.9)
PANANGIN	asparagines	Cardiovascular, cardiac therapy	1,354	1,294	60	4.6
AKTIL*	amoxicillin + clavulanic acid	Antibiotic	1,237	901	336	37.3
LAMOLEP	lamotrigine	Central nervous system, antiepileptic	1,177	1,209	(32)	(2.6)
POLITRATE*	leuprorelin	Urology, benign prostate hypertrophy	1,161	1,058	103	9.7
BEMFOLA®	follitropin alfa	Women's Healthcare, fertility	944	348	596	171.3
<b>Subtotal</b>			<b>16,086</b>	<b>15,183</b>	<b>903</b>	<b>5.9</b>
Other			23,723	23,553	170	0.7
<b>Total</b>			<b>39,809</b>	<b>38,736</b>	<b>1,073</b>	<b>2.8</b>
<b>Share of the TOP 10 products in Hungary</b>			<b>40.4%</b>	<b>39.2%</b>		

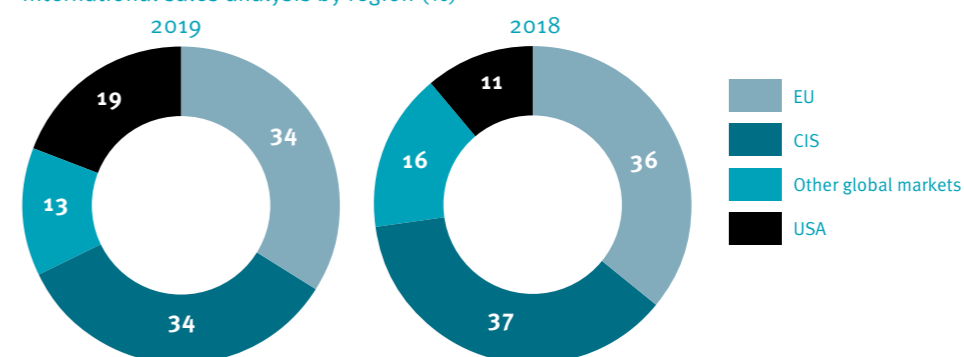
Note: \* Licenced-in product.

## International Sales

### Sales to TOP 10 International Markets

	2019 EURm	2018 EURm	Change EURm	Change %
Russia	267.1	290.0	(22.9)	(7.9)
USA	218.5	113.0	105.5	93.4
Poland	72.0	76.0	(4.0)	(5.2)
Germany	58.4	57.9	0.5	0.8
China	58.3	82.8	(24.5)	(29.6)
Ukraine	35.3	26.1	9.2	35.2
Romania	34.3	33.0	1.3	3.9
Spain	29.7	25.0	4.7	18.8
France	27.0	25.8	1.2	4.6
Italy	25.4	22.0	3.4	15.5
<b>Subtotal</b>	<b>826.0</b>	<b>751.6</b>	<b>74.4</b>	<b>9.9</b>
<b>Total international sales</b>	<b>1,129.6</b>	<b>1,023.2</b>	<b>106.4</b>	<b>10.4</b>
<b>Share of the TOP 10 international markets</b>	<b>73.1%</b>	<b>73.5%</b>		

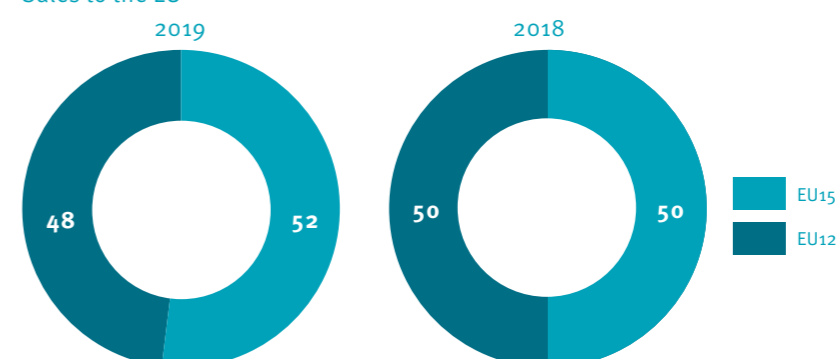
### International sales analysis by region (%)



### European Union

The EU12 region sales represented 48 percent of total EU sales of the Group's pharmaceutical segment.

### Sales to the EU\*



Note: \* All Member States of the EU, except for Hungary.

## New Products Launched in EU12 Countries During 2019

Brand name	Active ingredient	Therapeutic area	Launch date
ASSIMIL*	agomelatin	Central nervous system, antidepressant	Q1 2019
BEWIM	prasugrel	Cardiovascular, platelet aggregation inhibitor	Q1 2019
PAPILOCARE*	natural ingredients	Women's Healthcare, HPV	Q1 2019
REAGILA®	cariprazine	Central nervous system, antipsychotic	Q1 2019
DAYLETTE	drospirenone +20mcg EE	Women's Healthcare, oral contraceptive	Q2 2019
PANANGIN FORTE	K-Mg asparaginate	Cardiovascular, cardiac therapy	Q2 2019
TERROSA®	teriparatide	Osteoporosis	Q3 2019
LEVOSERT*	levonorgestrel IUS	Women's Healthcare, menorrhagia	Q4 2019

Note: \*Licenced-in product.

Poland's economic growth slowed in 2019 although remained strong at 4.0 percent according to the preliminary estimate by the Central Statistical Office of Poland. The main drivers of growth were consumer spending supported by soaring wages and generous social transfers, continuing low interest rates and the execution of EU funds-related investments.

In Poland a mild flu season and increasing competition in the antiviral market segment resulted in a sales decline of our leading product, GROPRINOSIN, which impacted adversely our performance in the reported period.

Romania's GDP achieved a growth of 4.1 percent mainly driven by strong domestic demand and expanding household spending on the back of a tight job market and robust wage growth.

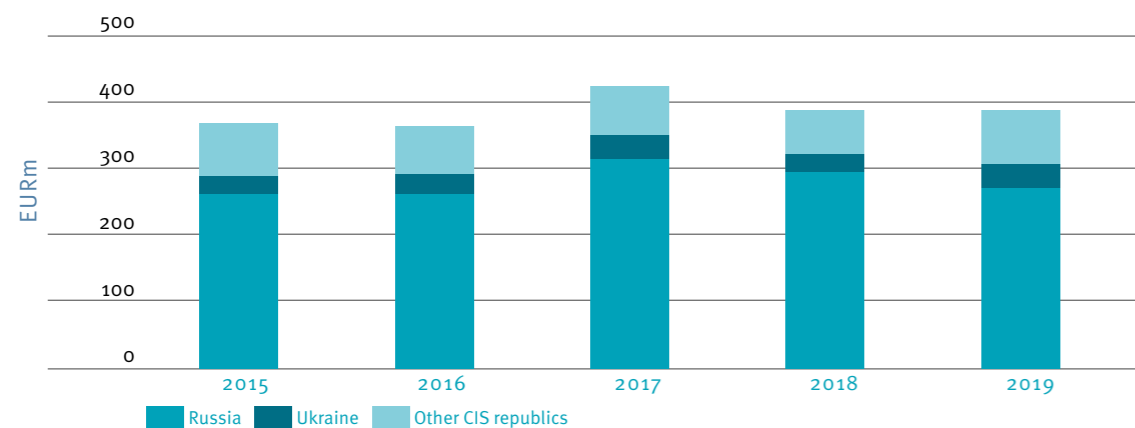
In Romania as a consequence of the substantial price decreases implemented by the Government in recent years, a number of original products were withdrawn from the market, which in turn provided sales opportunities for some generic alternatives including those manufactured by Richter.

Turnover in the EU15 region increased by 10.5 percent. Growth recorded in Spain, UK and Italy contributed the most to the sales level achieved during the reported year. As far as the product portfolio is concerned the increase was primarily due to higher turnover of BEMFOLA® and REAGILA®. The launch of TERROSA® also impacted positively the sales growth achieved. This region contributed 52 percent, to total EU pharmaceutical sales.

## CIS

Currency exchange rate fluctuations, primarily the appreciation of USD and the depreciation of the HUF impacted turnover in this region positively.

