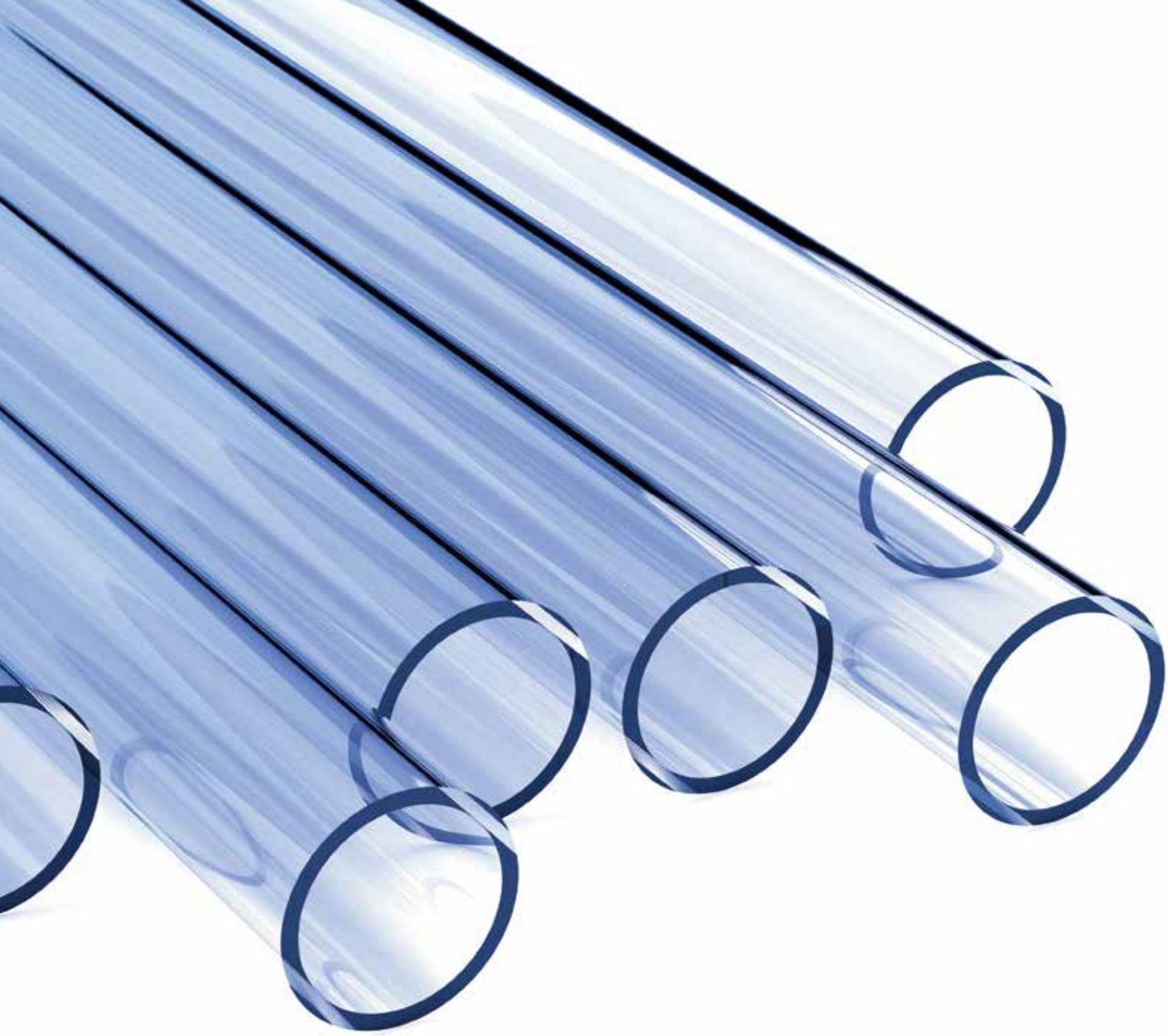
Gedeon Richter Annual Report 2018



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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	HU 10484878	
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

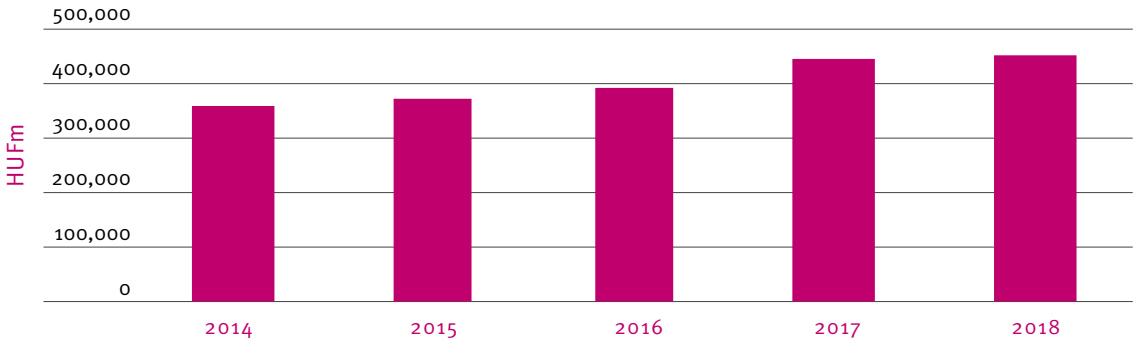
2. Financial Highlights

Consolidated financial highlights

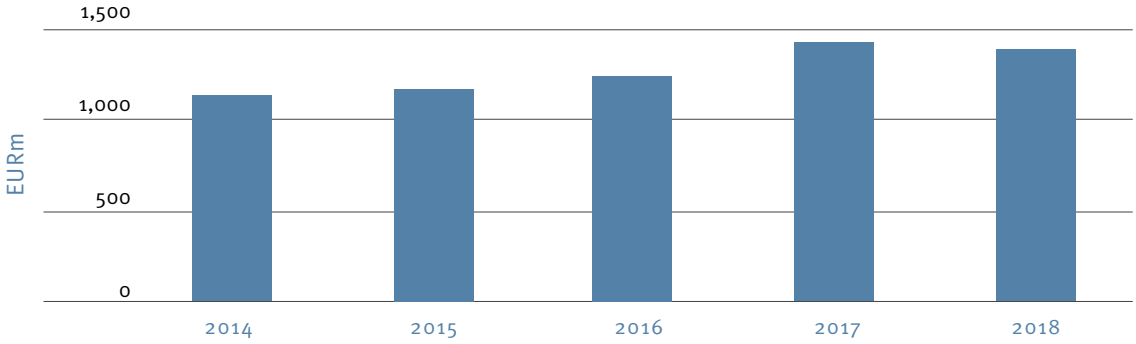
	2018 HUFm	2017 HUFm	Change %	2018 EURm	2017 EURm	Change %
Total revenues	445,484	444,356	0.3	1,398.2	1,436.8	(2.7)
Profit from operations	45,040	20,711	117.5	141.4	67.0	111.0
Profit for the year	36,193	10,070	259.4	113.5	32.6	248.2
	2018 HUF	**2017 HUF**	**Change %**	**2018 EUR**	**2017 EUR**	**Change %**
Earnings per share (EPS)[1]	190	48	295.8	0.60	0.15	300.0
Dividends per ordinary shares[2]	100	68	47.1	0.31	0.22	40.9

Notes: [1] Earnings per share calculations were based on the total number of shares issued.
[2] The amount of 2018 dividend per ordinary share is HUF 100 as proposed by the Board of Directors.

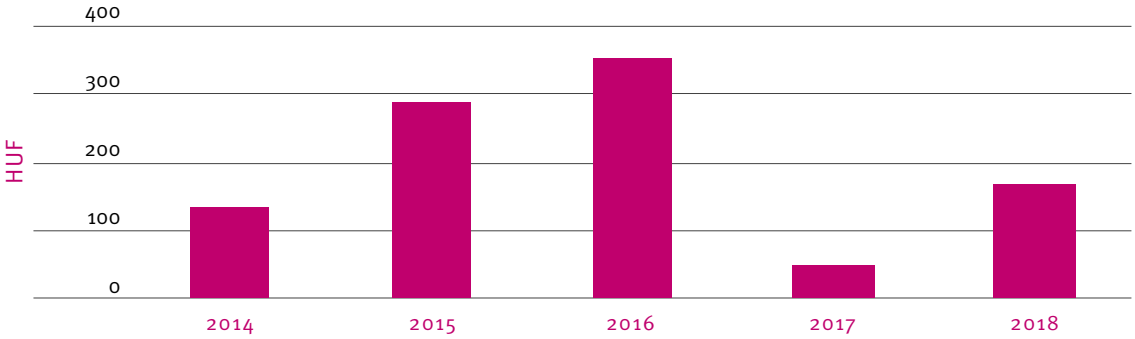
Revenues



Revenues



Earnigs per share*



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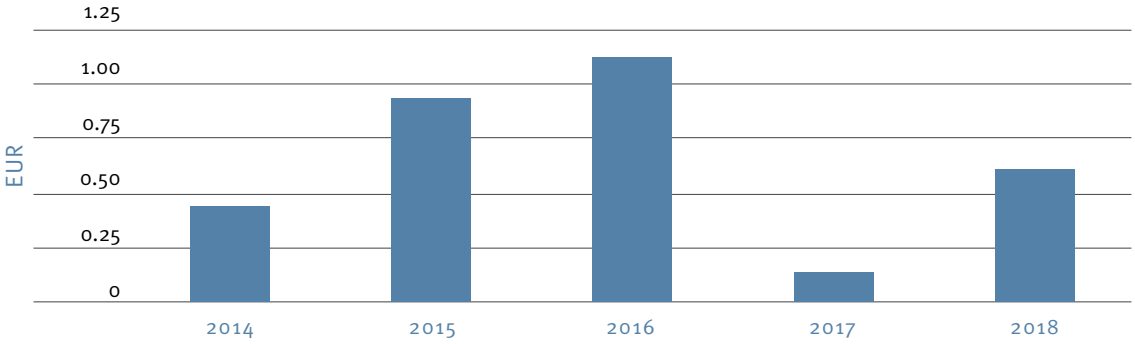
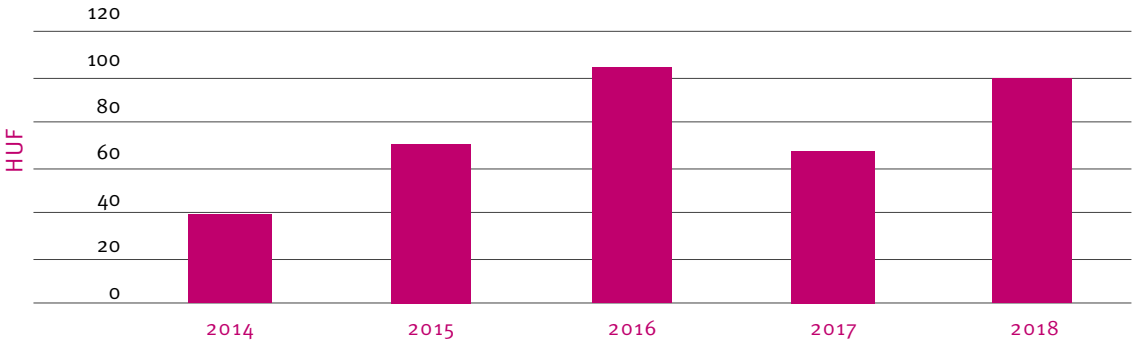
Earnigs per share*



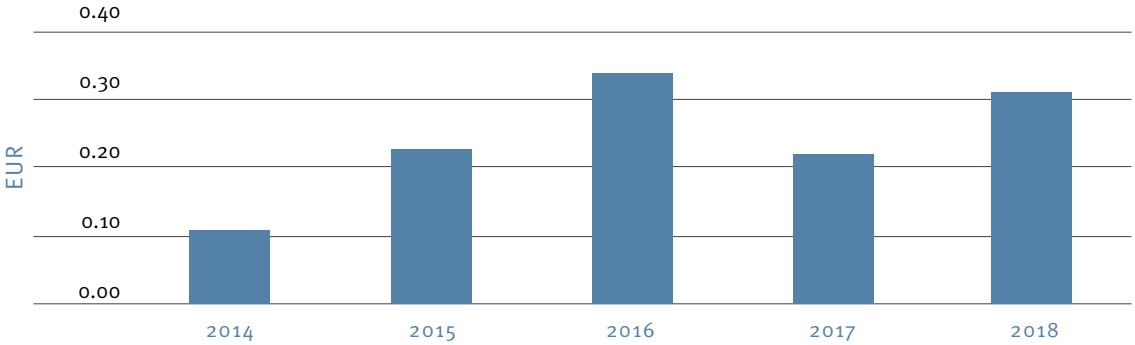
Note: *Earnings per share calculations were based on the total number of shares issued.

Dividends per ordinary share*



Note: *The amount of 2018 dividend per ordinary share is HUF 100 as proposed by the Board of Directors.

Dividends per ordinary share*



Note: *The amount of 2018 dividend per ordinary share is HUF 100 as proposed by the Board of Directors.

Erik Bogsch
Chairman

3. Chairman's Letter to the Shareholders

I am pleased to present the Annual Report for 2018. The year under review with both ups and downs represented for the three key specialty areas of the Group excellent results while at the same time certain most disappointing events as described below.

Royalty proceeds of cariprazine, marketed in the USA under the brand name VRAYLAR® contributed nearly USD 90 million to our topline performance increasing our gross and operating profits by virtually the same amount. The product currently awaiting a Supplemental New Drug Application to be granted by the FDA in the first half of 2019 is expected to grow further in 2019 and we are looking forward to completing ongoing Phase III trials to further expand the labelling of this novel atypical antipsychotic invented by Richter scientists. Turnover of REAGILA® in European markets, albeit at low levels, was reported for the first time during the year under review.

The business reporting year was, nevertheless, negatively impacted by the review of our flagship product, ESMYA®. Temporary sales restrictions in place from early February 2018 were replaced at the end of July by a revised labelling ruled by the European Commission which allowed for the relaunch of the product in the EU under closely monitored conditions. The temporary restriction and the slow pickup in sales recorded in the second half of the year resulted in a more than EUR 67 million loss in turnover when compared to 2017. Good performance of BEMFOLA® and other products belonging to the Women's Health franchise were unable to offset the loss in sales and profitability connected to ESMYA®.

Women's Healthcare, the Group's core specialty showed overall a somewhat confusing performance. While turnover declined by nearly EUR 60 million during the reported year as a result to the above mentioned review process of ESMYA®, we can report encouraging results achieved on our path to further enhancing our existing product portfolio. Following a license and distribution agreement signed in September 2018 an innovative oral contraceptive (OC), containing natural estrogen and deemed to lower the risk of venous thromboembolism (VTE) is expected to strengthen our product line as early as 2022, should the filing and authorization take place in accordance with our plans. Another innovative OC was licensed in subsequent to the end of the reported year, in February 2019. Being in an earlier development phase, requiring additional clinical trials to be performed prior to a filing this product is expected to ensure contraceptive efficacy while improving female sexual dysfunction, observed in some women using existing OCs.