### Sales to the CIS



According to a preliminary estimate released by Federal Statistics Service (Rosstat), GDP grew just 1.3 percent in 2019 making it the weakest annual expansion since 2016. Growth in the natural resources industries contributed the most to the increase achieved during the year. Finance and insurance sector also expanded, while exports turned into contraction for the first time in over a decade amid raised trade uncertainties. RUB denominated sales

to Russia declined primarily as a consequence of regulatory related preshipments which occurred mainly in the last quarter of 2018. In addition to wholesaler destocking experienced during the first half of 2019 certain price cuts implemented by the Authority in late August also impacted negatively the sales performance of some of our traditional portfolio. Prices of drugs included on the Essential Drug List will be reviewed by the Authority and any changes are expected to come into effect no later than 1 January 2021. A moderate price increase of approximately 4 percent on average was introduced to our overall portfolio as of 1 April 2019. Sales levels during the reported period at EUR 267.1m declined by EUR 22.9m or 7.9 percent when compared with the turnover reported in 2018. As a result of the ongoing restructuring of the Russian wholesaling market and deteriorating liquidity at pharmacy chains Richter continues to place special emphasis on conducting a cautious credit policy.

## New Products Launched in the CIS Republics During 2019

Brand name	Active ingredient	Therapeutic area	Launch date
LENZETTO®*	estradiol	Women's Healthcare, hormone replacement therapy (spray)	Q1 2019
RAENOM	ivabradin	Cardiovascular, cardiac therapy	Q1 2019
REAGILA®	cariprazine	Central nervous system, antipsychotic	Q1 2019
SIBILLA	dienogest+30 mcg EE	Women's Healthcare, oral contraceptive	Q1 2019
VIOLETTA	gestodene+15 mcg EE	Women's Healthcare, oral contraceptive	Q1 2019
AMLODIPINE+ PERINDOPRIL RICHTER	amlodipine+perindopril	Cardiovascular, antihypertensive	Q3 2019
LENUXIN	escitalopram	Central nervous system, antidepressant	Q3 2019
LEVOSERT*	levonorgestrel IUS	Women's Healthcare, menorrhagia	Q4 2019

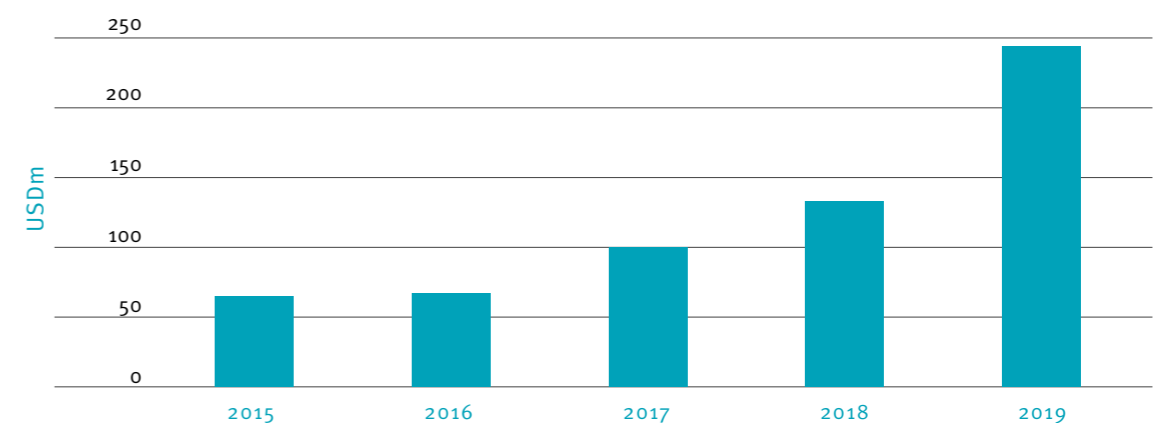
Note: \*Licenced-in product.

Turnover in Ukraine increased primarily due to a low base figure reported for 2018. Sales to Other CIS markets also reported growth partly due to a similar base effect and partly as a result of certain regulatory related preshipments realised during 2019.

## USA

The significant year-on-year growth was primarily due to accelerating royalty income earned in the current year based on turnover achieved by our partner, Allergan. In addition, the Group reported a one-off sales related milestone income linked to cariprazine (VRAYLAR®) of USD 24.3m. Higher API sales also contributed to the sales growth achieved during the reported period.

### Sales to the USA



## China

A reported year-on-year decrease occurred primarily due to certain preshipments of CAVINTON in the base period. In the second half of 2019 Chinese authorities announced the delisting of CAVINTON from the reimbursement list with effect from 1 January 2020, which also negatively impacted the turnover. Capacity losses that occurred at our manufacturing units subsequent to the implementation of the serialisation project also impacted negatively our twelve months to December 2019 performance.

## Latin America

Increasing sales of a range of oral contraceptives contributed primarily to the turnover achieved in the reported period.

## Rest of the World

Vietnam, Australia and Japan contributed the most to the sales performance.

## Women's Healthcare

Sales in WHC were higher in 2019 across all relevant markets with the exception of Russia. Turnover of WHC products increased primarily in the EU15 region as a result of higher BEMFOLA® and ESMYA® sales. Sales growth of this product segment in the USA originated primarily from higher profit sharing income related to both steroid APIs and the emergency contraceptive products.

Women's Healthcare Sales by Region						
	2019 HUFm	2018 HUFm	Change HUFm	Change %	2019 EURm	2018 EURm
<b>Hungary</b>	<b>4,924</b>	<b>4,586</b>	<b>338</b>	<b>7.4</b>	<b>15.2</b>	<b>14.4</b>
<b>EU(*)</b>	<b>65,518</b>	<b>59,816</b>	<b>5,702</b>	<b>9.5</b>	<b>201.4</b>	<b>187.7</b>
EU12	16,205	14,478	1,727	11.9	49.8	45.4
Poland	5,755	5,086	669	13.2	17.7	16.0
Romania	1,988	1,854	134	7.2	6.1	5.8
EU 15	49,313	45,338	3,975	8.8	151.6	142.3
<b>CIS</b>	<b>33,158</b>	<b>32,344</b>	<b>814</b>	<b>2.5</b>	<b>101.9</b>	<b>101.5</b>
Russia	26,807	27,039	(232)	(0.9)	82.4	84.9
Ukraine	2,348	1,738	610	35.1	7.2	5.4
Other CIS republics	4,003	3,567	436	12.2	12.3	11.2
<b>USA</b>	<b>12,630</b>	<b>10,468</b>	<b>2,162</b>	<b>20.7</b>	<b>38.8</b>	<b>32.9</b>
<b>China</b>	<b>9,128</b>	<b>9,095</b>	<b>33</b>	<b>0.4</b>	<b>28.1</b>	<b>28.6</b>
<b>Latin America</b>	<b>5,546</b>	<b>4,457</b>	<b>1,089</b>	<b>24.4</b>	<b>17.0</b>	<b>14.0</b>
<b>Rest of the World</b>	<b>10,156</b>	<b>9,347</b>	<b>809</b>	<b>8.7</b>	<b>31.2</b>	<b>29.3</b>
<b>Total</b>	<b>141,060</b>	<b>130,113</b>	<b>10,947</b>	<b>8.4</b>	<b>433.6</b>	<b>408.4</b>

Note: (\*) All Member States of the European Union, except for Hungary.

## 7. Corporate and Social Responsibility

Conducting our business in a responsible manner is an essential part of our strategy and the way we conduct our business operations is just as important to us as the economic achievements of our company. Developing innovative products and maximising access to them provide direct benefit to patients and consumers alike. Successful implementation of all these activities will deliver profitable and at the same time sustainable business performance. In turn it allows us to generate value that can to some measure be reinvested in the business. Beyond this it provides wider society benefits, since healthy people and communities are essential to building healthy societies. From year to year Richter provides significant contributions to countries and communities, wherever it makes its presence felt, directly through tax payments and charitable activities, and indirectly through the employment of more than 12,000 people.

The three elements of sustainability – social, environmental and economic – are interdependent. We will not be successful in the long-term without ensuring high level responsibility towards our environment and society. Equally, we cannot contribute to society and environmental protection without economic success.

At Richter, we seek to deliver sustainable business growth and value creation by:

- managing our business responsibly, with high levels of corporate governance;
- creating high-quality, rewarding employment;
- valuing our employees and protecting their safety;
- ensuring access to our products for those who need them;
- minimising the environmental impact of our products and operations;
- supporting community-based projects and encouraging innovation in science.

### Environmental Protection

Our role as a healthcare provider is not limited to providing medications to patients. We recognise that the environment, that people live in, is as much part of our care as the treatment of their illnesses. As a pharmaceutical manufacturing company, we take an active role in limiting the environmental impact of our operations; while following a systematic approach that ensures the sustainability of our business.

A number of risks are an inherent part of pharmaceutical manufacturing. In the course of pursuing our investment and development projects, we pay particular attention to ensuring that the environmental protection tasks related to our operations are carried out responsibly by using the best available technology (BAT) and continuously minimising the environmental footprint of our activities.

In 2019, the Company's Environmental Management System underwent a successful ISO 14001 re-certification audit as the launch of another cycle.

In order to comply with the law, we renewed our applicable licences:

- We reviewed the unified environmental permit of the Debrecen branch on the basis of a regulatory obligation.
- In Budapest we submitted the review material of the IPPC permit in December 2019.
- In Dorog, we amended our water permit to include our updated self-monitoring plan.

By the end of 2019, the Debrecen Branch Office had completed the investments for wastewater treatment related to the expansion of production. In accordance with the current official regulations we carry out remediation actions for the elimination of groundwater contamination from the past.

At the biological wastewater treatment plant in Dorog we accomplished a major reconstruction, which includes the preparation of sewage sludge dewatering technology, the installation of a carbon dioxide pH adjustment unit and the construction of an emergency storage basin.

To improve waste management and environmental awareness, a comprehensive waste management concept has been developed to enhance selective waste collection by pursuing the reconstruction and expansion of sewer systems and wastewater treatment plants at all three sites.

According to its environmental policy, the Company places great emphasis on the minimization of the environmental impacts of its activity. However, costs increased by 14.4 percent compared to 2018, with a 0.7 percent increase

in our electricity consumption, a 0.8 percent decrease in our heat consumption and a 6.9 percent increase in our water consumption (estimated data), in which the rise in energy prices played a decisive role.

We complied with our reporting requirements for water use and energy use, and our carbon reporting and quota surrender. We carried out the energy audit required by the Act on Energy Efficiency, evaluated the results of the audit and its recommendations will be included into our development plans.

We ensured the power supply of the sites; in one case there was a malfunction that significantly influenced the production, and due to the extraordinary heat and the simultaneous breakdown of several refrigeration equipment at the central site, cooling restrictions had to be introduced.

Programs to improve our cooling systems, energy efficiency and operational reliability still play an important role in our technical development. We modernized our liquefied gas supply to increase service security. The replacement of computer monitoring systems and the expansion of energy metering systems continued.

### Health and Safety at Work

Much of the work performed at the company involves the use of hazardous chemicals. These circumstances demand a highly responsible attitude towards safety at work in order to minimise the risks arising from these potential hazards.

No serious work related injuries or mass accidents or exposure occurred in 2019, nor did the inspections of the supervisory authorities reveal any deficiencies in the Company's activities.

We completed the supervisory audit of the Occupational Health and Safety Management System (OHSMS) and we started the mandatory transition to the OHSMS MSZ ISO 45001:2018 standard.

### Occupational Health and Safety Management System

Work safety is dependent on the technical state of working tools and equipment, and the conduct displayed by employees at work. The latter includes management's awareness of safety issues, and certainly the professional skills of the workers themselves.

The management of Richter is committed to the perpetual improvement of the organization's health and safety performance, to comply with current legislation and other requirements, and regards the prevention of occupational injuries and illnesses also in the future. It is the responsibility of work supervisors to familiarise themselves with the risks of any given workplace in their area and to manage and control workplace tasks accordingly. Workers have the right to demand safe working conditions and they have the obligation to comply with the health and safety regulations at work.

Representation of employees' interests with respect to occupational health and safety is performed by elected safety representatives within the confines of the Safety Committee.

### Practical Implementation

Richter pays particular attention to creating a safe workplace environment. Continuous improvement to technological standards in all of our plants, ongoing training in the field of safety and regular reviews of safety procedures are all factors taken into account in this initiative. We have developed test-based e-learning tutorials for new employees on security training, job-specific periodic exams, and fire safety exams.

Special precautions are taken in the case of tasks that involve the use of potentially hazardous materials. We make every effort to minimise the occupational health risks, and accordingly we strive to replace dangerous materials with less hazardous equivalents. We are committed to ensuring the safety of our employees through the use of closed technology wherever possible. If this is not feasible, then we implement appropriate special protective measures. To ensure the early detection of any signs of possible damage to health, our employees undergo regular medical surveillance and, as a preventive action, occupational risks are revealed through on-site measurements carried out by the Safety Laboratory.

Risk management related to occupational health has been reviewed and put on to new foundations, i.e. risk assessments are carried out in accordance with the employee's working place and his or her job title, also protocols designed to measure the employees' work suitability have been identified by personalised risk assessments. In accordance with the importance of chemical safety, the Chemical Safety Group has been established. Based on our toxicological evaluation methodology, 49 active substances were evaluated in a protocol. We have met the chemical safety requirements of REACH EU.

As a radiation protection measure, we have authorised and released for incineration waste that has been accumulated in isotopic laboratories over a number of years, with activity above the exemption level.

Our fire protection policy places particular emphasis on prevention. This includes a network of fire alarm and detecting devices covering the total area of our premises ensuring the early detection of any possible signs of fire that may nonetheless break out. At our sites our reservoir for fire extinguishing water capacities and extinguishing water network have been significantly upgraded and expanded thereby enhancing our fire protection capabilities.

A dedicated engineering team at the Company is responsible for ensuring the safe use of potentially dangerous equipment and to comply with authority regulations.

An assessment for industrial major accident hazards for the Budapest site has been submitted during 2015. This assessment is reviewed and revised every five years. According to a recently introduced change in the relevant regulations, the Budapest site remained as 'Lower Tier' under the SEVESO II Directive, the Dorog site has been re-rated as "Higher Tier", while the Vecsés site has been re-rated as "Under Tier".

### Community Involvement

Richter management have always been aware of the importance of community involvement. We recognise that as a leading pharmaceutical manufacturer and employer in Hungary it is our responsibility to maintain dialogue with society at large and with those who have an interest in the Company's activities. In this respect Richter supports projects in the areas of healthcare, science, education and environmental protection in line with its mission of improving health and the quality of life. The Company provides substantial support to healthcare institutions and organizations established with the aim of taking care of patients.

To encourage young people's interests, we sponsor a wide range of science-based school programmes, including chemistry education in secondary schools and university programmes both in Hungary and abroad. The organization of the "Extraordinary Chemistry Lesson" series also serve to promote chemistry. Special agreements have been concluded with universities of natural sciences in order to support specific education and research activities.

For talented and ambitious PhD students, we provide scholarships via the so called 'Talentum Foundation', which was established by the Company. The scope of the Foundation has been widened in order to include secondary school students, thereby providing them with future career opportunities. The number of these students further increased during 2019.

Our Company provides substantial support for healthcare institutions and other healthcare and patients' related organisations to improve the life and working conditions of the medical society.

We have implemented many programmes and initiatives to support the objective of improving quality of life. One of the most successful programmes has been "Richter City of Health", established in 2009. Groups of physicians and specialists from local medical institutions gather at various locations in towns all over the country to meet people interested in a number of health conditions. A special feature of these meetings is that visitors would participate in the financial support of hospitals and the purchase of medical equipment just by simply participating at the event as the initial donation (HUF 2m) offered by the Company to the town hospital is increased by every medical activity carried out.

The results of the "Richter City of Health" initiative are impressive: 75 towns have benefited and around 186,900 people have participated. Additionally, over the ten years some 75 hospitals have received a total of HUF 379m financial assistance from Richter. During this period specialists have carried out more than 168,000 screenings,

out of which approximately 38,051 returned with health warnings. Screened patients, when needed, have received prompt advice about further treatment options

### Ethical guidelines

The Group introduced its Global Compliance Programme in 2016, including the norms that are consistent with the values and objectives of Richter Group, specifying the behaviour expected from the employees. A Compliance Handbook consisting of eight regulations was issued as part of the programme. The Code of Ethics, one of the eight regulations, provides a set of ethical standards for all our stakeholders including employees, partners, investors, shareholders, suppliers etc. that shall be applied to their activity.