As far as the ownership structure of Richter is concerned, subsequent to the reported year, in February 2019 the Government announced that it would transfer 10 percent of its share ownership in Richter to a Foundation which has as its aim the financing of the Corvinus University. Details and timing of this transfer are unclear at the time of releasing this Annual Report. Additionally, Government bonds backed by Richter shares which were due in 2019 were redeemed ahead of time in October 2018 by State Holding Agency.

The Board is delighted to acknowledge the efforts of Mr Gábor Orbán, CEO, who together with his management team have taken important steps to safeguard all the resources needed for a sustainable increase of shareholder value.

Erik Bogsch
Chairman

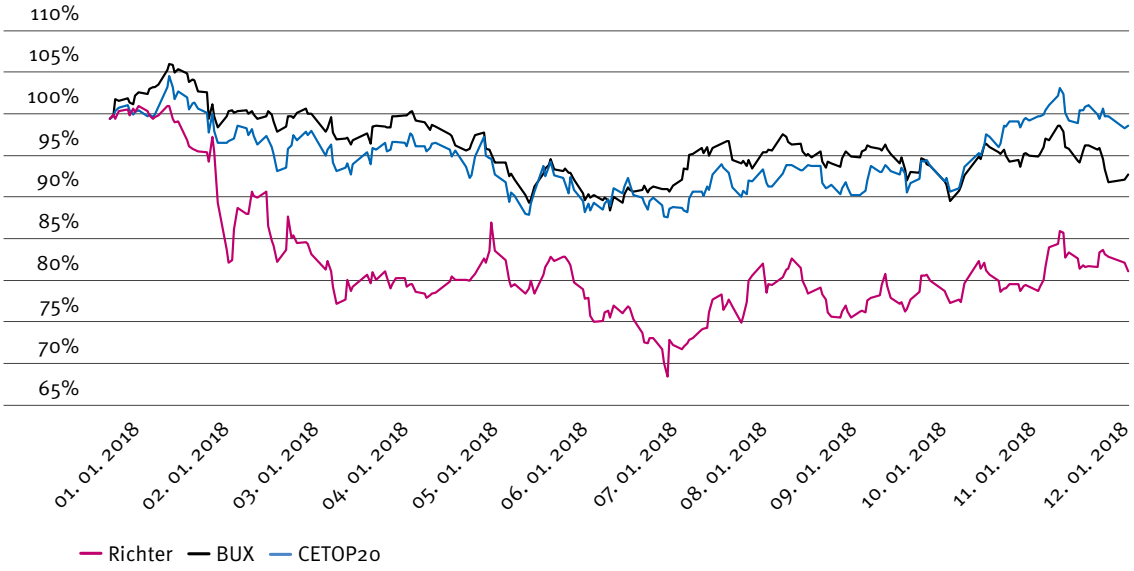
4. Investor Information

a) Share Price and Market Capitalisation

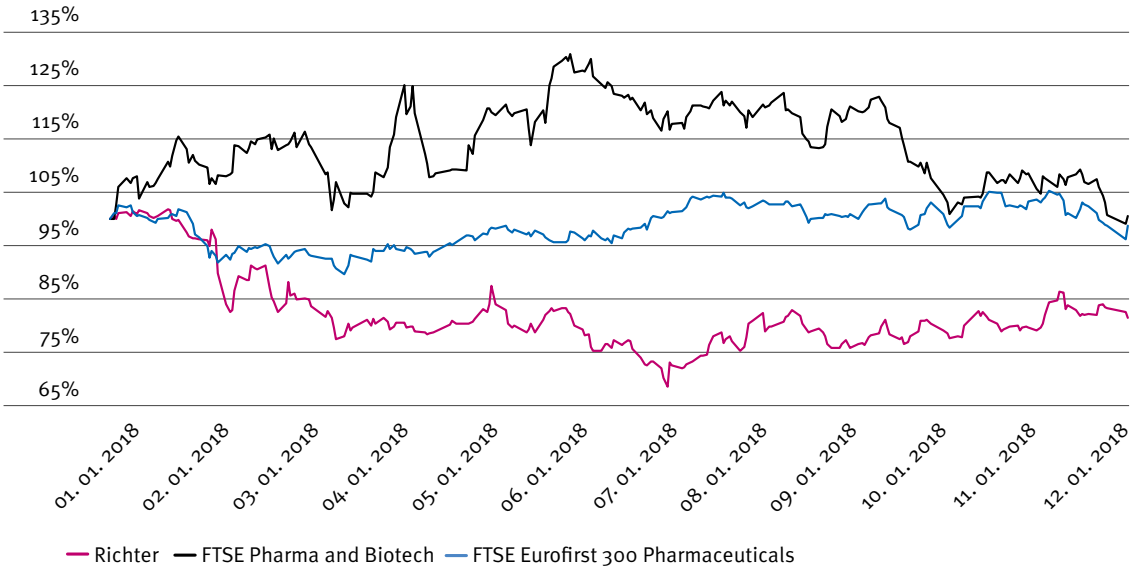
The Gedeon Richter Plc. share price on 2 January 2018 was HUF 6,670. The evolution of the share price was under pressure in the first half of the year due to the ongoing review procedure of Richter's key product, ESMYA® initiated by the Pharmacovigilance Risk Assessment Committee (PRAC) in late 2017. Temporary restrictive measures announced by PRAC on 9 February 2018 resulted in a HUF 905 or 14.1 percent price fall in the three trading days following the announcement leaving the shares at HUF 5,500. Following a short increase the share price again began to decline and it reached its annual minimum value, HUF 4,570 in mid July. Subsequently the share price strengthened during almost the whole period until the end of the year when it remained within a range of HUF 5,000 and 5,500. The closing price on 28 December 2018 was HUF 5,430.

The Company's market capitalisation linked to the performance of its share price on the Budapest Stock Exchange at the end of 2018 was HUF 1,012 billion reflecting an approximately 20 percent decline, in HUF terms when compared to its value recorded on 29 December 2017. Market capitalisation on 28 December 2018 in Euro terms was EUR 3.15 billion, about 23 percent below the EUR 4.07 billion recorded on 29 December 2017.

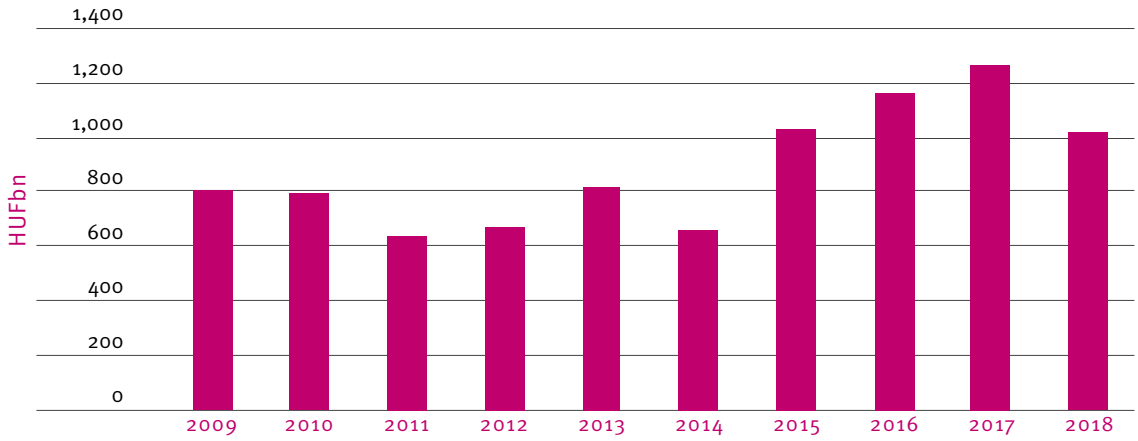
Gedeon Richter share price on the Budapest Stock Exchange compared to BUX and CETOP20 indices (%)



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

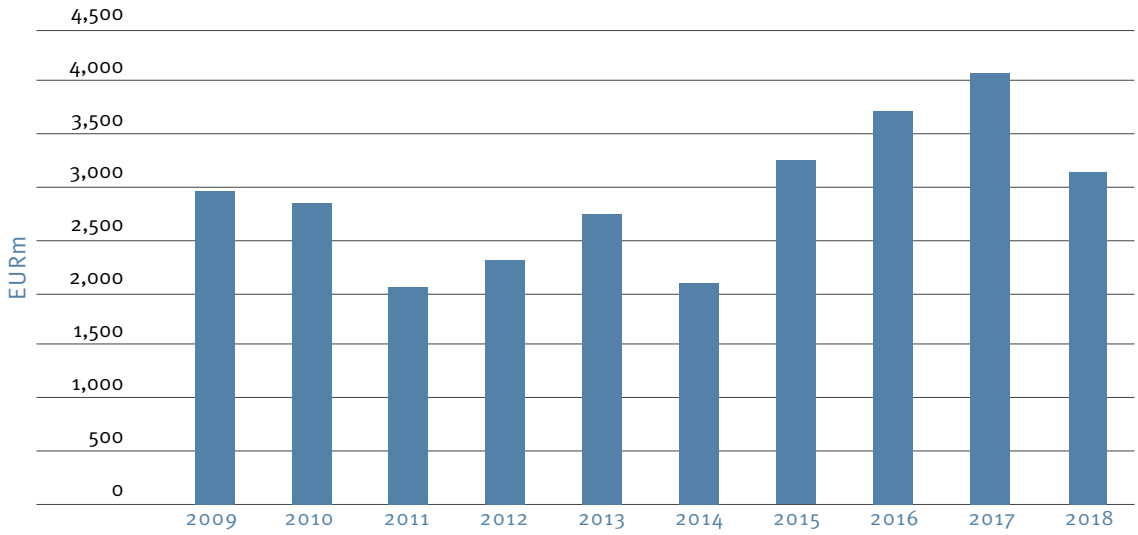


Market Capitalisation*



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

Market Capitalisation*



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

b) Annual General Meeting

The Annual General Meeting is the highest decision-making body of the Company, comprising all shareholders. The Annual General Meeting will be held at 14.00 on 24 April 2019 at Budapest 1093, Mátyás utca 8.

c) Dividend

In accordance with the dividend policy practised by the Company, the Board of Directors recommends the payment of 31.26 percent of Gedeon Richter Plc.'s consolidated profit attributable to owners of the parent adjusted for the impairment loss calculated according to International Financial Reporting Standards (IFRS) for 2018.

Dividends approved by the shareholders of Gedeon Richter Plc. at the Annual General Meeting held on 25 April 2018 totalled HUF 12.7 billion (EUR 41.0 million) in respect of 2017. The portion payable in relation to ordinary shares amounted to HUF 68 per share, 68 percent of the nominal share value. The record dates for these dividend payments were announced on 11 May 2018 with payments having commenced on 11 June 2018.

d) 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 2 additional investor roadshows in 2018. Gedeon Richter's management also held 17 meetings for approximately 25 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 20 additional conference calls were organised on request.

Conferences in 2018			
Wood&Co-BÉT	"Hungarian Investor Day in Warsaw"	Warsaw	20 March 2018
Concorde	"One on One Conference"	Budapest	3 April 2018
Bank of America Merrill Lynch (BAML)	Global Healthcare Conference 2018	London	11-14 September 2018

Investor roadshows in 2018	
London	22-23 February 2018
London	18-19 September 2018

The Company's website (www.richter.hu) includes an area which is intended to meet the specific stated needs of investors, analysts and media 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 Phone: +36 1 431 5764) with institutional shareholders.

e) Analysts Providing Coverage

Analysts providing regular coverage about the company during 2018	
Bank of America Merrill Lynch	Mr Jamie Clark
Citi	Mr Matthew Menezes
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

f) Information Regarding Richter Shares

Shares In Issue

The total number of shares in issue at 186,374,860 as of 31 December 2018 remained unchanged from the levels reported as at 31 December 2017.

Treasury Shares

Shares held by the Company in Treasury

	Reason of purchase	Number	Nominal value (HUF)	as of share capital %	Book value (HUF)
Opening balance		**66,183**	**6,618,300**	**0.035**	**415,295,181**
out of which owned by Parent Company		**60,683**	**6,068,300**	**0.033**	**404,352,813**
Purchased	Bonus, Remuneration, Programme approved by NTCA[1]	650,000	65,000,000	0.349	3,550,383,479
Shares repurchased (OTC)	Bonus, Remuneration, Programme approved by NTCA[1]	11,049	1,104,900	0.006	57,106,495
Repurchased through Programme approved by NTCA[1]	Programme approved by NTCA[1]	8,038	803,800	0.004	44,845,566
Total share purchased		**669,087**	**66,908,700**	**0.359**	**3,652,335,540**
Professional Development Programme		14,473	1,447,300	0.008	77,358,747
Remuneration		7,543	754,300	0.004	40,215,537
Granted through Programme approved by NTCA[1]		324,226	32,422,600	0.174	1,764,176,800
Total utilization		**346,242**	**34,624,200**	**0.186**	**1,881,751,084**
Closing balance		**389,028**	**38,902,800**	**0.209**	**2,185,879,637**
out of which owned by EPP Organization [2]		**333,698**	**33,369,800**	**0.179**	**1,891,526,545**
out of which owned by Parent Company		**49,830**	**4,983,000**	**0.027**	**283,410,724**

Notes: [1] National Tax and Customs Administration of Hungary
[2] Employee Participation Program

The number of shares held by the Group in Treasury increased during 2018.

The Company purchased 650,000 shares on the Budapest Stock Exchange, while a further 11,049 shares were acquired on the OTC market.

In early 2018 the Management of the Company established the Richter Gedeon Plc Employee Participation Program Organization ("Richter EPP Organization") aiming to strenghten the performance and loyalty of its officers and key employees.

In accordance with the foundation charter and the incentive policy of the Richter EPP Organization 333,698 treasury shares were transferred during the second quarter 2018 in two tranches to the EPP Organization.

The beneficiaries are entitled to receive cash amounts corresponding to the value of the shares.

Based on a decision of the Board of Directors of Gedeon Richter Plc., 22,016 shares held by the Company in Treasury were granted as bonuses during 2018 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 8,038 shares from employees who resigned from the Company during 2018.

In a programme related to employee share bonuses, the Company granted a total of 324,226 shares in respect of 4,346 of its employees for 2018. The above shares in the value of HUF 1,764 million were deposited at the employees' individual securities accounts at UniCredit Bank Hungary Zrt. to be held until 2 January 2021.

On 31 December 2018 the Group's subsidiaries held a total of 5,500 ordinary Richter shares, a holding unchanged when compared to the number reported as of 31 December 2017.

The total number of Company shares at Group level held in Treasury at 31 December 2018 was 389,028 out of which 333,698 were owned by the EPP Organization.