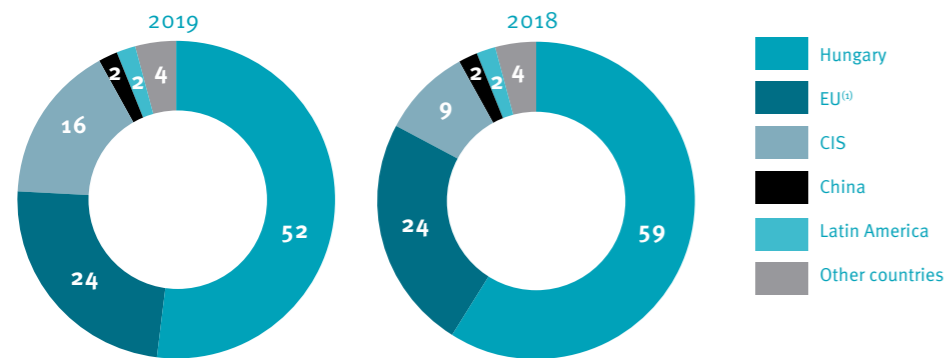
As a global pharmaceutical company, it has always been important for the Group to carry on its activity according to honesty, ethics and compliance and it is henceforward committed to operate legally and responsibly.

## 8. People

Changes in the pharmaceutical sector over the past decade have made inevitable the transformation of our business model to one that is more innovative. In order to be effective within an external environment of growing complexity and change with exponential speed we require highly skilled, passionate and motivated people.

We value the talents, skills and capabilities that our global workforce of more than 12,000 people in more than 35 countries brings to our business. We work in an international environment which requires that although Richter employees have a very diverse cultural background, they are very much connected with the Company's core values and goals. Our target is to align these skills and capabilities with strategic and operational needs.

Employee structure<sup>(2)</sup> by region (%)



Notes: (1) Excluding Hungary.  
(2) As at 31 December 2018 and 31 December 2019.

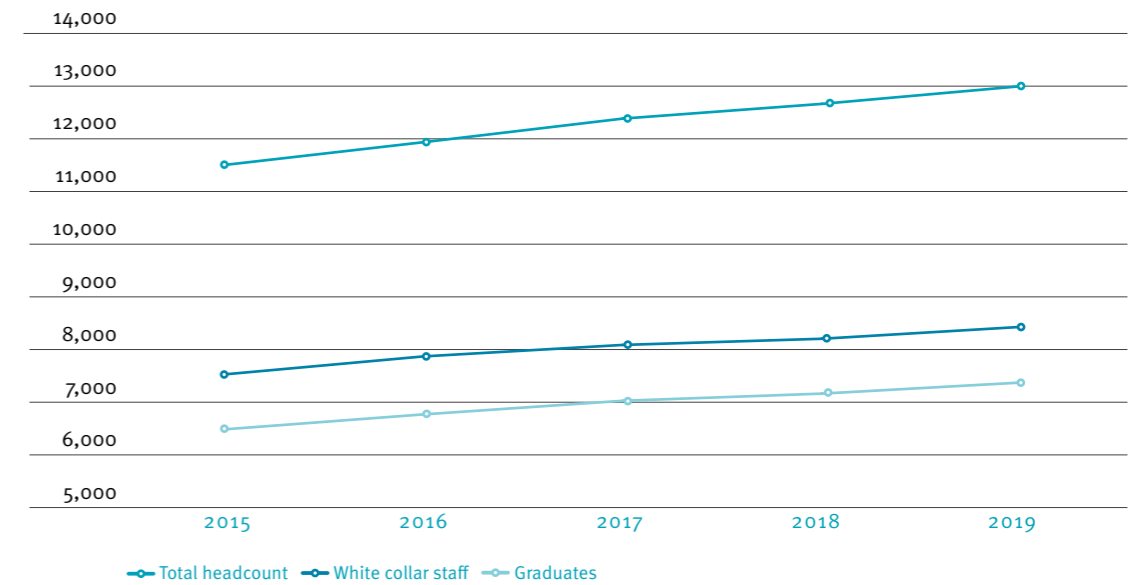
Successful and great companies are defined by people who embrace a shared sense of purpose, put extra energy and passion into their jobs and identify with common goals. That is the kind of engagement we aim for at Richter. We start from a foundation of respect; we passionately believe that a company can perform to the highest level while maintaining a caring, respectful working culture. Taking a genuine interest in people is a fundamental part of that and if we get that right, everything else falls into place.

### Employees

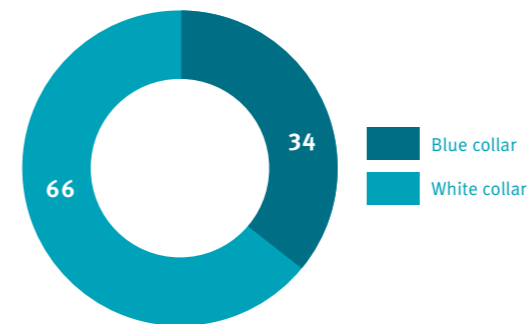
The total headcount for the Group was 13,025 at the end of 2019, a 2.8 percent (350) increase when compared to 2018. The growth was primarily due to the increasing number of personnel in manufacturing and in IT.

The number of skilled employees at the Group increased to 7,450 at the end of 2019, from 7,200 reported in 2018. Graduate educated personnel represented 87 percent of white collar staff and 57 percent of the total number of employees at the Group.

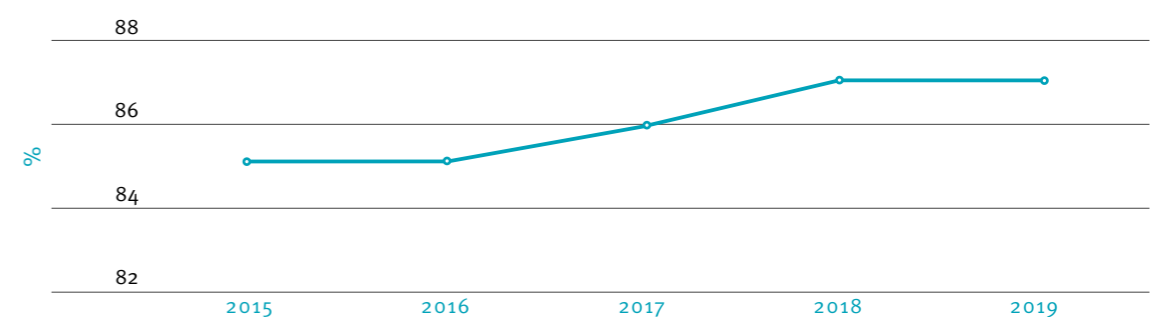
Number of staff



Proportion of blue and white collar staff (%) in 2019



Proportion of graduates\*



Note: \*Within the white collar staff at the Group.

## Recruitment and Individual Development

Attracting, motivating and retaining values-driven, talented and high-performing individuals is a business priority at Richter. To help our people flourish we provide a safe working environment, offer fair and competitive compensation and benefits, foster an inclusive and diverse culture and provide ample opportunity for learning and development.

Generally we pursue a personnel policy that focuses on long-term employee support creating loyalty to the Group and carrying out those personnel changes that are required for sustainable development. In the recruiting process we pay high attention to the selection of those candidates whose professional skills and experiences are expected to contribute the most to Richter's success and whose career plans and attitudes are expected to fit with the Company's corporate culture. We have implemented a competency-based interview technique which focuses not only on the professional knowledge and experience of candidates but equally on his or her personal skills and characteristics. This method is well complemented by a competence-based psychological test, which all together ensures a more efficient and valid analysis about the candidates' potential future performance.

## Workplace Initiatives

We encourage employees to develop their careers within Richter rather than looking outside the Company. We want all our employees to achieve their full potential and at the same time strengthen our business.

The Company implemented a new Welcome Programme in the previous year including a Buddy system which aims to support all new employments during the first weeks. Following entry into the company employees participate in welcome training to promote engagement and to give an insight into the organization of Richter.

Employees receive regular feedback on their performance and meet with their managers to discuss development opportunities and their career goals. This annual performance and development planning process ensures that employees set business aligned objectives and behavioural goals and helps them identify the training they need to develop their careers.

The Company makes special efforts to assist at scientific and professional education and advanced training. Accordingly, during 2019 more than 600 employees participated in Hungarian scientific conferences and near 1,000 staff at professional seminars. We paid particular attention to training programmes also in the field of basic IT skills.

We pay higher attention to ensuring the supply of professionals for the Company. As a result of our close co-operation with several partner institutions we supported the 4-6 weeks summer internships of 164 students as well as the completion of more than 20 theses during 2019. In this work, we rely on the expertise and devoted work of our 146 student supervisors, who are members of the Student Supervising Program, started in March 2019.

To support innovation and knowledge sharing within our Group in 2019 we organised again the competition called RITA (Richter Innovation and Knowledge Base Archive), which encourages and rewards those with innovative ideas. RITA has clearly demonstrated how efficiently innovation and teamwork can encourage and motivate people at our Company.

To analyse some of the organisational and structural challenges and mediate between various departments we are increasingly using advisory companies. In order to optimise the cooperation of different departments at the Company and increase their efficiency we initiated a number of organisational development projects.

## Developing Leaders

We recognise that good leadership plays a critical role in stimulating high levels of performance and engagement. Since we need good succession planning not just for senior roles but for all critical positions across the organisation we maintain a well-established leadership strategy to identify and develop our highly skilled candidates and use a systematic and disciplined approach to leadership development.

Our leadership development programmes provide employees at all levels with the skills they need to become effective leaders.

Our career development program, started in 2006, which focuses on further development of high potential management talent, continued in 2019. A comprehensive competence assessment was provided for those colleagues who

participated in this programme as a potential option to develop their self-knowledge. It is pleasing to report that a number of participants have been promoted to new management positions during the development programme. New candidates have been admitted to this programme each year since its inception.

We continued organising a special manager training programme for recently appointed managers so as to identify and develop management skills and self-knowledge.

During 2019 our primary aim was to develop the process of establishing targets and managing feedback for employees in order that business objectives for 2020 could be defined utilising the so-called SMART method based on integrated principles. Accordingly, a related training course was organised for all leaders (approx. 350 employees) during the reported year.

## Remuneration and Other Employee Programmes

Compensation philosophy at Richter is based on the Company's commitment to a performance culture. Performance based salary, share awards, other forms of allowances as well as career development planning, various training activities and continuing education all contribute to the retention of key talent, superior performance and the accomplishment of business targets.

With effect from the end of 2018 we have gradually implemented a new employee and leadership self-service electronic system, the SuccessFactors, which aims to decrease administration and contribute to the prompt and effective managing of HR processes. The annual performance assessment and the process to establish business aligned objectives for 2019 were recorded on this system.

We take a progressive approach to protecting the health and wellbeing of our people with focus on sustaining a strong health and safety culture, which seeks to ensure employees are aware of health and safety risks.

We focus on the health factors that enable employees to perform at the highest level by sustaining energy and engagement. All employees are able to participate in a wide-ranging medical programme which aims to minimise illness by early diagnosis. In addition, we provide health insurance to our people, which includes a number of services, unlimited internal medicine examinations and eight defined specialist visits annually.

Providing a safe workplace and promoting the health and well-being of all our people has always been a core priority for Richter. Well-being programmes including sport and recreational opportunities at the Company are planned to promote physical and psychological welfare and to help employees cope with demanding roles.

**Dr Gábor Gulácsi**  
Chief Financial  
Officer



# 6

## Financial Report





## 1. Key Financial Data

Key Financial Data					
	2019 HUFm	2018 HUFm	Change %	2019 EURm	2018 EURm
Revenues	507,794	445,484	14.0	1,560.7	1,398.2
Gross profit	283,294	253,836	11.6	870.7	796.7
<b>Gross margin %</b>	<b>55.8</b>	<b>57.0</b>		<b>55.8</b>	<b>57.0</b>
Profit from operations	39,896	45,040	(11.4)	122.6	141.4
<b>Operating margin %</b>	<b>7.9</b>	<b>10.1</b>		<b>7.9</b>	<b>10.1</b>
Profit before income tax	50,848	43,953	15.7	156.3	137.9
Profit for the year	48,430	36,193	33.8	148.9	113.6
<b>Net margin %</b>	<b>9.5</b>	<b>8.1</b>		<b>9.5</b>	<b>8.1</b>
EPS (HUF, EUR) <sup>(1)</sup>	253	190	33.2	0.78	0.60
Total assets and total equity and liabilities	858,651	797,883	7.6	2,597.9	2,481.8
Capital and reserves <sup>(2)</sup>	724,873	685,745	5.7	2,193.1	2,132.9
Capital expenditure	58,085	58,055	0.1	178.6	182.2
Number of employees at year-end	13,025	12,675	2.8		

Notes: <sup>(1)</sup> EPS calculations were based on the total number of shares issued.  
<sup>(2)</sup> Includes minority interest.

## 2. Consolidated Turnover

Sales by Region						
	2019 HUFm	2018 HUFm	Change HUFm	Change %	2019 EURm	2018 EURm
<b>Hungary</b>	<b>40,502</b>	<b>39,472</b>	<b>1,030</b>	<b>2.6</b>	<b>124.5</b>	<b>123.9</b>
<b>EU<sup>(*)</sup></b>	<b>208,847</b>	<b>181,766</b>	<b>27,081</b>	<b>14.9</b>	<b>641.9</b>	<b>570.5</b>
EU12	143,257	123,615	19,642	15.9	440.3	388.0
Poland	23,428	24,204	(776)	(3.2)	72.0	76.0
Romania	93,972	75,343	18,629	24.7	288.8	236.5
EU15	65,590	58,151	7,439	12.8	201.6	182.5
<b>CIS</b>	<b>137,399</b>	<b>133,356</b>	<b>4,043</b>	<b>3.0</b>	<b>422.3</b>	<b>418.5</b>
Russia	86,911	92,404	(5,493)	(5.9)	267.1	290.0
Ukraine	11,540	8,380	3,160	37.7	35.5	26.3
Other CIS republics	38,948	32,572	6,376	19.6	119.7	102.2
<b>USA</b>	<b>71,101</b>	<b>35,985</b>	<b>35,116</b>	<b>97.6</b>	<b>218.5</b>	<b>113.0</b>
<b>China</b>	<b>18,975</b>	<b>26,384</b>	<b>(7,409)</b>	<b>(28.1)</b>	<b>58.3</b>	<b>82.8</b>
<b>Latin America</b>	<b>10,665</b>	<b>9,207</b>	<b>1,458</b>	<b>15.8</b>	<b>32.8</b>	<b>28.9</b>
<b>Rest of the World</b>	<b>20,305</b>	<b>19,314</b>	<b>991</b>	<b>5.1</b>	<b>62.4</b>	<b>60.6</b>
<b>Total</b>	<b>507,794</b>	<b>445,484</b>	<b>62,310</b>	<b>14.0</b>	<b>1,560.7</b>	<b>1,398.2</b>

Note: (\*) All Member States of the European Union, except for Hungary.

## 3. Balance Sheet Items

Consolidated Balance Sheet			
at 31 December	2019 HUFm	2018 HUFm	Change %
<b>ASSETS</b>	<b>858,651</b>	<b>797,883</b>	<b>7.6</b>
<b>Non-current assets</b>	<b>449,071</b>	<b>439,812</b>	<b>2.1</b>
Property, plant and equipment	244,754	214,880	13.9
Investment property	111	135	(17.8)
Goodwill	29,503	35,386	(16.6)
Other intangible assets	127,635	151,648	(15.8)
Investments in associates and joint ventures	16,192	11,755	37.7
Other financial assets	19,030	9,452	101.3
Deferred tax assets	6,988	7,895	(11.5)
Loans receivable	2,021	2,626	(23.0)
Long term receivables	2,837	6,035	(53.0)
<b>Current assets</b>	<b>409,580</b>	<b>358,071</b>	<b>14.4</b>
Inventories	98,995	92,687	6.8
Trade receivables	154,426	129,006	19.7
Contract assets	3,466	1,425	143.2
Other current assets	21,376	16,187	32.1
Investments in securities	1,545	4,728	(67.3)
Current tax asset	1,199	1,017	17.9
Cash and cash equivalents	128,573	113,021	13.8
<b>EQUITY AND LIABILITIES</b>	<b>858,651</b>	<b>797,883</b>	<b>7.6</b>
<b>Capital and reserves</b>	<b>724,873</b>	<b>685,745</b>	<b>5.7</b>
<b>Equity attributable to owners of the parent</b>	<b>717,981</b>	<b>680,185</b>	<b>5.6</b>
Share capital	18,638	18,638	0.0
Treasury shares	(3,870)	(2,186)	77.0
Share premium	15,214	15,214	0.0
Capital reserves	3,475	3,475	0.0
Foreign currency translation reserves	22,213	14,182	56.6
Revaluation reserves for securities at FVOCI	8,620	4,810	79.2
Retained earnings	653,691	626,052	4.4
Non-controlling interest	6,892	5,560	24.0
<b>Non-current liabilities</b>	<b>24,216</b>	<b>19,987</b>	<b>21.2</b>
Borrowings	-	2	(100.0)
Deferred tax liability	1,925	7,176	(73.2)
Other non-current liabilities and accruals	18,004	9,255	94.5
Provisions	4,287	3,554	20.6
<b>Current liabilities</b>	<b>109,562</b>	<b>92,151</b>	<b>18.9</b>
Borrowings	-	-	-
Trade payables	61,770	54,549	13.2
Contract liabilities	745	85	776.5
Current tax liabilities	382	438	(12.8)
Other payables and accruals	42,721	33,664	26.9
Provisions	3,944	3,415	15.5

Please note that changes for all balance sheet items are reported in comparison to 31 December 2018 audited figures.