On 2 January 2019, following the expiry of the lock-up period the Company was able to remove all restrictions on 285,459 Richter ordinary shares granted to its employees on 16 December 2016 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.) remained at 25 percent, a level similar to that of 31 December 2017. The proportion held by domestic investors increased to approximately 9 percent while that of international investors slightly decreased to approximately 66 percent. The proportion of treasury shares including the above mentioned holding of subsidiaries was 0.21 percent at the end of 2018.

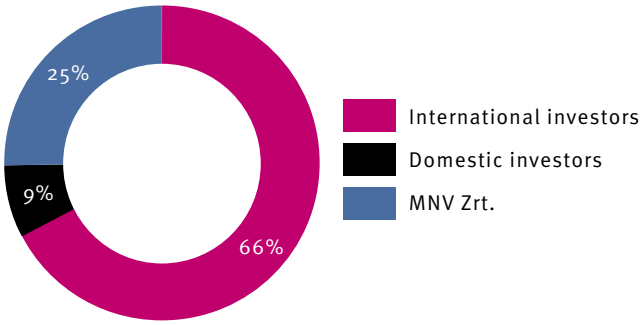
Data in the table below was compiled based on the share registry adjusted for information provided by KELER Zrt. as clearing company, global custodians and nominees.

Ownership structure on 31 December 2018

Ownership	Ordinary shares Number	Voting rights[2] %	Share capital %
Domestic ownership	63,716,497	34.20	34.19
State ownership total	47,051,794	25.25	25.25
out of which MNV Zrt.	47,051,668	25.25	25.25
out of which Municipality	126	0.00	0.00
Institutional investors	7,443,002	3.99	3.99
Retail investors	9,221,701	4.95	4.95
International ownership	122,249,372	65.61	65.59
Institutional investors	121,914,003	65.43	65.41
Retail investors	335,369	0.18	0.18
Treasury shares[1]	389,028	0.18	0.21
Undisclosed ownership	19,963	0.01	0.01
Share capital	**186,374,860**	**100.00**	**100.00**

Notes: [1]Treasury shares include the combined ownership of the parent company, the EPP Organization and subsidiaries.
[2] Shares owned by EPP Organization are voting shares.

Detailed ownership structure as of 31 December 2018 (%)



Ordinary shareholdings by the members of the Company's Boards

	31 December 2018 Number of ordinary shares	31 December 2017 Number of ordinary shares
Board of Directors	51,599	51,374
Supervisory Committee	2,313	3,140
Executive Board	24,119	23,600
Total	**78,031**	**78,114**

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

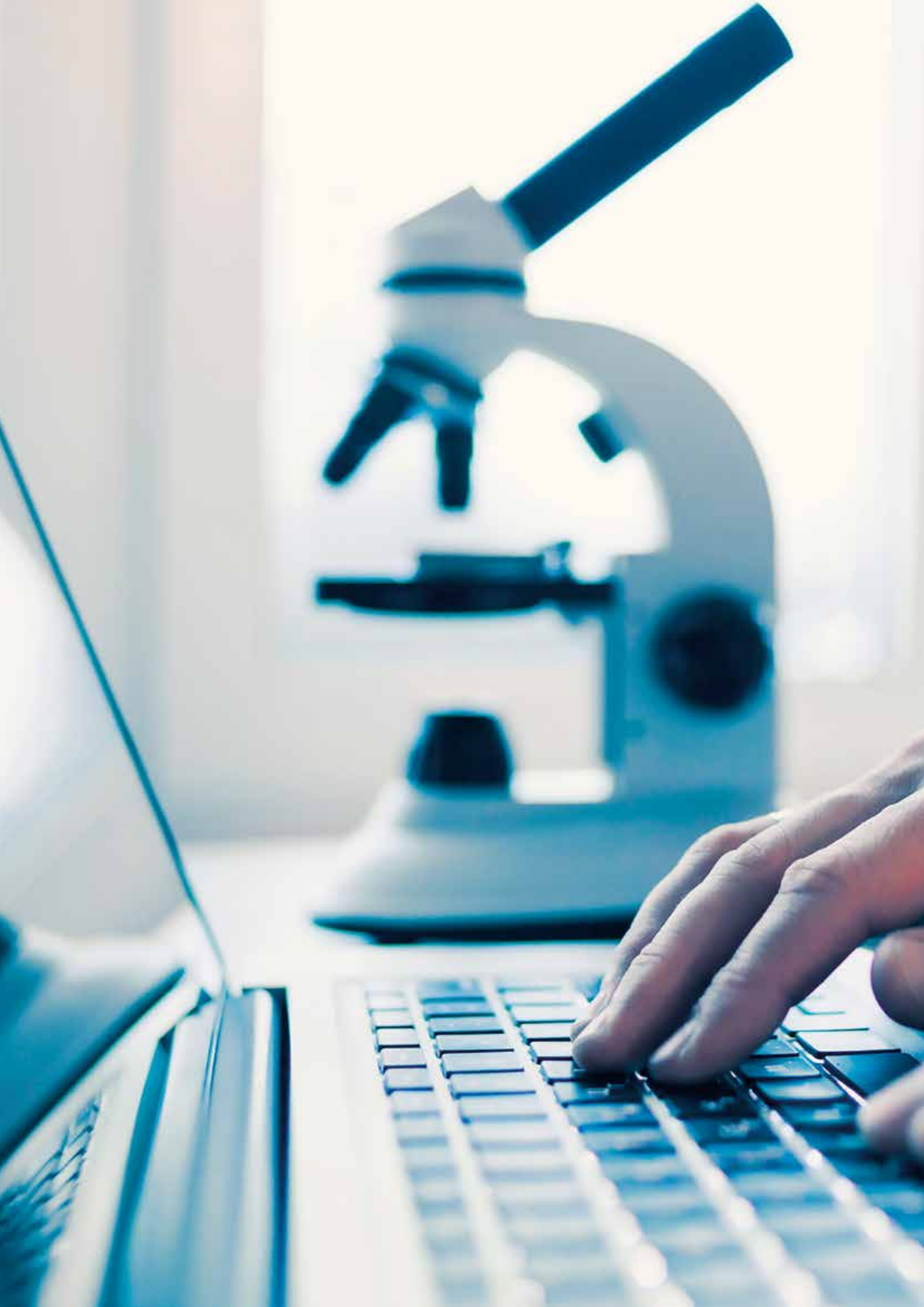
5. Corporate Governance

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. In order to maintain a sharp focus on strategic management the Board comprises only the Executive Directors.

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.

6. 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 from1995 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.

Mr János Csák (1962)

Economist, sociologist, management and strategic consultant. Ambassador of Hungary to the UK between 2011 and 2014. Previously member of the Board of Directors and advisory boards of several companies (MOL – Hungarian Oil and Gas Co., Westel - now T-Mobile, Matáv - now Magyar-Telekom, CA-IB Investment Bank) Mr Csák is a trustee for a number of NGOs and a lecturer in social sciences. In 2009-10 visiting fellow in political economy at The Heritage Foundation in Washington DC. Joined the Board in April 2014.

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 carreer 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 Pénzintézeti 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.

Ms 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.

Dr Norbert Szivek (1975)

A law school graduate having commenced his studies in Germany graduated in Hungary. Has worked in the Hungarian public sector followed by a position at a real-estate company. Subsequently he established his own asset management company. From 2015 to September 2018 Dr Szivek was the CEO and member of the Board of Directors at the Hungarian National Asset Management Inc. Joined the Board in 2016.

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. Since July 2015 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 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 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 carreer 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 Pénzintézeti 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.

Mr Lajos Kovács (1960)

Appointed Director in 2005. Responsible for Technical services. Chemical engineer, with postgraduate degree in pharmaceutical research. With Richter since 1984 in a number of different roles. Research fellow at the University of Liverpool (UK) between 1987 and 1989.

Mr András Radó (1954)

Appointed Director in 1995. Responsible for Production and Logistics. Deputy Managing Director since 2000. Chemical engineer, economic engineer. With Richter since 1979 in a number of management positions.

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 2018

With effect from 25 April 2018 Dr Gábor Perjés resigned from his position held in the Board of Directors of Richter.

At the Annual General Meeting on 25 April 2018, the following were appointed to the Board of Directors for a 3 (three) year period until the 2021 AGM
Ms Anett Pandurics
Mr Bálint Szécsényi.

At the Annual General Meeting the following were reappointed to the Supervisory Board for a 3 (three) year period until the 2021 AGM
Dr Attila Chikán
Prof Dr Jonathán Róbert Bedros,

together with employee representatives
Ms Klára Kovácsné Csikós
Dr Éva Kovácsné Kozsda.

At the Annual General Meeting
Dr Zsolt Harmath
was appointed to the Supervisory Board for a 3 (three) year period until the 2021 AGM.

The Annual General Meeting approved the reelection as members of the Audit Board for a 3 (three) year period until the 2021 AGM of the following
Dr Attila Chikán
Prof Dr Jonathán Róbert Bedros.

The Annual General Meeting approved the election as member of the Audit Board for a 3 (three) year period until the 2021 AGM of the Supervisory Board member,
Dr Zsolt Harmath.

The membership of Mrs Tamásné Méhész in the Supervisory Board and the Audit Board expired on the date of the 2018 AGM.

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;
- the Executive Board is directly responsible for 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 2018 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 2018
Risks of developing and distributing proprietary original or biosimilar products or in-licensed specially products	• Delay of clinical trials and registration, risk of high failure cost; • Side effects from the data collected in the PV system following the launch of the original product; • Impairment of intangible assets in case of weaker than expected performance at acquisition.	• Development cooperation for cost sharing and knowledge building; • In-depth risk assessment during the licensing phase; • Contingent payment terms in the license agreement; • Product development within project frameworks, go-no go decisions at milestones; • Developing unified regulatory management and processes ("Regulatory lead"); • Employing CROs and cross-border specialists; • Product implementation project teams, priority promotion.	▲
Risks related to further exploiting the declining market opportunities of the classic product portfolio	Risks of limitations on indications or product withdrawal in the event of failure to meet more stringent regulatory requirements over time.	• Special attention in the PV system, active regulatory dialogue with authorities, maintenance development projects	▲
Dependency on uncertain CIS markets	Regional conflicts, imposition of sanctions and market shrinkage due to protectionist measures, extreme devaluation of local currencies.	• Outsourcing to reduce the impact of protectionist measures; • Major effort to increase the weight of sales markets and specialty products outside the CIS region; • Providing customer loans in CIS.	►
Price pressure on medicines subsidized by the health budget, introducing special taxes on European markets	Decrease in product markup and corporate profitability in these markets.	• Developing cheaper own drug production processes, finding cheaper alternative drug sources, introducing new products, making efforts to increase the turnover of items not supported by the health budget (WHC, OTC)	►
Risks arising from the increasing market diversification and activity complexity of the Group	• In highly diverse markets, the lack of standardization of corporate processes can lead to malfunctions and non-conformities, while uniformisation is cost-increasing and flexibility-reducing; • Lack of experience in responding to new challenges in new markets; • As a medium-sized company, it is difficult to ensure the critical mass of resources alone in order to expand our portfolio at the same time in 3 completely different therapies (CNS, WHC, Biosimilar).	• Strengthening and consolidating the three lines of HQ management of subsidiaries (functional management; legal governance, financial reporting); • Development of globally unified processes, introduction of more advanced management and support systems; • Development of corporate partnerships for development and sales; • Creating project teams, implementing preparatory programs when entering new business areas and introducing new special products.	►

Pharmaceutical industry related operational and compliance risks

Risk area	Description of risks	Major risk management actions taken	Impact changes in 2018
Risk of losing qualified pharmaceutical labour	In the Hungarian, Romanian and Polish labor markets, it is becoming increasingly difficult to recruit and replace qualified pharmaceutical workers.	• Wage increases and the use of constructions that support long-term commitment to the company; • In 2018, implementation of the priority wage increase in domestic production plants and launch of own vocational training; • Relocate manufacturing to Russia	▲
• Compliance with high quality requirements for the development and manufacture of pharmaceutical products, dependence on suppliers; • Product liability risk throughout the life cycle	• Non-compliance with GMP, GLP, GCP, GDP, IT GXP, PV may result in the revocation of activity licenses; • Quality defects, delays, uncompetitive cost levels, reputation loss due to supplier deficiencies; • New side effects, contamination, manufacturing fault, intentional damage, counterfeiting; • From 2019, the use of unique identifiers ("serialization") on drug boxes becomes a condition for market entry and for ongoing market presence.	• Production based on Market Authorization, Quality Assurance; • Application of quality assurance systems, SOP controlled operation; • In the case of key products, development of own API; • Applying a supplier rating system, seeking to register alternative suppliers; • Complex preliminary implementation project for Serialization; • Product liability insurance, general liability insurance, compensation.	▲
Selling practices that comply with ethical standards in the industry, high level of data protection	• Employee behavior that violates the ethical and advertising rules of drug promotion; • Non-compliance with GDPR requirements due to unauthorized use of personal data or inadequate data protection.	• Compliance programme approved by the Board of Directors; • By-laws on GDPR and getting ready to comply, responsible person, education; • IT security development.	▶
Ensuring high availability of pharmaceutical equipment and IT systems	• API manufacturing is a dangerous operation, risk of fire and explosion; • Lack of products due to unexpected plant shutdown; • Individual machine failure due to failure, inspection risk due to obsolescence; • IT server failure, scarcity of data transfer capacities, unauthorized access, data theft.	• Based on the recommendations of the Risk Survey, production safety measures, insurance on property and on downtime, ex-post insurance compensation; • Adequate level of capacity maintenance and maintenance, troubleshooting; • Initiating IT investments and measures to improve availability and security.	▶
• Maintaining a high standard workplace safety and health system; • Applying procedures to reduce environmental load to limit values	• API exposure, workplace accidents, labour loss, compensation; • Stringent environmental load limits (noise, dust, sewage) must be adhered to, expensive waste disposal must be carried out.	• Application and certification of MEBIR system; • Comprehensive life and accident insurance; • Operating corporate environmental organization, Environmental Management System (EMS), monitoring, qualification, investments.	▶

Financial risks

Risk area	Description of risks	Major risk management actions taken	Impact changes in 2018
Currency risk	The Group is highly exposed to RUB and USD on the revenue side, exchange rate fluctuations may distort all income in HUF and EUR.	• Natural hedge to some extent by cost items occurring in the same currency; • Financial hedging operation on the basis of authorization granted by the Board of Directors.	►
Buyer credit risk	Certain markets in the Richter Group (CIS markets) and some member firms (Romanian wholesale company) face increased buyer credit risk.	• MEHIB insurance for trade receivables from CIS partners at manufacturing units of the Richter Group; • Market COFACE insurance for Romanian Pharmafarm customers.	►
Risk of investing in free funds	• At the parent company a secured reinvestment scheme for temporary free cash must be achieved; • At subsidiaries, a secured management of occasionally significant amounts of free funds is sometimes required.	• Parent company: Adoption, strict adherence to, and control of financial regulations at board level; • Centralized control of excess funds at subsidiaries.	►
Taxation related risks	• Parent company: certification of eligibility for tax benefits on basis of R&D and royalty; • Group: certification of transfer pricing between affiliated companies.	• At the parent company, requests for ministerial resolutions and discount accounting supported by the resolutions received; • Group transfer price: Masterfile based on established rates, local transfer pricing documentation.	►

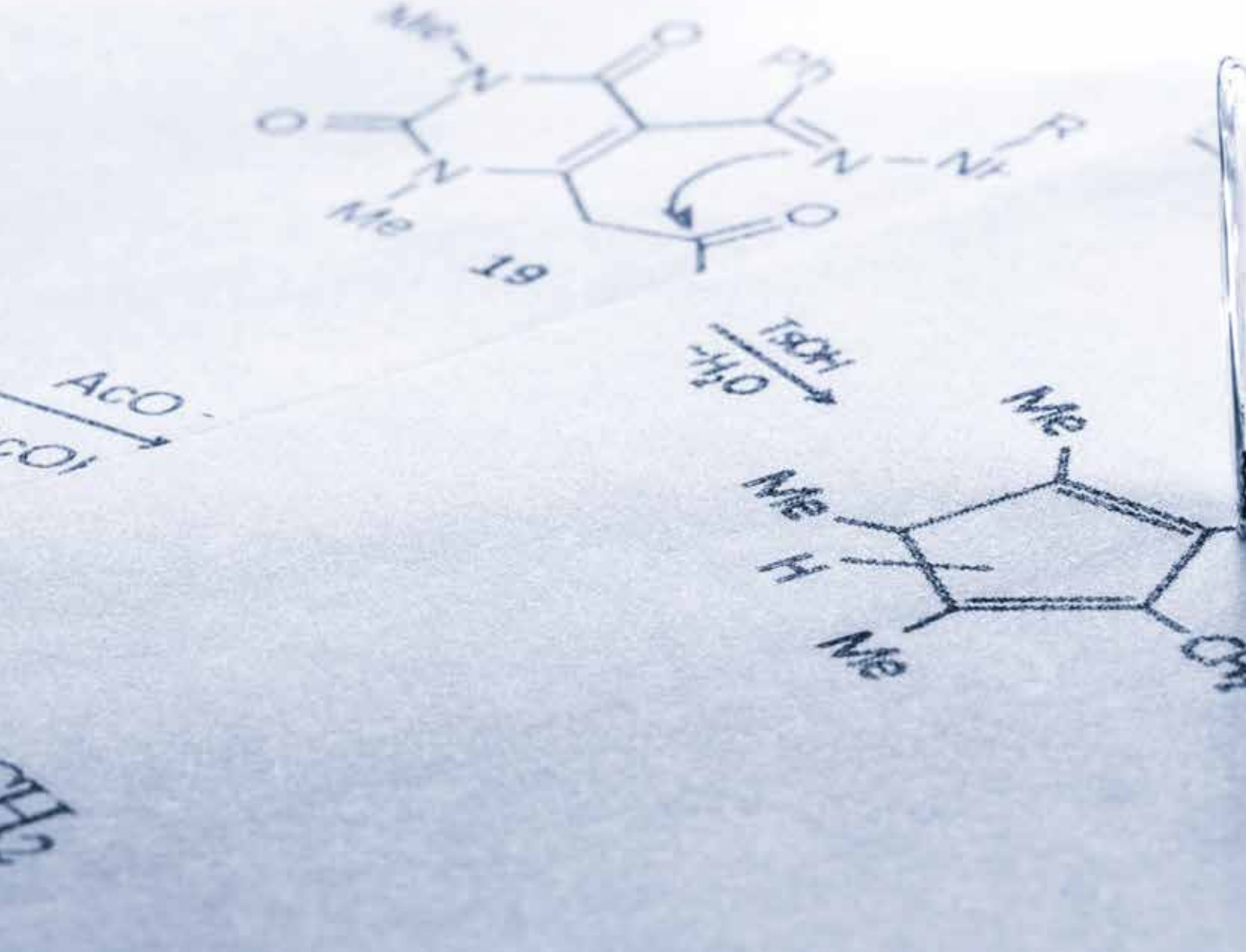
8. Litigation Proceedings

There are no ongoing legal proceedings which are considered to involve any material effect on Gedeon Richter Group's financial results.


250ml
APPROX

2

Chief Executive Officer's Review



Gábor Orbán
Chief Executive Officer

I believe that 2018 was a year characterized by a complex business environment comprising significant challenges and noteworthy achievements.

VRAYLAR® continued to be the fastest-growing atypical antipsychotic brand in the US, physician and patient experience and satisfaction with this product was very high. Allergan continued to support VRAYLAR® with a market-leading peer-to-peer promotional program and direct-to-consumer advertising, which produced what was generally regarded as exceptional returns. We, together with Allergan, reported positive Phase III clinical data, as a consequence of which in September 2018 FDA acknowledged the sNDA filing of the bipolar depression indication. The regulatory submission under review has an FDA action date in May 2019. As a potential attempt to further extend the label, additional phase III clinical studies for cariprazine as an adjunctive treatment in major depressive disorder have also been initiated in 2018. At the same time the submission procedure of application files for the reimbursement for REAGILA® is advancing well on individual European markets.

In parallel to the progress achieved with market developments of cariprazine, we had to face serious challenges regarding one of our flagship products, ESMYA®. In December 2017 the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) initiated a review procedure of drug induced liver injury potentially related to the product. While the review procedure was ongoing in February 2018 the product has been withheld from commercialization as a consequence of the implementation of temporary precautionary measures. In July 2018 a European Commission decision opened the way for the relaunch of this product although with a restricted use. Consequently in late August/early September while Richter sales team commenced a focused relaunch of ESMYA® on major European markets, while Allergan received a Complete Response Letter from FDA in respect of the NDA filing for ulipristal acetate. Allergan management continues a dialogue with the Authority in order to determine the potential next steps for the ulipristal acetate NDA.

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 2018 we have entered into a license and supply agreement with Mithra Pharmaceuticals to commercialize a novel combined oral contraceptive, which is expected to lower the risk of venous thromboembolism, pending the outcome of future clinical trials. A similar agreement has been signed with Pantarhei Bioscience BV to commercialise its combined oral contraceptive product which is expected to ensure contraceptive efficacy while improving female sexual dysfunction.

I am convinced that a pharmaceutical company which aims to remain competitive over the long-term must create a portfolio of high added value products. Exploration into new innovative areas such as original research or biosimilar product development, carries high risks but also provide opportunities for higher revenues in the future.
While we decided to withdraw the Marketing Authorisation Application for EFGRATIN (biosimilar pegfilgrastim) subsequent to the reported year in February 2019, we have prepared for the launch in August 2019 of our biosimilar teriparatide, TERROSA for the treatment of osteoporosis.

Our Group reported EUR 1,398.2 million consolidated sales in 2018, representing a 3 percent decrease when compared with 2017.

Given the negative impact on business of both the restrictions implemented to the label and the delay in the US regulatory procedure (for details please refer to Women's Healthcare section on ESMYA® on page 39) the Management considered it prudent to account for an impairment loss amounting to HUF 24,270 million (EUR 76.2 million) with regard to the intangible asset and goodwill linked to ESMYA®. The above impairment impacted the operating profit to a lesser extent than the ESMYA® related write off accounted for in the base period, and as a result operating profit amounting to EUR 141.4 million in 2018 showed an increase when compared to the previous year.

Profit for the year was EUR 113.5 million in 2018, representing a EUR 80.9 million year-on-year increase. When adjusted for the accounted impairment loss, the profit for the year was EUR 189.8 million.

We have made a number of changes in our senior leadership throughout the year, bringing in fresh expertise from outside the company. I am delighted to present Dr Tamás Szolyák who joined us in a new role as Regulatory Affairs Director in September 2018. He gained an exceptional reputation as Chief Executive Officer of Novartis Hungary and broadened his scope in pharma industry as a Chief Executive Officer of National Institute of Pharmacy and Nutrition.

Katalin Erdei also joined us as a Human Resource Director following the retirement of her predecessor with effect from 1 January 2019. Her role is to strategically plan and direct the management of the Groups' human assets and

reshape the organization to cope with future challenges. She gained good international experience as Human Resource Manager of Mars GmbH.

As we progress in our journey, the fundamentals of our specialty strategy and plans remain unchanged. We will carry on building up our global presence and leveraging our strength in our traditional markets, while pursuing the development of strong, balanced portfolios of both specialty and branded generic medicines. The world around us is changing, so we too are shifting the way in which we deliver our strategy. I am confident that by pursuing a strategy of specialty pharma, together with sustainable long term partnerships, Richter is well positioned for the future.

Finally, my thanks go to all my colleagues in Richter for their tireless efforts and achievements. None of our accomplishments would have been possible without the talented people we have in the organization. And I convey to our shareholders, my heartfelt thanks for the trust they have placed in us.

Gábor Orbán
Chief Executive Officer

3

“Specialty Pharma” model

Richter – Innovation and High Added Value

As a response to a number of challenges that emerged during the last decade (such as lengthy product development, increasing regulatory hurdles, exposure to constraints on national healthcare budgets, aging populations and substantial changes in the lifestyle of urbanized Western societies) Richter's management decided to implement a high added value driven specialty pharma business model with a primary focus on an organic growth strategy complemented with selected acquisitions primarily in the field of Women's Healthcare. Consequently Richter has invested significant resources in building up one of the widest Women's Healthcare portfolios worldwide, it has preserved its original research founded over a century ago and, uniquely in Central and Eastern Europe, it established biosimilar development and manufacturing facilities to address the changing demand for oncological and immunological diseases.

a) Women's Healthcare

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. This was at a time when they had complete novelty. Since then 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.

Our Women's Healthcare franchise traditionally has had a strong presence in Central and Eastern Europe and in the CIS region. In the mid 1990's our USA business was scaled up initially by signing a strategic agreement with Duramed Inc. focusing on Richter's niche specialty area, Women's Healthcare, notably on oral contraceptives, which was extended both in scope and in duration with Barr Inc., who acquired Duramed. 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.

A key element of the Company's strategy has been and remains the development of its Women's Healthcare product portfolio. In accordance with this strategy, two acquisitions were concluded during 2010, both of which further strengthened the Women's Healthcare portfolio. The acquisition of PregLem enabled Richter to enhance its portfolio with ESMYA®, a first in class product initially approved for pre-operative treatment of uterine fibroids in 2012 for the member states of the European Union. Subsequent indications followed in 2014 and 2015 with a two-cycle treatment and a long-term intermittent treatment, respectively. The purchase of Grünenthal's well-established oral contraceptive franchise boosted both our existing gynaecological sales and also created a platform for establishing a Women's Healthcare sales network in Western Europe.

In addition to this well-established portfolio a very promising product has been added in June 2016, when we acquired Finox Holding, a privately held Swiss biotech company focused on the development and commercialisation of innovative and cost effective products addressing female fertility. Finox represented a unique opportunity for Richter to widen its core Women's Healthcare franchise and further emphasises its commitment to the biosimilar business. This acquisition allows Richter to establish its presence in the female fertility therapeutic area – a major growth market.

Further expanding the fertility portfolio we have agreed with L.D. Collins & Co. Limited, a UK based company, to commercialize its 400 mg progesterone containing assisted reproduction technology (ART) product, CYCLOGEST®.

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 such fast growing regions as China and Latin America.

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.

Agreements have been signed with companies including the Australia based Acrux for an estradiol transdermal spray therapy for menopause symptoms, with the US based Evestra Inc., to co-finance the development of its innovative advanced contraceptive devices, namely vaginal rings, through clinical development. In addition further agreements

have been established with Pharmanest AB to commercialise its Short Acting Lidocaine (SHACT) technology, a novel innovative proprietary pain relief pharmaceutical formulation, as well as with PrimaTemp US, a Colorado based company, to commercialize its innovative medical device, PRIYARING.

Broadening the range of oral contraceptives products we have entered into a license and supply agreement with Mithra Pharmaceuticals to commercialize ESTELLE®, a combined oral contraceptive, containing 15 mg estetrol / 3 mg drospirenone. A similar agreement has been signed with Pantarhei Bioscience BV to commercialise its combined oral contraceptive, containing 30 µg ethynil estradiol, 150 µg levonorgestrel and 50 mg dehydroepiandrosterone (DHEA).

Richter makes available one of the world's broadest range of Women's Healthcare products while still continuing to extend its product portfolio.

ESMYA®

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. To date, GnRH agonists have been the only approved pre-operative treatment for uterine fibroids and their use has been relatively limited due to side effects resulting from the suppression of oestrogen to post-menopausal levels (hot flashes, depression, mood swings, loss of libido, vaginitis and loss of bone mineral density).

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. It improves quality of life and has no castration side effects unlike GnRH agonists.

In February 2012, the European Commission (EC) granted marketing authorization to ESMYA® 5 mg tablet as pre-operative treatment of moderate to severe symptoms of uterine fibroids. Following receipt of the marketing approval, the product has been registered and launched all across Europe, in the CIS region and also by our partner Allergan in Canada.

Following the acquisition of PregLem in 2010, Richter received exclusive licensing rights to develop and market ESMYA® in the EU region. At the same time such rights were licensed out to Allergan plc for the USA and Canada. The data used in the EU approval were from studies run mainly in Europe with no North American sites. The FDA requested inclusions of US population in the clinical trial and requested modification to the indication and primary efficacy endpoint to support a US approval.

In December 2011, Richter obtained from HRA Pharma an extension of its geographical scope for ESMYA® to the CIS and China. During 2013 Richter and HRA Pharma entered into a further licensing agreement in connection with marketing rights of ulipristal acetate for the treatment of benign gynaecological disorders with respect to the territories of Latin America.

In May 2015 the EC granted approval for the intermittent use of ESMYA® 5 mg in the long-term management of uterine fibroids providing an opportunity for women to potentially avoid surgery.

Recent developments

In December 2017 the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) commenced a review of drug induced liver injury potentially related to ESMYA®.

In February 2018 PRAC initiated the implementation of temporary precautionary measures as a part of its review procedure. The PRAC recommended regular liver monitoring for women taking ESMYA® for uterine fibroids. The PRAC also recommended that no new patients should be started on ESMYA® and no patients who had completed a course of treatment should start another one. Treatments commenced prior to this decision were allowed to be completed.

In May 2018 the PRAC made its final recommendation as a conclusion of its review procedure on drug induced liver injury potentially related to ESMYA®, an opinion which was also endorsed in June 2018 by CHMP.

In July 2018 the European Commission decision adopted the opinion of CHMP on the ESMYA® referral, which opened the way for the relaunch of this product with a restricted use.

In late August/early September Richter sales team commenced the focused relaunch of ESMYA® on the European markets. Marketing communication was tailored to Healthcare Professionals (HCPs) and patients. Meetings, congresses and webinars were organised in all EU countries informing HCPs about ESMYA® efficacy and safety, and training them to comply with the recent measures implemented by the European Commission.