#### Non-current assets

Higher levels of Property, plant and equipment were primarily the consequence of IFRS16 coming into effect at 1 January 2019. IFRS16 standard qualifies the 'Right-of-use' of resources exploited on the basis of lease contracts as on-balance sheet assets. At the same time, the obligation of leasing payments is included among the liabilities. The amount of Buildings includes the most relevant 'Right-of use' assets of the Group.

The level of Other intangible assets declined primarily as the negative balance of impairment losses accounted for in respect of intangible assets Esmya for the USA (HUF 5,928m), for the non-USA territories (HUF 24,148m) and also for trastuzumab (HUF 2,096m) was only partially offset by the positive impact of the recently acquired intangible asset Mycovia (HUF 6,025m).

Goodwill declined primarily as a result of impairment losses accounted for in respect of our Chinese subsidiaries and PregLem.

The amount of Investments in associates and joint ventures grew primarily as a result of new shares being issued at Evestra amounting to HUF 4,840m, while the level of Other financial assets increased mostly as a result of having purchased a right to a certain portion of future USA sales proceeds of Mycovia amounting to HUF 5,427m and the higher fair value of Richter's investment in the Russian wholesaler and retail Group, Protek.

#### Current assets

Trade receivables increased as a result of the expansion in the USA business together with improving period end exchange rates both for USDHUF and RUBHUF.

Higher levels of Inventories were impacted primarily by an improving RUBHUF period end exchange rate.

Investments in securities declined during the first quarter 2019 on maturity of sovereign bonds previously owned by the Parent.

Cash and cash equivalents increased as a result of both the positive net cash flow from operating activities of the Group and the term deposit following consideration of the Investments in securities matured.

#### Capital and reserves

Retained earnings increased by HUF 27,639m and amounted to HUF 653,691m. A higher translation difference of HUF 8,031m included in Foreign currency translation reserve also contributed to the above increase.

#### Non-current liabilities

Other non-current liabilities and accruals increased mainly due to the impact of IFRS16 standard mentioned above on Non-current assets that stipulates the inclusion among non-current liabilities of such long term leasing payment obligations that correspond to the 'Right-of-use' of resources being exploited on the base of leasing contracts. The share of the deferred purchase price of intangible asset Mycovia due beyond the completion of the financial year also contributed to the above increase.

As a consequence of the restructuring of Finox's activities the Intangible asset Bemfola was transferred to the Parent with effect from 1 January 2019. Thus its value is calculated in HUF and related deferred tax is determined based on the Parent's corporate tax rate. Such deferred tax liability was therefore recalculated with a lower, 9 percent rate. In addition deferred tax liability also declined at PregLem as a result of the impairment loss accounted for in respect of the Esmya intangible asset.

#### Current liabilities

The increase in Other current liabilities and accruals is mainly due to the impact of IFRS16 mentioned above in the section on Non-current assets that stipulates the inclusion among current liabilities of such short term leasing payment obligations that correspond to the 'Right-of-use' of resources being exploited on the base of leasing contracts. The share of the deferred purchase price of intangible asset Mycovia due during this financial year also contributed to the above increase.

## 4. Profit and Loss Items

Consolidated Income Statement			
For the years ended 31 December	2019 HUFm	2018 HUFm	Change %
<b>Revenues</b>	<b>507,794</b>	<b>445,484</b>	<b>14.0</b>
Cost of sales	(224,500)	(191,648)	17.1
<b>Gross profit</b>	<b>283,294</b>	<b>253,836</b>	<b>11.6</b>
Sales and marketing expenses	(121,819)	(115,584)	5.4
Administration and general expenses	(28,977)	(24,070)	20.4
Research and development expenses	(48,860)	(40,545)	20.5
Other income and other expenses (net)	(44,793)	(29,004)	54.4
Net impairment losses on financial and contract assets	1,051	407	158.2
<b>Profit from operations</b>	<b>39,896</b>	<b>45,040</b>	<b>(11.4)</b>
Finance income	20,500	19,285	6.3
Finance costs	(10,206)	(21,427)	(52.4)
<b>Net financial income/(loss)</b>	<b>10,294</b>	<b>(2,142)</b>	<b>n.a.</b>
Share of profit of associates and joint ventures	658	1,055	(37.6)
<b>Profit before income tax</b>	<b>50,848</b>	<b>43,953</b>	<b>15.7</b>
Income and deferred tax	2,275	(3,698)	n.a.
Local business tax and innovation contribution	(4,693)	(4,062)	15.5
<b>Profit for the year</b>	<b>48,430</b>	<b>36,193</b>	<b>33.8</b>
Profit attributable to:			
<b>Owners of the parent</b>	<b>47,135</b>	<b>35,348</b>	<b>33.3</b>
Non-controlling interest	1,295	845	53.3

Consolidated Statement of Comprehensive Income			
For the years ended 31 December	2019 HUFm	2018 HUFm	Change %
<b>Profit for the year</b>	<b>48,430</b>	<b>36,193</b>	<b>33.8</b>
Actuarial loss on retirement defined benefit plans	(640)	(353)	81.3
Changes in the fair value of equity investments at fair value through other comprehensive income	3,810	(5,154)	n.a.
<b>Items that will not be reclassified to profit or loss (net of tax)</b>	<b>3,170</b>	<b>(5,507)</b>	<b>n.a.</b>
Exchange differences arising on translation of foreign operations	8,460	4,609	83.6
Exchange differences arising on translation of associates and joint ventures	(179)	(95)	88.4
<b>Items that may be subsequently reclassified to profit or loss (net of tax)</b>	<b>8,281</b>	<b>4,514</b>	<b>83.5</b>
<b>Other comprehensive income for the year</b>	<b>11,451</b>	<b>(993)</b>	<b>n.a.</b>
<b>Total comprehensive income for the year</b>	<b>59,881</b>	<b>35,200</b>	<b>70.1</b>
Attributable to:			
<b>Owners of the parent</b>	<b>58,336</b>	<b>34,168</b>	<b>70.7</b>
Non-controlling interest	1,545	1,032	49.7
<b>Earnings per share (EPS)</b>	<b>HUF</b>	<b>HUF</b>	<b>%</b>
Basic	253	190	33.2
Diluted	253	190	33.2

Consolidated Income Statement		
For the years ended 31 December	2019 EURm	2018 EURm
<b>Revenues</b>	<b>1,560.7</b>	<b>1,398.2</b>
Cost of sales	(690.0)	(601.5)
<b>Gross profit</b>	<b>870.7</b>	<b>796.7</b>
Sales and marketing expenses	(374.4)	(362.8)
Administration and general expenses	(89.1)	(75.5)
Research and development expenses	(150.2)	(127.3)
Other income and other expenses (net)	(137.6)	(91.0)
Net impairment losses on financial and contract assets	3.2	1.3
<b>Profit from operations</b>	<b>122.6</b>	<b>141.4</b>
Finance income	63.0	60.5
Finance costs	(31.3)	(67.3)
<b>Net financial income/(loss)</b>	<b>31.7</b>	<b>(6.8)</b>
Share of profit of associates and joint ventures	2.0	3.3
<b>Profit before income tax</b>	<b>156.3</b>	<b>137.9</b>
Income and deferred tax	7.0	(11.6)
Local business tax and innovation contribution	(14.4)	(12.7)
<b>Profit for the year</b>	<b>148.9</b>	<b>113.6</b>
Profit attributable to:		
<b>Owners of the parent</b>	<b>144.9</b>	<b>110.9</b>
Non-controlling interest	4.0	2.7
Average exchange rate (EURHUF)	325.36	318.61