In August 2018 Allergan received from the U.S. Food and Drug Administration (FDA) a Complete Response Letter in respect of the New Drug Application (NDA) filing for ulipristal acetate, as an investigational drug for the treatment of abnormal uterine bleeding in women with uterine fibroids. Allergan management met in December with the FDA and discussed the Complete Response Letter in order to determine the potential next steps for the ulipristal acetate NDA.

ESMYA® reported total sales of EUR 25.9 million in 2018, compared to the EUR 93.0 million turnover recorded in the previous year. The year-on-year decline resulted from the temporary suspension of ESMYA® commercialization and amendments made to the initial label as announced by the European Commission based on previous CHMP opinion.

Female Fertility

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. Focusing on the meaningful widening of our core Women's Healthcare portfolio Richter acquired the global rights (except for the USA) 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.

In July 2018 the intellectual property rights of BEMFOLA® for the use in the United States were acquired by us for CHF 5 million.

Sales of BEMFOLA® recorded during 2018 amounted to EUR 41.9 million (USD 49.5 million) when compared to a turnover of EUR 34.6 million (USD 39.1 million) realised in the previous year.

Younger generations require new, non-oral approaches to contraception such as hormone releasing devices. Generally speaking new delivery technologies are well received by lifestyle driven patient groups. 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, in October 2017 we signed an exclusive license and distribution agreement with Prima-Temp, a US based company, to commercialize its innovative medical device, PRIYARING globally, except for the USA and Canada.

PRIYARING is an internal sensor that identifies the subtle temperature changes that occur prior to ovulation. The ring measures core temperature of a woman every 6 minutes and sends the data directly through a wireless connection to a smart device every two hours. The data is sent to the cloud where it is stored and analyzed based on a proprietary Prima-Temp algorithm. The ring does not contain any active ingredient but a temperature measurement sensor. The device detects the subtle changes in temperature prior to ovulation and sends a notification to the smart device.

The regulatory procedure for the device has been delayed to a certain extent due to changes which occurred in the API supplier, therefore the expected launch date in Europe is in first quarter 2020.

As a useful addition to our fertility portfolio we concluded an agreement with L.D. Collins & Co. Limited, a UK based company, to commercialize its 400mg progesterone containing assisted reproduction technology (ART) product, CYCLOGEST® in 27 EU countries. Marketing authorizations have already been granted in the above territory and following the transfer of the marketing authorization to Richter, the launch of the product is expected to be executed from early 2019.

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).

Female Contraception

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.

Recent developments

Further extending our Women's Healthcare franchise, a levonorgestrel releasing Intrauterine System (IUS), LEVOSERT® was licensed-in from Allergan in January 2017 for Western and Northern European countries and in February 2019 for Latin American countries.

LEVOSERT® was launched in Denmark, Norway and Iceland in April 2018. In addition the product was also introduced during the third quarter 2018 in Italy and Spain.

Total turnover achieved by this product in 2018 amounted to EUR 3.0 million.

To be in the position to offer the broadest range of contraceptives to women in September 2018 we signed an agreement with Mithra Pharmaceuticals to commercialize ESTELLE®, a combined oral contraceptive, containing 15 mg estetrol / 3 mg drospirenone. We are going to commercialize the product under a different brand name. The product is considered a novel oral contraceptive with natural, native estrogen acting selectively in tissues combined with drospirenone's non contraceptive benefits. The geographic scope of the agreement covers Europe and Russia.

The contract which has been signed with Pantarhei Bioscience BV in February 2019 also fits into the above mentioned endeavor. According to the agreement we are going to commercialise Pantarhei's combined oral contraceptive , containing 30 µg ethynil estradiol, 150 µg levonorgestrel and 50 mg dehydroepiandrosterone (DHEA). The product is under development with successfully completed Phase II trials and is ready for further clinical studies prior to making an application for marketing approval. 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 50 mg DHEA to the pill, the testosterone levels are normalised.

Products for Menopause (Hormone Replacement Therapy, Osteoporosis Medications)

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.

Recent developments

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. LENZETTO® received multiple marketing approvals in European territories in 2015. The product has been launched through 2016 and 2018 in most of the EU12 countries and certain EU15 markets. LENZETTO® was included on reimbursement lists on a number of these markets. During the first three quarters 2018 the product was launched on a number of smaller Latin American, European and CIS markets. These introductions continued during the fourth quarter 2018 and during January 2019 on certain smaller European and CIS markets.

Turnover of LENZETTO® during 2018 amounted to EUR 3.8 million.

Other Women's Healthcare Products

Richter's overall target is to offer a complete range of Women's Healthcare products and in accordance with this objective we also provide treatment for gynaecological infections.

Recent developments

In October 2017 we agreed with the Sweden based company, Pharmanest about the commercialization of its SHACT (Short Acting Lidocaine) technology in Europe, in Latin America and in certain other markets.

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 registration dossier has been submitted to the EMA in the last quarter of 2018.

Main Women's Healthcare products of Richter Group

Brand name	Active ingredients	Product type	Regions where launched [1]
Oral contraceptives (OC)			
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 / JOLIAN	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
Emergency contraceptives (EC)			
POSTINOR / RIGESOFT / LEVONELLE-2 / PLAN B	LVG (2×)		Hungary; EU; CIS; USA; RoW; China; Latin America
ESCAPELLE / LEVONELLE ONE-STEP / POSTINOR 1 / PLAN B ONE-STEP / EVITTA	LVG (1×)		Hungary; EU; CIS; USA; RoW; Latin America; China

Main Women's Healthcare products of Richter Group

Brand name	Active ingredients	Product type	Regions where launched [1]
Contraceptive device (CD)			
GOLDLILY / SILVERLILY	Au + Cu, Ag + Cu	IUD	Hungary; EU; CIS; RoW
LEVOSERT®[2]	levonorgestrel	IUD	Hungary; EU; RoW
Menopausal care			
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 [2]	tibolone	Hormone replacement therapy	EU
ESTRIMAX	estradiol	Hormone replacement therapy	Hungary; EU
LENZETTO®[2]	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
Pregnancy care and Obstetrics			
GRAVIDA[2]	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
Fertility			
BEMFOLA®	follitropin alfa	Fertility treatment	Hungary; EU; RoW
Gynaecological infections			
MYCOSYST / MYCOSYST GYNO / FLUCON	fluconazole	Antifungal	Hungary; EU; CIS; RoW; Latin America
GYNO FEMIDAZOL	miconazole nitrate	Antifungal	EU
GYNOFORT / GYNAZOL[2]	butoconazole nitrate	Antifungal (cream)	Hungary; EU; CIS; RoW
KLION D	metronidazole + miconazole	Antifungal	Hungary; EU; CIS; RoW; Latin America
FLUOMIZIN[2]	dequalinium chloride	Anti-infective, antiseptic	EU; CIS
GYNOFLOR[2]	estriol + lactobacillus	Women's Healthcare, restoration of vaginal flora and atrophic vaginitis	EU
Other Gynaecological conditions			
ESMYA®	ulipristal acetate	Uterine myoma	Hungary; EU; CIS; RoW; Latin-Amerika
LEVOSERT®[2]	levonorgestrel	Menorrhagia	Hungary; EU; CIS; RoW
NORCOLUT	norethisterone	Premenstruation syndrome, mastodynia, dysfunctional uterine bleeding, endometriosis	Hungary; CIS; RoW; China; Latin America
Bulk products		**Oral contraception**	**EU; USA; RoW; Latin America**

Abbreviations used in the table: DRP: Drospirenone; LVG: Levonorgestrel; GST: Gestodene; EE: Ethynil estradiol; DSG: Desogestrel; CLM: Chlormadinone; BCLM: Biphasic chlormadinone

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

b) Original Research – Focus on Central Nervous System (CNS)

Overview

Research of new chemical entities has always been of paramount importance to our corporate strategy. Since 1998 major changes have occurred in the structure of Richter's research organisation. State-of-the-art laboratories have been built in the area of neuropharmacology, molecular biology, kinetics and metabolism and during the late 1990's pharmacological facilities have also been upgraded, while a new chemical-analytical research centre that meets the highest quality and technological requirements has also been constructed in 2007. In addition to modernisation of the technological infrastructure, a restructuring strategy has been implemented to ensure that the quality of science, innovation and speed are critically important factors in our research and to increase the opportunities for the research system to deliver high quality compounds. Following a major review of our research pipeline and resources, a strategic decision was taken to focus our original research activities exclusively on the CNS area. Aware of our capabilities and limits it was concluded that cooperation was required in order to share our knowledge, experience and the significant related development costs and risks. In line with this aim, in 2004 we signed a research and development collaboration agreement with Allergan for our atypical antipsychotic, cariprazine and related compounds. In March 2013, we entered into a comprehensive and long-term collaboration agreement with Orion Corporation for the discovery and development of new chemical entities in the field of cognitive disorders.

As a consequence of increasing pressure to improve cost efficiency, we conducted a thorough review of our CNS portfolio in 2014, which resulted in a number of projects being either terminated or suspended and a related reduction in personnel. We have also rationalised our research activities, as far as the target areas are concerned, as a result of which we have narrowed our focus to obesity, cognitive disorders and autism.

Bipolar I Disorder

Bipolar disorder affects approximately 3.6 million people in the United States. Bipolar I disorder is also known as manic-depressive illness. People with bipolar I disorder experience "mood episodes" ranging from manic episodes (i.e., overexcited, extreme irritability, racing thoughts, difficulties with sleep), depressive episodes (i.e., extreme sadness, fatigue, hopelessness) or mixed episodes (a combination of both mania and depression).

Schizophrenia

Schizophrenia is a chronic and disabling disorder that affects more than 2.6 million American adults. It imposes a significant burden on patients, their families and society. Symptoms fall into three broad categories: positive symptoms (hallucinations, delusions, thought disorders and movement disorders), negative symptoms (such as loss of motivation and social withdrawal) and cognitive symptoms (problems with executive functioning, focusing and working memory).

Cariprazine

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 central dopamine D_2 and serotonin 5-HT_{1A} receptors and antagonist activity at serotonin 5-HT_{2A} receptors.

Pharmacodynamically, cariprazine acts as a partial agonist at the dopamine D_3 and D_2 receptors with high binding affinity and at the serotonin 5-HT_{1A} receptors. Cariprazine acts as an antagonist at 5-HT_{2B} and 5-HT_{2A} receptors with high and moderate binding affinity as well as it binds to the histamine H_1 receptors. Cariprazine shows lower binding affinity to the serotonin 5-HT_{2C} and α_{1A}-adrenergic receptors and has no appreciable affinity for cholinergic muscarinic receptors.

Cariprazine is also being investigated for the treatment of bipolar depression and as adjunctive treatment for major depressive disorder in adults.

Recent developments

In our endeavor to continue the development programme of cariprazine and widen its therapeutic fields Richter and Allergan initiated a phase III clinical trial programme investigating the use of cariprazine as a treatment for bipolar I depression in 2016. The two companies announced in December 2017 positive topline results for the second pivotal trial of cariprazine in the treatment of bipolar I depression. In that trial both cariprazine 1.5 mg and 3 mg were statistically greater than placebo. In April 2018 Allergan and Richter announced another positive topline results for a Phase III study of cariprazine carried out in the same indication.

In September 2018 the U.S. FDA has accepted for review the Allergan's supplemental New Drug Application (sNDA) for VRAYLAR®, seeking to expand the indication to include the treatment of bipolar depression in adults in the current product label. The expected Prescription Drug User Fee Act (PDUFA) date is in May 2019.

Application files for the reimbursement of REAGILA® on individual European markets were compiled during the second half of 2017 and the submission procedure is advancing well. REAGILA® was launched in a number of European countries during 2018.

MitsubishiTanabe Pharma decided to cancel the clinical development programme of cariprazine, as a consequence of which a new agreement was settled in the fourth quarter 2017 in respect of cariprazine clinical and regulatory status in Asian countries.

The success of cariprazine could be considered as an important historical event not just for the Company but equally for the whole Hungarian pharmaceutical industry. This is the first FDA and EMA approved pharmaceutical compound which was discovered by a Hungarian company and the preclinical research and development were also carried out in the same Hungarian pharmaceutical company.

c) Biosimilar product development

Overview

Biopharmaceuticals (often referred to as 'biologics') have taken a significant share of the global pharmaceutical market in the last two decades. Within the European Union, every third new drug authorisation is of biotechnological origin. In 2017, globally, seven of the top ten selling drugs were biopharmaceuticals. Biologics account for just under 40 percent of all products at clinical phases of pharmaceutical companies globally and accounted overall for around EUR 250 billion in sales worldwide in 2017, projected to reach the EUR 400 billion level by 2022.

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 commercialization 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 Immunology. 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 and another one with DM Bio, a joint venture company formed by Dong-A Socio Holdings of Korea and Meiji Seika Pharma of Japan. Further partners are sought with the aim of establishing joint product development activities.

Biosimilars

A biosimilar medicine is a biological medicine that is developed to be highly similar to an already authorized 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.

Teriparatide

Teriparatide is identical to the biologically active fragment of the human parathyroid hormone, it replaces the natural hormone and stimulates bone formation. Teriparatide is used for the treatment of osteoporosis as it reduces the risk of bone fracture in various patient groups. Osteoporosis is more common in women after the menopause, and it can also occur in both men and women as a side effect of glucocorticoid treatment.

Pegfilgrastim

Pegfilgrastim, a pegylated recombinant, human granulocyte-colony stimulating factor is used in cancer patients to help with some of the side effects of their treatment. Chemotherapy that is cytotoxic also kills white blood cells, which can lead to neutropenia and the development of infections. Pegfilgrastim is used to reduce the duration of neutropenia and the occurrence of febrile neutropenia.

Recent developments

In February 2019 we have withdrawn our Application for a Marketing Authorisation from the European Medicines Agency (EMA) for EFGRATIN, its biosimilar pegfilgrastim. This withdrawal occurred subsequent to a MAA resubmission, which was based on completion of an additional clinical study. The decision to withdraw the MAA was taken because Richter could not address the CHMP concerns within the given timeframe. The Company reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

Richter is also working on a portfolio of biosimilar monoclonal antibodies, which vary between clinical and late to early stage preclinical stages of development. This portfolio includes a rituximab biosimilar as well as a trastuzumab biosimilar, the latter being part of a technology transfer and license-in agreement in respect of its development and commercialization signed in October 2016 with DM Bio, a Korean developer.

The current and future portfolio of mammalian cell fermentation products will fill capacities at the Company's Debrecen facilities, which have been further extended in 2018, with building of a new production line comprising of single-use bioreactor capabilities, the line will be commissioned in 2019. As a result of the facility extension, the Debrecen drug substance plant becomes multi-faceted, allowing for parallel production lines and providing multiple technologies in order to meet the biomanufacturing needs of both internal use and external clients.

4

Business Review


Dr István Greiner
Research Director
Dr György Thaler
Development Director

1. Pharmaceuticals

a) 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 1,000 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 three strategic areas, notably research and development of new chemical entities (NCEs), recombinant biotechnological activities and the development of generic products. The original research activities are focusing on the disorders of the Central Nervous System, notably the treatment of autism, obesity and cognitive impairment.

At the end of 2018, in addition to cariprazine the Company has a research portfolio of 14 ongoing projects, two of which are in their early clinical phase with the remainder in preclinical research and development phase.

Besides the early clinical and preclinical development programmes, 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.

The management of both Richter and Allergan remain determined to continue the development programme of cariprazine. In addition to the authorized indications we are jointly seeking further therapeutic approvals, pursuing a supplemental New Drug Application (sNDA) in the treatment of bipolar depression and conducting Phase III clinical trials with cariprazine in the treatment of major depression as adjunctive therapy. In April 2018 the third positive topline results for a Phase III study of cariprazine for the treatment of adults with bipolar I depression were made public. Subsequently in September 2018 the U.S. FDA has accepted for review the Allergan's sNDA to expand the indication to include the treatment of bipolar depression in adults in the current product label. The expected PDUFA date is in May 2019.

Our Japanese partner, MitsubishiTanabe Pharma, deleted cariprazine from its development pipeline, although the two companies set up new terms for future collaboration in respect of the registration and marketing of cariprazine in the Asian markets.

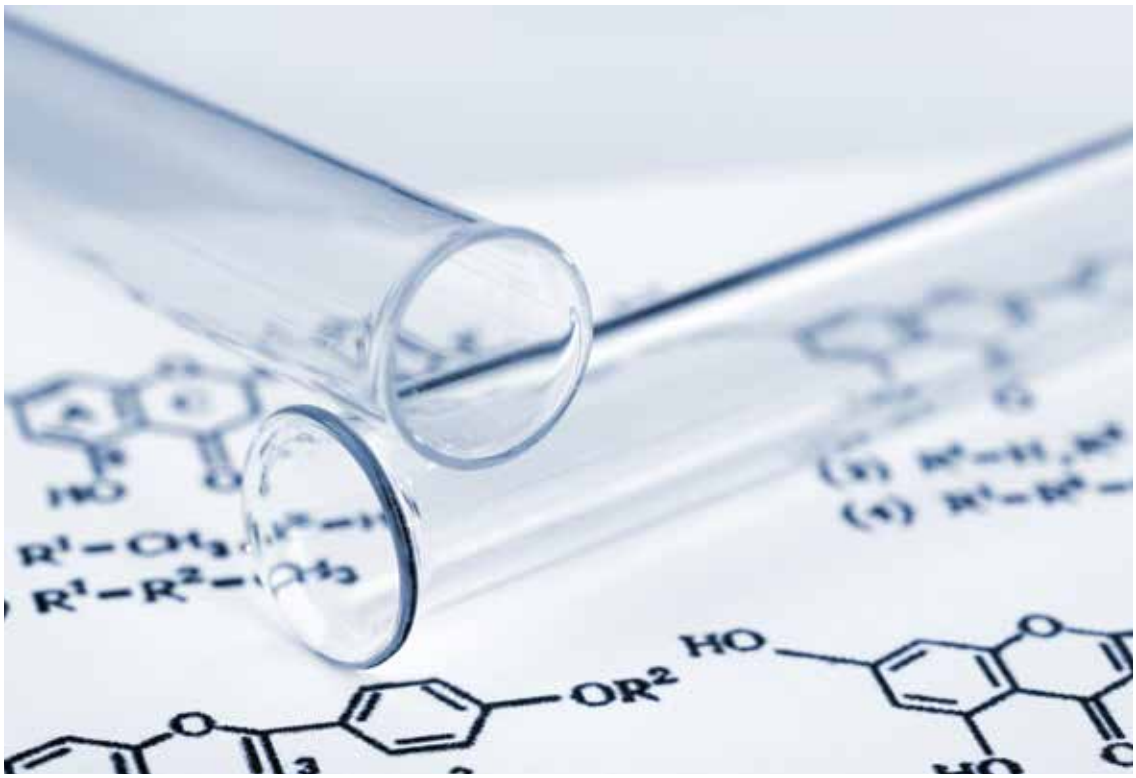
Application files for the reimbursement of REAGILA® on individual European markets were compiled during the second half of 2017 and the submission procedure advanced well in 2018.

In respect of our flagship Women's Healthcare product, ESMYA® the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) initiated a review procedure of drug induced liver injuries in December 2017. In February 2018, PRAC initiated the implementation of temporary precautionary measures. In July 2018 a European Commission decision opened the way for the relaunch of this product with a restricted use. In August 2018 Allergan received from the FDA a Complete Response Letter in respect of the New Drug Application (NDA) filing for ulipristal acetate. Allergan management met in December with the FDA and discussed the Complete Response Letter in order to determine the potential next steps for the ulipristal acetate NDA.

Tasks related to pharmacovigilance on our recently introduced original products (cariprazine, ESMYA®), have increased substantially, and have resulted in some increase in employment of advisors and related personnel.

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 in Budapest became operational in 2009. Meanwhile a greenfield investment commenced in Debrecen in 2008 targeting the production of the most complex mammalian cell products, and was inaugurated and became operational in 2012. In 2016 Richter initiated capacity expansion dedicated to biosimilar development and manufacturing in Debrecen.

In February 2019 we have withdrawn our Application for a Marketing Authorisation (MAA) from the European Medicines Agency (EMA) for EFGRATIN, its biosimilar pegfilgrastim. This withdrawal occurred subsequent to a MAA resubmission, which was based on completion of an additional clinical study. The decision to withdraw the MAA was taken because Richter could not address the CHMP concerns within the given timeframe. The Company reserves the right to make further submissions at a future date in this or other therapeutic indication(s).



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

In addition to the comprehensive and long-term license and collaboration agreement signed in late 2010 with Mochida Pharmaceutical Co. Ltd. in respect of the development and marketing of Richter's biosimilar product portfolio, we announced in August 2011 two separate license and collaboration agreements in respect of the development and marketing of two biosimilar products, two monoclonal antibodies, with STADA. In 2014 and during 2015 the cooperation with STADA in the field of biosimilar product development was further broadened as the two companies signed non- exclusive license and distribution agreements to commercialise Richter's biosimilar teriparatide and pegfilgrastim in Europe (excluding Russia). In October 2016 Richter further expanded its partnership base signing a technology transfer and license-in agreement in respect of the development and commercialisation of DM Bio's biosimilar monoclonal antibody, trastuzumab. DM Bio is a joint venture company formed by Dong-A Socio Holdings of Korea and Meiji Seika Pharma of Japan and is responsible for constructing and operating production facilities for bio-pharmaceuticals that are jointly developed by the two companies.

Generic development work in several therapeutic areas continued in 2018. Due to the substantial decline in the number of global patent expiries, generic product development opportunities are also decreasing, the trend of which is expected to prevail in the medium-term. At the same time the proportion of more complex, high added value development programmes increased, while lifecycle management projects have become increasingly frequent over the past few years. All these changes are linked to our strong commitment to reshape substantially our business 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 table on the next pages highlights all products which were either developed in-house, acquired or licensed-in during 2018.

Own-Developed products / Acquired

Brand name	Active ingredient	Therapeutic area	Country
AMDOAL	aripiprazole	Central nervous system, antipsychotic	Moldova
AZALIA	desogestrel	Women's Healthcare, oral contraceptive	Guatemala, Colombia, Luxemburg, Slovenia
BEATIL®	amlodipine + perindopril	Cardiovascular	Vietnam
BELARA®	chlormadinone + 30 mcg EE*	Women's Healthcare, oral contraceptive	Malaysia
BEMFOLA®	follitropin alfa	Women's Healthcare, fertility	United Arab Emirates, Kosovo, Serbia
CANDISET	clotrimazol	Women's Healthcare, antifungal (cream)	Portugal
COLTOWAN	ezetimibe	Cardiovascular, cholesterol-lowering	Czech Republic, Poland, Hungary, Germany
CURIOSIN	zinc hyaluronate	Dermatology, anti-acne	Peru, Suriname
CYCLOFEMINA	medroxi-progesterone + estradiol	Women's Healthcare, contraceptive injection	Ecuador
DIROTON PLUS	lisinopril + indapamid	Cardiovascular, antihypertensive	Russia
EKVAPRESS	amlodipin + indapamid + llsinopril	Cardiovascular, antihypertensive	Russia
EPISTAT	fenspiride	Respiratory, anti-inflammatory	Moldova
ESCAPELLE	levonorgestrel (1x)	Women's Healthcare, emergency contraceptive	Australia, Dominica
ESMYA®	ulipristal acetate	Women's Healthcare, uterine myoma	Dominica, Guatemala
GYNOSITOL	inozitol	Women's Healthcare, nutritional supplement	Bulgaria
LINDYNETTE	gestodene + 20 mcg EE*	Women's Healthcare, oral contraceptive	Saudi Arabia
MIDIANA	drospirenone + 30 mcg EE*	Women's Healthcare, oral contraceptive	Saudi Arabia
MIRVEDOL	memantine-hidroklorid	Central nervous system, Alzheimer's diseas	Moldova
NORCOLUT	norethisterone	Women's Healthcare, premenstruation syndrome, mastodynia, dysfunctional uterine bleeding, endometriosis	Iraq
REAGILA®	cariprazine	Central nervous system, antipsychotic	Belgium, United Kingdom, Estonia, Poland, Hungary, Germany, Italy, Romania, Switzerland, Sweden, Slovenia
RIGEVIDON	levonorgestrel + 30 mcg EE*	Women's Healthcare, oral contraceptive	Iraq
ROSINA	drospirenone + 30 mcg EE*	Women's Healthcare, oral contraceptive	Peru
SIBILLA	dienogest + 30mcg EE*	Women's Healthcare, oral contraceptive	Mexico
TANYDOL	telmisartan	Cardiovascular, antihypertensive	Russia
TIBOLONE	tibolone	Women's Healthcare, hormone replacement therapy	Belgium
VENDIOL	gestodene + 15 mcg EE*	Women's Healthcare, oral contraceptive	Belarus

Note: * Ethynil estradiol

Licensed-in products

Brand name	Active ingredient	Therapeutic area	Country
COSIM	lacosamid	Central nervous system, antiepileptic	Poland, Hungary
FLUOMIZIN	dequalinium-chloride	Women's Healthcare, anti-infective, antiseptic	Estonia, Croatia, Poland, Latvia, Lithuania, Slovenia
GYNOFLOR	estriol + lactobacillus	Women’s Healthcare, restoration of vaginal flora and atrophic vaginitis	Poland
GYNOSITOL	inozitol	Women’s Healthcare, nutritional supplement	Latvia, Lithuania, Luxemburg
LENZETTO®	estradiol	Women's Healthcare, hormone replacement therapy (spray)	Belarus, Chile, Ecuador, Montenegro, Norway, Peru, Portugal, Serbia, Uzbekistan
LEVOSERT®	levonorgestrel	Women’s Healthcare, other contraceptive method, IUS	Denmark, Izland, Norway, Italy, Spain, Switzerland

The Group reported 2018 spending of HUF 40,545 million (EUR 127.3 million) on research and development, representing a year on year increase 1.6 percent in HUF terms (a 1.3 percent decrease in EUR terms) and 9.1 percent of 2018 consolidated sales.

András Radó
Director,
Production and Logistics

b) Manufacturing and Supply

Our focus

During 2018, 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 a targeted operation of a supply system with successful integration of its subsidiaries. Operated in conformity with the volatile market environment the production and supply chain ensured uninterrupted supply and preserved the competitiveness of the Group.

In 2018 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 and efficiency saving programme.

Production

Manufactured volumes of finished products (number of boxes as packaging units) at Group level increased by 2.6 percent in 2018, while API production exceeded by 3.7 percent the levels achieved a year ago. Volumes of finished products manufactured at the parent company showed an increase of 1.8 percent during the year. This growth was due to increasing quantities of injectables and solid state pharmaceutical products while the volume of ointments were produced at the same level as in the previous year. In respect of manufacturing subsidiaries the volume of finished drugs produced in Russia increased by 5.9 percent, in Romania by 4.2 percent, while in Poland the volume of finished form products stagnated when compared to the previous year.

With regard to our API production in Hungary steroid API volumes increased by 10.6 percent due to a change in product structure modified in line with actual demand on the market. In line with the workload allocations contribution of the facility in Dorog to the total API production of the parent company increased, and represents now approximately 70 percent.

Investments

Capital expenditure for the Group, including payments for intangible assets, totaled HUF 58,055 million in 2018.

Preparation to get ready for "serialization" represented the most important challenge in the area of manufacturing of finished drugs during 2018. 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. In order to comply, the Company invested substantial time, effort and financial resources to introduce the required new technology to the existing packaging lines.

In March the construction of a molecular biology laboratory in Debrecen was completed and similarly the expansion and improvement of manufacturing capacities of steroid intermediates and preparative chromatographic units at our Dorog facility, another multiple-year project was concluded and inaugurated.

Significant amounts were allocated in 2018 to activities in Research and Development supporting the empowerment of specialty pharma orientation in the core of our strategy. Items of large laboratory equipment were acquired and installed at our Budapest research centre, and additionally, construction and fitting out of the molecular biology laboratory in Debrecen took place.

A complex three-year program aiming at the modernization of our API production unit in India, has been commenced in 2018. In addition, 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.

c) 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.

Operating the Quality Management System entails multi-faceted and extremely complex regulatory adherence by the Total Quality Management Directorate. In order to focus on the key objective our internal potential is continually being optimized and our ability to create value is evolving while simultaneously the method of LEAN management has been implemented. The aim is to explore the losses with ongoing development methods and to optimize the lead time of creating value. The MIR LEAN motivating system is focusing on promotion of employees to exploit development opportunities, to suggest solutions and to complete changes in a way that meet the Quality Management System and business requirements.

During 2018 we outlined a digital vision for the Quality Management System, including expectations over a 5 years 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 certificate 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.

It is very important for us to maintain a good relationship with our partners, and first of all to preserve the honourable confidence of the patients and the 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 2018 international authority audits at our Budapest site totalled 10 days, while at our Debrecen site such visits lasted 4 days. The Hungarian National Institute of Pharmacy and Nutrition extended our GMP certificate following its inspection.

Audits conducted by our partners took 46 days at three of our sites. We received no significant observations, except some proposals during the inspections and audits.

The Russian subsidiary successfully passed the ISO 9001-2015 audit which is crucial for marketing authorizations and renewals. Russian auditors and WHO inspectors carried out a training audit in 2018.
Our Romanian subsidiary successfully passed customer audits conducted by 4 partners and completed 2 inspections in 2018. As a result of the Romanian Authority (ANMDM) inspection, the serialization project was approved and the Authority extended our manufacturing license and GMP certificate.
The Company has received no significant warnings during the inspections and audits contributing to the Company's positive status.

d) Products

Whilst the dominant part of its turnover still originates from generic drugs the share of Richter's specialty portfolio grew to above 40 percent over the past few years. These high added value products include steroid based pharmaceuticals and its original CNS molecule both of them carrying higher than average margins.