Consolidated Statement of Comprehensive Income		
For the years ended 31 December	2019 EURm	2018 EURm
<b>Profit for the year</b>	<b>148.9</b>	<b>113.6</b>
Actuarial loss on retirement defined benefit plans	(2.0)	(1.1)
Changes in the fair value of equity investments at fair value through other comprehensive income	11.7	(16.2)
<b>Items that will not be reclassified to profit or loss (net of tax)</b>	<b>9.7</b>	<b>(17.3)</b>
Exchange differences arising on translation of foreign operations	26.0	14.5
Exchange differences arising on translation of associates and joint ventures	(0.5)	(0.3)
<b>Items that may be subsequently reclassified to profit or loss (net of tax)</b>	<b>25.5</b>	<b>14.2</b>
<b>Other comprehensive income for the year</b>	<b>35.2</b>	<b>(3.1)</b>
<b>Total comprehensive income for the year</b>	<b>184.1</b>	<b>110.5</b>
Attributable to:		
<b>Owners of the parent</b>	<b>179.3</b>	<b>107.3</b>
Non-controlling interest	4.7	3.2
<b>Earnings per share (EPS)</b>	<b>EUR</b>	<b>EUR</b>
Basic	0.78	0.60
Diluted	0.78	0.60

## Gross profit and margin

Gross profit was positively impacted by

- a significant year-on-year increase (HUF 23,392m) in royalties receivable from VRAYLAR<sup>®</sup>,
- a one-off milestone received in the first quarter in respect of USA sales of VRAYLAR<sup>®</sup> (HUF 7,072m),
- an overall favourable FX environment with a strengthening USD and RUB together with a weakening HUF which impacted on gross profit by increasing HUF denominated turnover,
- an increasing share of the turnover of certain higher margin OCs, emergency contraceptives and BEMFOLA<sup>®</sup>,

while it was negatively impacted by the following:

- a decline in sales of approximately HUF 7bn experienced by a number of our traditional products,
- the serialization project, which resulted in increasing costs of operation and shrinking production capacities,
- considerable increases of wages in Central and Eastern Europe and
- price erosion experienced on our traditional markets.

## Gross margin

Gross margin at 55.8 percent declined during the reported year when compared to the 57.0 percent achieved in 2018 as a result of the previously detailed contradictory items in addition to higher turnover of the low profitability Wholesale and retail activity, which itself significantly exceeded the sales growth rate achieved by the Pharmaceutical segment.

## Sales and marketing expenses

The proportion to sales of such expenses was 24.0 percent during the reported year when compared to 25.9 percent reported in 2018. The above proportion declined significantly during the reported period mainly as a result of the robust growth of royalty-linked incomes. The increase of the amount of Sales and marketing expenses was primarily due to the exchange rate movements and wage increases incurred in the Central and Eastern European countries.

## Amortisation of acquired portfolio

Amortisation of the marketing and intellectual property rights of the OC portfolio acquired from Grünenthal in the amount of HUF 4,389m represented 0.9 percent of sales achieved in the reported year.

## Registration fee for medical representatives

The annual registration fee payable in respect of medical representatives in Hungary amounted to HUF 282m in 2019. In accordance with the regulations tax payable in 2019 on this ground can be offset by 90 percent of the tax liability depending on the level of R&D expenditures and wage related expenses of the staff employed in this field. Given the high amounts directed to this activity Richter is practically exempted from the payment of this extraordinary tax from the second quarter of each year.

## Administrative and general expenses

These expenses grew primarily due to higher employee costs, together with higher IT related expenses.

## Research and development expenses

The proportion to sales of these expenses increased to 9.6 percent in 2019 when compared to 9.1 percent reported in the previous year.

The Research and development expenses include the ongoing clinical trials being carried out in co-operation with Allergan together with development programs executed in the field of biotechnology and women's healthcare. In addition certain CNS projects have moved into the clinical phase.

## Other income and other expenses

### Claw-back

During the reported period Other income and expenses include liabilities amounting to HUF 3,300m in respect of the claw-back regimes. Such expenses declined by HUF 1,484m mostly as a result of the sales restrictions applied to ESMYA®.

### One-off items

One-off items accounted for as Other income in the reported period include milestones received from Allergan, Sequirus, Recordati, Hikma and Mitsubishi and amounted to a total of HUF 5,717m when compared to HUF 8,429m accounted for in the base period.

One-off expenses include among others impairment losses amounting to HUF 37,971m accounted for in 2019:

- HUF 29,114m in respect of the Esmya intangible asset. This amount includes the impairment accounted for at the 9 months to September 2019 period.
- In line with IAS 36 regulation the Group performs impairment assessment on a yearly basis of the book value of its intangible assets. When calculating the recoverable amount of intangible asset Esmya the Management decided to account for an impairment loss in this respect having in mind the termination of data exclusivity in the EU territories with effect from May 2020 and a lower turnover achieved in 2019 than initially expected in 2018.
- impairment of the goodwill related to PregLem amounting to HUF 2,319m.
- impairment of the goodwill related to the Group's Chinese subsidiaries amounting to HUF 4,442m
- development of trastuzumab was discontinued, and consequently a HUF 2,096m impairment loss was accounted for in respect of the intangible asset.

Impairment losses accounted for in respect of Esmya intangible asset and impairment of the goodwill related to PregLem amounted to HUF 24,270m in 2018.

## 20 percent tax obligation payable

In 2019 an expense of HUF 631m was accounted for in respect of the 20 percent tax obligation payable with regard to turnover related to reimbursed sales in Hungary. In accordance with the regulations tax payable on this ground can be offset by 90 percent of the tax liability depending on the level of R&D expenditures and wage related expenses of the staff employed in this field. Given the high amounts directed to this activity Richter is practically exempted from the payment of this extraordinary tax from the second quarter of each year.

## Profit from operations and operating margin

Profit from operations declined during 2019 when compared to 2018. When adjusting profit from operations with both the milestones received and impairment losses accounted for in 2019 and 2018, it amounted to HUF 72,150m during the reported year while the similarly adjusted profit from operations reached HUF 60,881m in 2018.

Operating margin reported for 2019 at 7.9 percent declined from 10.1 percent achieved in 2018.

When adjusted with one-off items detailed above the Operating margin was 14.2 percent in 2019 when compared to the similarly calculated figure of 13.7 percent recorded in the base year.

## EBITDA

EBITDA in the reported year amounted to HUF 75,524m when compared to HUF 79,947m achieved in 2018.

The Group defines EBITDA as operating profit increased by depreciation and amortization expense. From 1 January 2019 the Group has applied the IFRS 16 Leases standard. As a result of the new standard certain rental expenses are capitalised and the expense is charged as depreciation and interest expense. Such depreciation related to the right of use assets is not added back when determining the EBITDA.

## Consolidated net financial income

Consolidated Net Financial Income					
For the years ended 31 December	2019 HUFm	2018 HUFm	Change HUFm	2019 EURm	2018 EURm
<b>Unrealised financial items</b>	<b>(740)</b>	<b>(2,106)</b>	<b>1,366</b>	<b>(2.2)</b>	<b>(6.6)</b>
Exchange gain/(loss) on trade receivables and trade payables	360	(3,259)	3,619	1.1	(10.2)
Gain on foreign currency loans receivable	1,166	1,276	(110)	3.6	4.0
Foreign exchange and fair valuation difference of other financial assets and liabilities	(1,582)	(96)	(1,486)	(4.8)	(0.3)
Result of unrealised forward exchange contracts	-	(27)	27	-	(0.1)
Interest expenses related to IFRS 16 standard	(594)	-	(594)	(1.8)	-
Year-end foreign exchange difference related to IFRS 16 standard	(90)	-	(90)	(0.3)	-
<b>Realised financial items</b>	<b>11,034</b>	<b>(36)</b>	<b>11,070</b>	<b>33.9</b>	<b>(0.1)</b>
Exchange gain realised on trade receivables and trade payables	8,971	316	8,655	27.6	1.0
Foreign exchange difference on conversion of cash	1,283	1,305	(22)	3.9	4.1
Dividend income	1	15	(14)	0.0	0.0
Interest income	914	1,349	(435)	2.8	4.2
Interest expense	(1)	(2)	1	0.0	0.0
Other financial items	(134)	(3,019)	2,885	(0.4)	(9.4)
<b>Net financial income / (loss)</b>	<b>10,294</b>	<b>(2,142)</b>	<b>12,436</b>	<b>31.7</b>	<b>(6.7)</b>

Net financial gains reported on Realised financial items were achieved primarily by Exchange gains realised on trade receivables and trade payables as well as those achieved on Foreign exchange difference on conversion of cash.