Traditionally it has been a priority for Richter management to strengthen its Women's Healthcare business capitalizing on its special steroid chemistry knowledge possessed in-house. Continously widening its oral Women's Healthcare portfolio Richter has built up a complete range of such products comprising latest generation contraceptives and emergency contraceptives. Over the past decade Richter has concluded a number of relevant acquisitions in the field of Women's Healthcare including ESMYA® as a treatment for uterine fibroids and a range of oral contraceptives divested by Grünenthal. The acquisition of Finox Holding allowed Richter to establish its presence in the female fertility therapeutic area – a major growth market. A steady growth characterized the market performance of BEMFOLA® over the past two years. In spite of strong headwinds experienced in 2018 by our flagship product, ESMYA® the Management remained convinced to further expand this core franchise. In this endeavour Richter concluded two complex development, license-in and distribution agreements for two novel oral contraceptives. Expanding the reach of this therapeutic area beyond traditional product types Richter has acquired a number of lifestyle and contraception devices to meet the changing needs of female population. A separate section of the Annual Report on Women's Healthcare describes our gynaecological products in detail.

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	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
Procare Health	Spain	PAPILOCARE	Women's Healthcare, HPV

Original research carried out at Richter brought to market a novel atypical antipsychotic co-developed and promoted with excellent results in the USA by our partner Allergan. While the two companies are engaged in the label extension

of VRAYLAR® (cariprazine) Richter devotes significant resources to research new drug candidates treating diseases of the Central Nervous System. Separate sections of this Annual Report describe both the Research activities conducted at Richter and cariprazine related recent developments in detail.

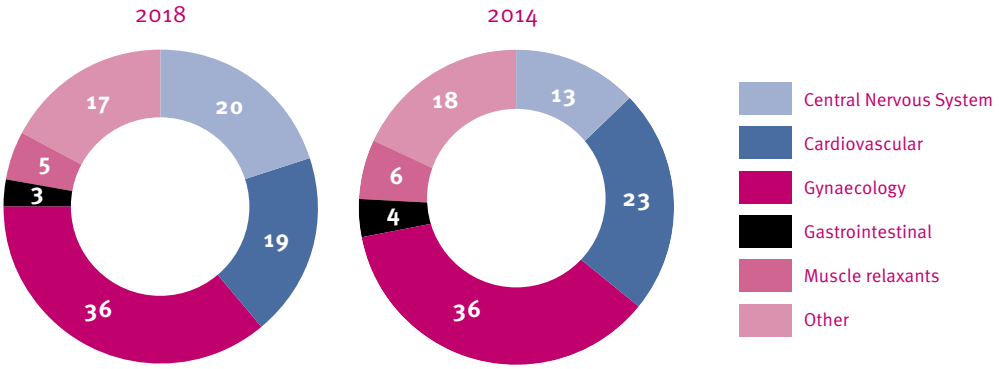
The continuous enhancement of Richter's product portfolio is based on its vertically integrated research, development, manufacturing and distribution capacities complemented by selective licensing agreements. Licensing-in has become an important route for the Group to renew its specialty product portfolio primarily in the field of Women's Healthcare.

Richter's management continues to endeavour to provide greater focus to selected therapeutic areas thus improving the shape to the product portfolio. With this background it is understandable that most of the top ten products in 2018 originated from the three largest therapeutic categories. Products belonging to the therapeutic areas of Women's Healthcare, Central Nervous System and Cardiovascular together generated 75 percent of total pharmaceutical sales.

Products included in the core franchise of Women's Healthcare contributed altogether 36 percent of total pharmaceutical sales. The range of oral contraceptives showed a flat performance during the reported year while BEMFOLA® sales increased by 24.7 percent when compared to 2017. Turnover of ESMYA® declined by HUF 20.5 billion during the reported year as a consequence to the review procedure initiated by PRAC.

Central Nervous System related drugs contributed altogether 20 percent of total pharmaceutical sales and showed an increase of 21.2 percent compared to 2017. Royalty income related to our original product, the cariprazine containing VRAYLAR®, contributed substantially to the sales growth reported in this therapeutic group. In its first year on the European market REAGILA® sales reached HUF 953 million during 2018. Turnover of CAVINTON (vinpocetine), the leading traditional CNS drug invented by Richter increased by 3.1 percent compared with the previous year primarily due to higher sales levels in China.

Products by therapeutic groups (%)



Cardiovascular drugs showed a 1.7 percent sales decrease in 2018, accounting for 19 percent of total pharmaceutical sales. The cardiac therapy PANANGIN (asparaginates) the leading product in this therapeutic area, decreased by 10.1 percent in 2018 as sales declined in Russia, the main market for this product. According to IQVIA (successor of IMS) market intelligence the market segment of PANANGIN also showed a decline in Russia. However, the sales of VEROSPIRON (spironolactone) increased in Russia during the reported year, could not offset the decline recorded primarily in the Other CIS countries and in Ukraine. The turnover of rosuvastatin containing ZARANTA/MERTENIL/XETER increased as a result of the higher sales levels achieved in Hungary and in Russia. In addition, the sales of LISOPRESS also contributed substantially the turnover achieved during 2018.

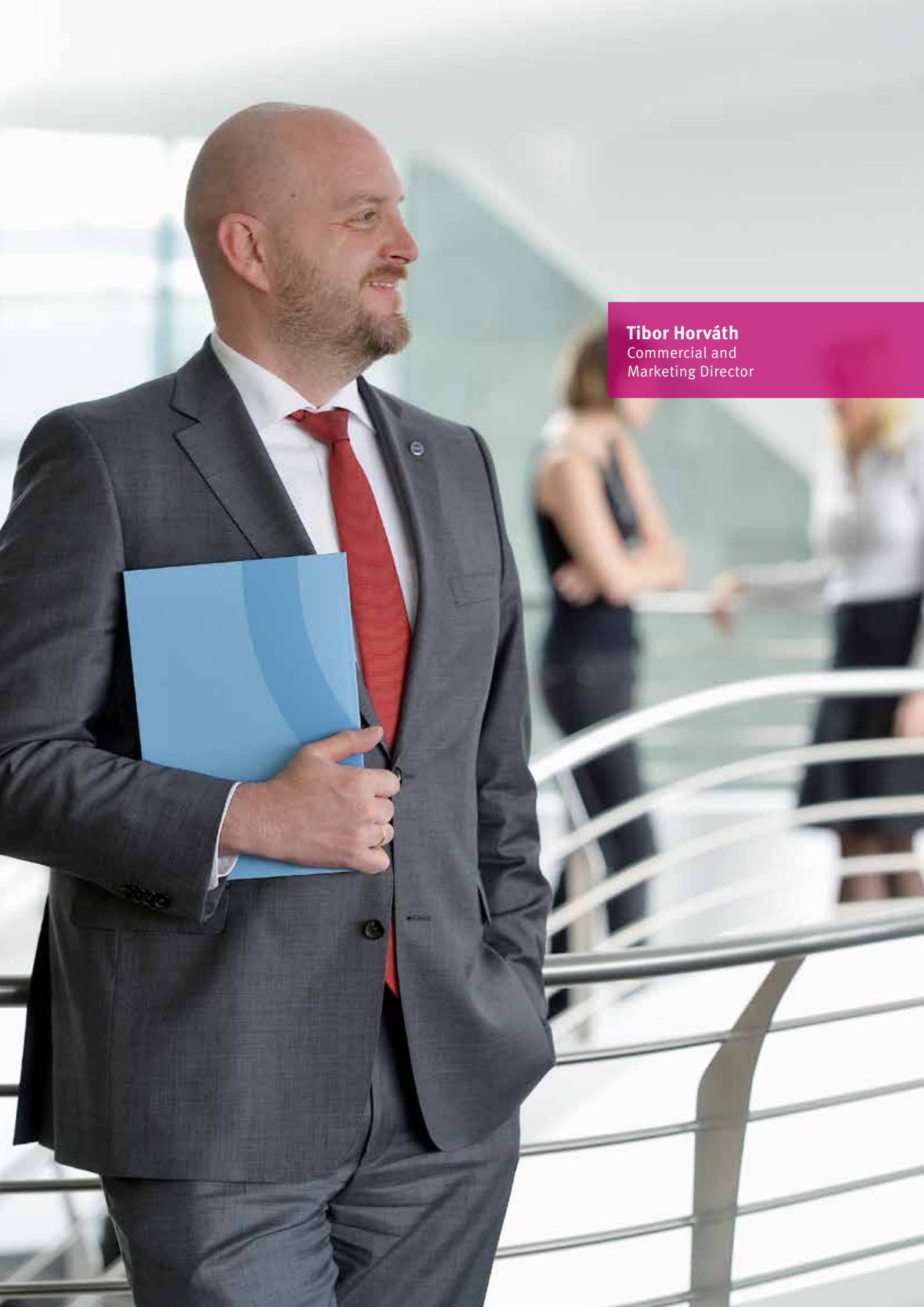
Muscle relaxant drugs amounted to 5 percent of total pharmaceutical revenue of the Group in 2018. Sales of the original product MYDETON / MYDOCALM (tolperisone) decreased by 5.6 percent in the reported year due to lower sales levels achieved in the CIS region and in the EU12.

TOP 10 products

Brand name	Active ingredient	Therapeutic area	2018 HUFm	2017 HUFm	Change HUFm	Change %
Oral contraceptives	hormones	Women's Healthcare, oral contraceptives	90,047	90,576	(529)	(0.6)
CAVINTON	vinpocetine	Central nervous system, nootropic	31,791	30,832	960	3.1
VRAYLAR® / REAGILA®	cariprazine	Central nervous system, antipsychotic	25,127	13,986	11,140	79.6
MYDETON	tolperisone	Muscle relaxant	18,913	20,042	(1,129)	(5.6)
PANANGIN	asparaginates	Cardiovascular, cardiac therapy	15,106	16,799	(1,693)	(10.1)
BEMFOLA®	follitropin alfa	Women's Healthcare, fertility	13,348	10,706	2,642	24.7
VEROSPIRON	spironolactone	Cardiovascular, diuretic	12,189	12,925	(736)	(5.7)
AFLAMIN*	aceclofenac	Non-steroid antiinflammatory	9,931	7,854	2,077	26.4
LISOPRESS	lisinopril	Cardiovascular, antihypertensive	9,087	9,557	(470)	(4.9)
GROPRINOSIN	inosine pranobex	Antiviral	8,841	8,355	486	5.8
Subtotal			**234,380**	**221,632**	**12,748**	**5.8**
Other			130,351	143,208	(12,857)	(9.0)
Total			**364,731**	**364,840**	**(109)**	**0,0**
Share of the TOP 10 products			**64.3%**	**60.7%**		

Note: *Licenced-in product.

In line with Group strategy the product portfolio which was enhanced in 2017 has been under continuous renewal during 2018. Focusing on specialty therapeutic areas we have withdrawn low volume and low margin products while continuing to introduce new products with improved profitability.


Tibor Horváth
Commercial and
Marketing Director

e) Sales by Markets

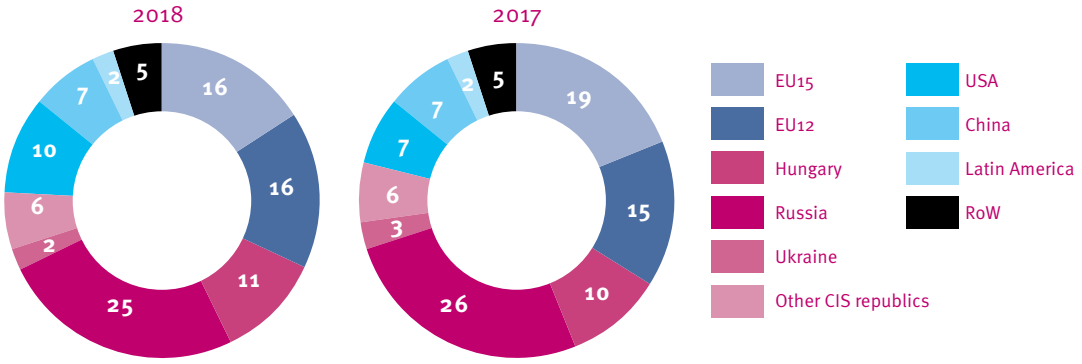
Sales in the Pharmaceutical segment totalled HUF 364,731 million in 2018 nearly as much as in the previous year, however 3.0 percent lower in EUR terms (EUR 1,144.8 million) compared to last year.

Sales by region

	2018 HUFm	2017 HUFm	Change HUFm	Change %	2018 EURm	2017 EURm	Change EURm	Change %
Hungary	**38,736**	**35,417**	**3,319**	**9.4**	**121.6**	**114.5**	**7.1**	**6.2**
EU*	**116,887**	**125,719**	**(8,832)**	**(7.0)**	**366.8**	**406.5**	**(39.7)**	**(9.8)**
EU 12	58,789	56,759	2,030	3.6	184.5	183.5	1.0	0.5
Poland	24,204	23,060	1,144	5.0	76.0	74.6	1.4	1.9
Romania	10,517	10,054	463	4.6	33.0	32.5	0.5	1.5
EU 15	58,098	68,960	(10,862)	(15.8)	182.3	223.0	(40.7)	(18.3)
CIS	**121,661**	**129,089**	**(7,428)**	**(5.8)**	**381.8**	**417.4**	**(35.6)**	**(8.5)**
Russia	92,404	95,732	(3,328)	(3.5)	290.0	309.5	(19.5)	(6.3)
Ukraine	8,320	10,769	(2,449)	(22.7)	26.1	34.8	(8.7)	(25.0)
Other CIS republics	20,937	22,588	(1,651)	(7.3)	65.7	73.1	(7.4)	(10.1)
USA	**35,985**	**27,472**	**8,513**	**31.0**	**113.0**	**88.8**	**24.2**	**27.3**
China	**26,384**	**24,004**	**2,380**	**9.9**	**82.8**	**77.6**	**5.2**	**6.7**
Latin America	**5,779**	**6,134**	**(355)**	**(5.8)**	**18.2**	**19.9**	**(1.7)**	**(8.5)**
Rest of the World	**19,299**	**17,005**	**2,294**	**13.5**	**60.6**	**55.0**	**5.6**	**10.2**
Total	**364,731**	**364,840**	**(109)**	**0.0**	**1,144.8**	**1,179.7**	**(34.9)**	**(3.0)**

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

Sales analysis by region (%)



Hungary

In Hungary pharma sales of the Group totalled HUF 38,736 million (EUR 121.6 million) in 2018 which means an increase of 9.4 percent (6.2 percent in EUR terms) compared to the previous year.

Based on the latest available market audit (IMS) data for the twelve months to December 2018 the pharmaceutical market increased by 8.4 percent year-on-year. Retail sales of Richter products increased by 5.3 percent compared to 2017 and the Company is the fifth player on the Hungarian pharmaceutical market with a 5.0 percent share. When considering only the market for retail prescription drugs, Richter qualifies for second place with a market share of 7.5 percent.