Net financial gains on Unrealised financial items during the reported year resulted primarily from Gain on foreign currency loans receivable, which was partly offset by an Exchange loss on other items currency related items.

Unrealised financial gains were further decreased by financial expenses related to IFRS16 standard.

Reassessment gains were a consequence of the period end appreciation of USD, EUR and RUB against HUF.

## Corporate and income tax

By virtue of Hungarian Tax Regulations, the base income of the Company, on which corporate tax is applied, may be reduced by the amount of direct costs incurred on R&D activities and 50 percent of royalties received. Other members of the Group are subject to customary tax regulations effective in their respective countries of incorporation.

Income tax allowance linked to intensive R&D activities of the Parent together with increasing proceeds from cariprazine related royalties resulted in a negative tax base for the third consecutive year. This impact is expected to last in the future also, therefore the deferred tax asset was entirely derecognized.

In 2019 the Group reported HUF 2,275m tax income which resulted from a HUF 2,465m corporate tax expense and a HUF 4m extraordinary tax expense which was more than offset by a credit of HUF 4,744m deferred tax.

## Net income and net income margin

Net income attributable to owners of the parent amounted to HUF 47.135m in the reported year when compared with HUF 35.348 in 2018 while net income margin attributable to owners of the parent increased to 9.3 percent in the reported year from 7.9 percent.

## 5. Cash Flow

Consolidated Cash Flow Statement		
For the years ended 31 December	2019 HUFm	2018 HUFm
<b>Operating activities</b>		
Profit before income tax	50,848	43,953
Depreciation and amortisation	39,320	34,907
Non cash items accounted through Consolidated Income Statement	(503)	2,130
Net interest and dividend income	(320)	(1,362)
Changes in provision for defined benefit plans	733	249
Reclass of results on changes of property, plant and equipment and intangible assets	1,725	312
Impairment recognised on intangible assets and goodwill	38,055	24,680
Expense recognised in respect of equity-settled share-based payments	1,636	1,743
Movements in working capital		
Increase in trade and other receivables	(33,063)	(4,617)
Increase in inventories	(6,308)	(8,772)
Increase in payables and other liabilities	13,452	13,300
Interest paid	(1)	(2)
Income tax paid	(7,360)	(6,178)
<b>Net cash flow from operating activities</b>	<b>98,214</b>	<b>100,343</b>
<b>Cash flow from investing activities</b>		
Payments for property, plant and equipment	(39,507)	(39,073)
Payments for intangible assets	(18,578)	(18,982)
Proceeds from disposal of property, plant and equipment	1,449	736
Government grant received related to investments	2,428	901
Payments to acquire financial assets	(11,633)	(3,291)
Proceeds on sale or redemption on maturity of financial assets	4,731	17,498
Disbursement of loans net	492	(646)
Interest received	914	1,349
Dividend received	1	15
Net cash outflow on purchase of group of assets	-	(2,881)
<b>Net cash flow to investing activities</b>	<b>(59,703)</b>	<b>(44,374)</b>
<b>Cash flow from financing activities</b>		
Purchase of treasury shares	(3,539)	(3,653)
Dividend paid	(18,850)	(12,673)
Principal elements of lease payments	(3,791)	-
Repayment of borrowings	(2)	-
<b>Net cash flow to financing activities</b>	<b>(26,182)</b>	<b>(16,326)</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>	<b>12,329</b>	<b>39,643</b>
<b>Cash and cash equivalents at beginning of year</b>	<b>113,021</b>	<b>76,041</b>
Effect of foreign exchange rate changes on the balances held in foreign currencies	3,223	(2,663)
<b>Cash and cash equivalents at end of year</b>	<b>128,573</b>	<b>113,021</b>

## Cash Flow

	2019 HUFm	2018 HUFm
<b>Net cash flow</b>		
From operating activities	98,214	100,343
From investing activities	(59,703)	(44,374)
From financing activities	(26,182)	(16,326)
Effect of foreign exchange rate changes	3,223	(2,663)
<b>Increase/(Decrease) in cash and cash equivalents</b>	<b>12,329</b>	<b>39,643</b>

As indicated by the cash flow statement, the Group generated net cash from operating activities of HUF 98,214m during 2019. Cash from operating activities remained below the levels reported for the previous year mainly due to significantly higher trade and other receivables.

Not insignificant amounts of cash were directed towards capital expenditure and payment of dividends.

Capital expenditure for the Group including payments for intangible assets (HUF 18,578m) totalled HUF 58,085m in 2019 when compared to HUF 58,055m reported for the previous year. The high figure incurred in the base period included a downpayment linked to the acquisition of a novel contraceptive from Mithra Pharmaceuticals in the third quarter 2018.

Overall, during 2019 cash and cash equivalents increased by HUF 12,329m.

## 6. Treasury Policy

The treasury activities of the Richter Group are centrally managed by the treasury function of the Parent Company. The centralised responsibilities include group-level financing, coordination of cash pooling, management of FX risks, investment of short-term liquidity and the management of receivables.

The Parent Company assumes responsibility for the financing of subsidiaries through parent company loans as funding instruments for the subsidiaries; centralised financing provides a cost effective solution for the subsidiaries while at the same time providing an investment opportunity for group-level liquidity.

The Group operates cash pooling structures in certain regions where it is legally and commercially feasible; the concentration of free cash positions assists more efficient financing and liquidity management.

As the FX composition of Group revenues and expenditures significantly differ, operating profit is exposed to numerous currency fluctuations. The management of foreign exchange risk is based on a strategy approved by the Board of Directors. The treasury function regularly evaluates the risk exposure and analyses potential hedging opportunities. The Group uses only plain vanilla derivative instruments (e.g. forward contracts) for hedging purposes. Hedging transactions are concluded exclusively by the Parent Company and are executed in cases where the risk situation and the potential benefits are considered to be reasonable. In 2019 the Group did not apply any hedge accounting rules under IFRS9 in respect of these transactions. The management of FX risk is periodically reviewed by the Board of Directors. There were two open forward contracts recorded by the Group as of 31 December 2019 with total notional value of HUF 668m.

Investment of short-term liquidity at Richter is coordinated and managed in accordance with policies approved by the Board of Directors. Investment decisions are made in a regulated environment and are based on conservative investment principles, ensuring only low risk instruments (e.g. high quality securities, bank deposits and mutual fund shares) are used.

As the Group markets its products in several countries, which could be considered to be medium-to high-risk, the sovereign and counterparty risk can affect profitability. The Group use credit insurance products in higher-risk regions to partially mitigate its risk exposure. Management of receivables and impairment losses are closely monitored and subject to supervision by the Chief Financial Officer of the Company.

## 7. Business Segment Information

Business Segment Information										
	Pharmaceuticals		Wholesale and retail		Other		Eliminations		Group total	
	HUFm		HUFm		HUFm		HUFm		HUFm	
	2019	2018	2019	2018	2019	2018	2019	2018	2019	2018
Total revenues	407,342	364,731	109,246	88,598	6,642	6,255	(15,436)	(14,100)	507,794	445,484
Gross profit	271,996	245,465	10,436	7,509	880	676	(18)	186	283,294	253,836
Profit from operations	38,835	44,631	734	(97)	340	331	(13)	175	39,896	45,040
Share of profit of associates	(388)	(431)	1,230	1,428	43	27	(227)	31	658	1,055
Number of employees at period end	11,090	10,738	1,512	1,487	423	450	-	-	13,025	12,675

Pharmaceutical sales by geographies are presented on page 63 of this Annual report.

Wholesale and Retail Sales					
	2019	2018	Change	2019	2018
	HUFm	HUFm	%	EURm	EURm
Romania	88,162	69,571	26.7	271.0	218.4
Other CIS republics	16,674	14,797	12.7	51.2	46.4
Latin America	4,410	4,230	4.3	13.6	13.3
<b>Total</b>	<b>109,246</b>	<b>88,598</b>	<b>23.3</b>	<b>335.8</b>	<b>278.1</b>





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