Hungarian Regulatory Environment

The Hungarian market has been relatively stable during the year. In accordance with the regulations extraordinary taxes levied on the pharmaceutical industry and payable in 2018 can be offset by up to 90 percent of the tax liability depending on the level of R&D expenditures and wage related expenses of staff employed in this field. Given the high amounts directed to this activity Richter has been exempted from the payment of this extraordinary tax from the second quarter of each year.

Price cuts had no significant effect on sales during 2018, thus the Group's Hungarian sales performance was not impacted by these factors.

The original product of the Company, REAGILA® (cariprazine) was launched in the domestic market in October 2018.

New products launched in Hungary during 2018

Brand name	Active ingredient	Therapeutic area	Launch date
COLTOWAN	ezetimibe	Cardiovascular, cholesterol-lowering	Q2 2018
COSIM*	lacosamid	Central nervous system, antiepileptic	Q3 2018
REAGILA®	cariprazine	Central nervous system, antipsychotic	Q4 2018

Note: *Licenced-in product.

TOP 10 products in Hungary

Brand name	Active ingredient	Therapeutic area	2018 HUFm	2017 HUFm	Change HUFm	Change %
Oral contraceptives	hormones	Women's Healthcare, oral contraceptive	2,947	2,964	(17)	(0.6)
CAVINTON	vinpocetine	Central nervous system, nootropic	2,054	1,955	99	5.1
QUAMATEL	famotidine	Gastrointestinal, antiulcer	1,891	1,704	187	11.0
TANYDON	telmisartan + hydrochlorothi-azide	Cardiovascular, antihypertensive	1,772	1,154	618	53.6
XETER	rosuvastatin	Cardiovascular, cholesterol-lowering	1,709	1,440	269	18.7
PANANGIN	asparaginates	Cardiovascular, cardiac therapy	1,294	1,229	65	5.3
LAMOLEP	lamotrigine	Central nervous system, antiepileptic	1,209	1,048	161	15.4
POLITRATE*	leuprorelin	Urology, benign prostate hypertrophy	1,058	521	537	103.1
LISONORM	lisinopril + amlodipine	Cardiovascular, antihypertensive	947	926	21	2.3
AKTIL*	amoxicillin + clavulanic acid	Antibiotic	901	992	(91)	(9.2)
Subtotal			**15,782**	**13,933**	**1,849**	**13.3**
Other			22,954	21,484	1,470	6.8
Total			**38,736**	**35,417**	**3,319**	**9.4**
Share of the TOP 10 products in Hungary			**40.7%**	**39.3%**		

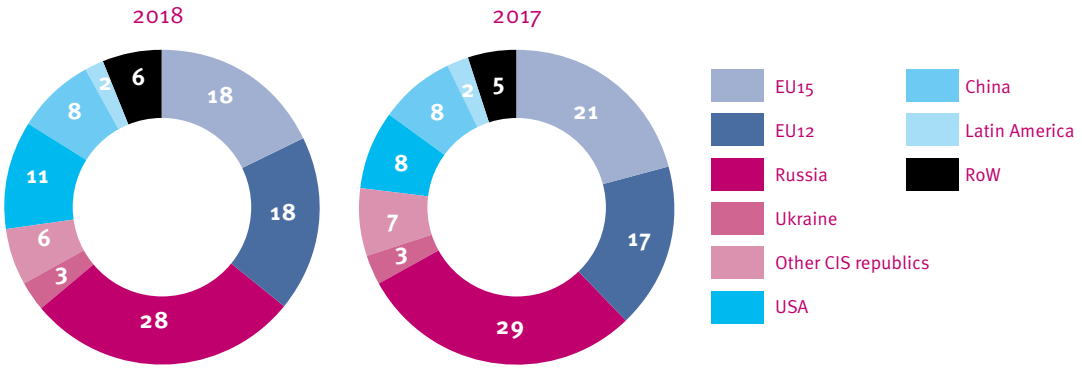
Note: * Licenced-in product.

International Sales

Sales to TOP 10 international markets

	2018 EURm	2017 EURm	Change EURm	Change %
Russia	290.0	309.5	(19.5)	(6.3)
USA	113.0	88.8	24.2	27.3
China	82.8	77.6	5.2	6.7
Poland	76.0	74.6	1.4	1.9
Germany	57.9	60.6	(2.7)	(4.5)
Romania	33.0	32.5	0.5	1.5
Ukraine	26.1	34.8	(8.7)	(25.0)
France	25.8	31.9	(6.1)	(19.1)
Spain	25.0	31.5	(6.5)	(20.6)
Czech Republic	22.8	22.8	0.0	0.0
Subtotal	**752.4**	**764.6**	**(12.2)**	**(1.6)**
Total international sales	**1,144.8**	**1,179.7**	**(34.9)**	**(3.0)**
Share of the TOP 10 international markets	**73.5%**	**71.8%**		

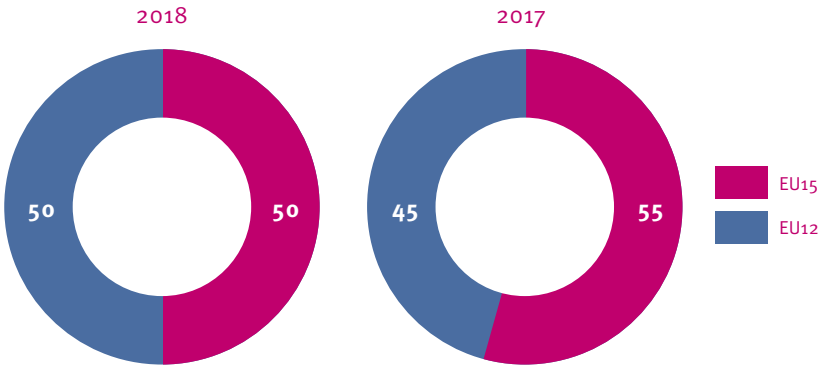
International sales analysis by region (%)



European Union

Sales in the European Union, excluding Hungary, amounted to EUR 366.8 million in 2018, EUR 39.7 million (9.8 percent) below the level recorded in 2017.

Sales to the EU*



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

In the EU12 region sales totalled EUR 184.5 million in 2018, EUR 1.0 million higher when compared to previous year. This region represented 50 percent of total EU sales of the Group's pharmaceutical segment.

New products launched in EU12 countries during 2018

Brand name	Active ingredient	Therapeutic area	Launch date
AZALIA	desogestrel	Women's Healthcare, oral contraceptive	Q1 2018
FLUOMIZIN*	dequalinium-chloride	Women's Healthcare, anti-infective, antiseptic	Q1 2018
GYNOFLOR*	estriol + lactobacillus	Women's Healthcare, restoration of vaginal flora and atrophic vaginitis	Q1 2018
GYNOSITOL	inozitol	Women's Healthcare, nutritional supplement	Q1 2018
REAGILA®	cariprazine	Central nervous system, antipsychotic	Q1 2018
COLTOWAN	ezetimibe	Cardiovascular, cholesterol-lowering	Q2 2018
COSIM*	lacosamid	Central nervous system, antiepileptic	Q3 2018

Note: * Licenced-in product.

In Poland the Group recorded sales of PLN 323.4 million (EUR 76.0 million) in 2018, an increase of PLN 5.9 million (EUR 1.4 million) compared to 2017. Nevertheless, sales continued to be adversely impacted by price erosion on some of our generic products and parallel imports of certain other products, although at a lower level than previously.

Poland's GDP grew 5.1 percent in 2018 according to the preliminary estimate by the Central Statistical Office of Poland, which was the strongest growth in the past six years. The main drivers of growth were the rebound in fixed investment as a result of the recovering inflows of EU funds and the marked increase in household spending.

In Romania sales amounted to RON 153.6 million (EUR 33.0 million) in 2018, a slight increase of RON 5.0 million (EUR 0.5 million) when compared with the previous year. As a consequence of 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 products. The revised price list, following multiple delays, entered into force with effect from 1 January 2019.

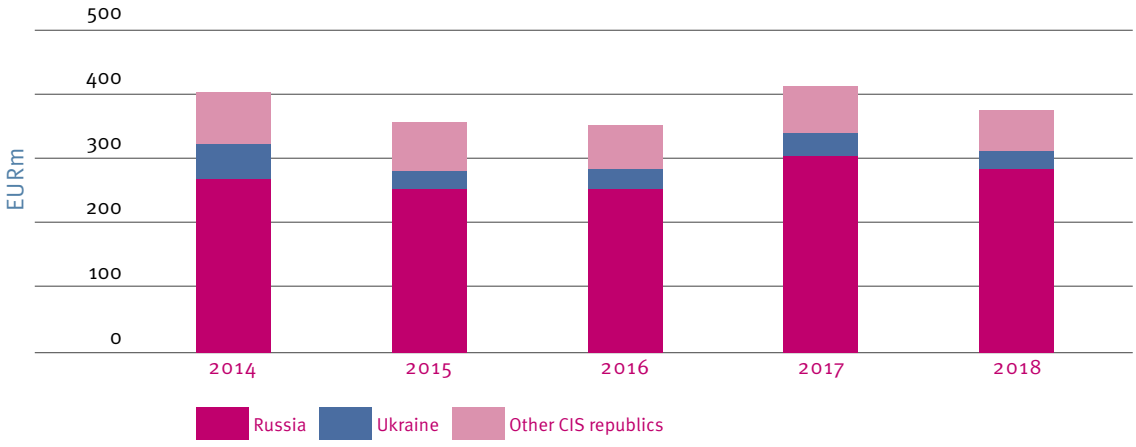
Romania's GDP continued to grow by 4.1 percent in 2018, driven by strong domestic consumption, low interest rates and labour market improvements. Nevertheless the government is facing a crucial challenge keeping the budget deficit under control.

In the EU15 region sales amounted to EUR 182.3 million in 2018, EUR 40.7 million lower than in the previous year. This region contributed 50 percent of total EU pharmaceutical sales.

CIS

Sales to the CIS totalled EUR 381.8 million in 2018, this a decrease of EUR 35.6 million (8.5 percent) compared to the sales achieved in the previous year. Declining sales expressed in EUR were driven primarily by weakening of local currencies, primacity the RUB and the KZT.

Sales to the CIS



The treaty establishing the common Eurasian Economic Union (EEU) with the membership of Russia, Belarus, Kazakhstan, Kyrgyzstan and Armenia entered into force during 2017. A new set of tightening regulations define the market presence of foreign companies.

Spending on healthcare remains stable in Russia at around 3.3.-3.6 percent of GDP. Increased life expectancy leads to increasing demand and spending on pharmaceuticals. Richter's sales totalled RUB 21,389.9 million in 2018, RUB 1,064.6 million (5.2 percent) higher when compared to the previous year. The sales increase resulted from an improving product mix, particularly a higher share of the Women's Healthcare franchise, and from stockpiling of distributors in the last quarter. A depreciating average exchange rate of the Rouble against the Euro (12.3 percent) had a significant adverse effect on our sales performance in Russia when reported in Euros. Our turnover in EUR terms amounted to EUR 290.0 million in 2018, falling short by EUR 19.5 million or 6.3 percent when compared with the turnover reported in 2017.

Sales to Ukraine amounted to USD 30.9 million (EUR 26.1 million) in 2018, showing a decline of USD 8.4 million (EUR 8.7 million) compared to the base year. A 4.6 percent weaker USD exchange rate against the EUR during the reported period impacted negatively the sales performance reported in EUR. The weak annual performance is partly due to the base effect of legislative change driven pre-shipments implemented in 2017. The Ukrainian economy has stabilized to some extent, with purchasing power having slightly increased. The average exchange rate of the local currency, UAH, remained within a narrow range, around the level of 27.2 to the USD during 2018.

Sales in Other CIS republics totalled EUR 65.7 million (USD 77.7 million) in 2018, representing a decrease of EUR 7.4 million (USD 4.8 million) compared to 2017. Currency depreciations in certain countries negatively impacted the overall performance of this region.

New products launched in the CIS republics during 2018

Brand name	Active ingredient	Therapeutic area	Launch date
LENZETTO®[1]	estradiol	Women's Healthcare, hormone replacement therapy (spray)	Q1 2018
MIRVEDOL	memantine-hidroklorid	Central Nervous System, Alzheimer's diseas	Q2 2018
AMDOAL	aripiprazole	Central nervous system, antipsychotic	Q3 2018
DIROTON PLUS	lisinopril + indapamid	Cardiovascular, antihypertensive	Q3 2018
EKVAPRESS	amlodipine + indapamid + llsinopril	Cardiovascular, antihypertensive	Q3 2018
TANYDOL	telmisartan	Cardiovascular, antihypertensive	Q3 2018
VENDIOL	gestodene + 15mcg EE[2]	Women's Healthcare, oral contraceptive	Q3 2018
EPISTAT	fenspiride	Respiratory, anti-inflammatory	Q4 2018

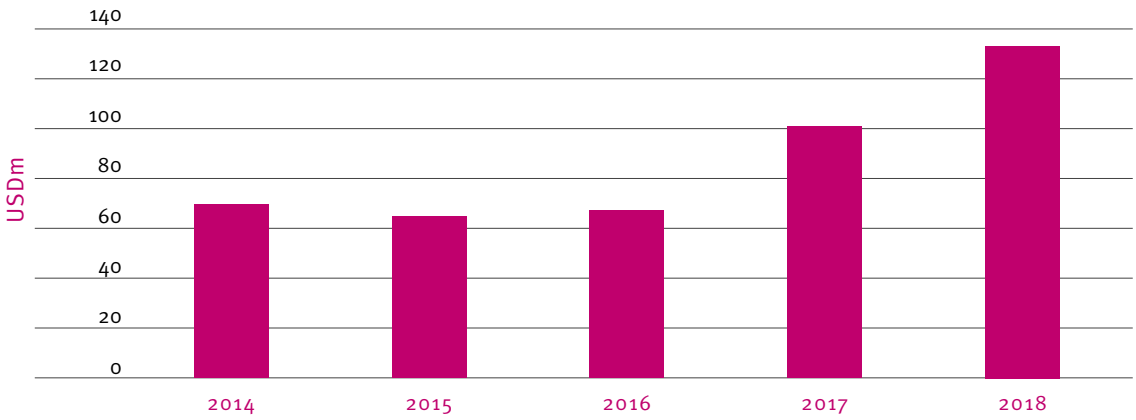
Notes: [1] Licenced-in product.
[2] Ethynil estradiol.

USA

Sales in the USA totalled US$ 133.6 million (EUR 113.0 million) in 2018 representing an increase of USD 33.2 million (EUR 24.2 million) compared to the previous year. The significant year-on-year growth was mainly due to VRAYLAR® (cariprazine) royalty income which increased by USD 38.7 million.

Royalty income for the year 2018 based on the figures published by Richter's local partner, Allergan in respect of cariprazine amounted to USD 89.7 million (EUR 75.9 million) in 2018.

Sales to the USA



China

Sales to China amounted to EUR 82.8 million in 2018, an increase of EUR 5.2 million when compared with the base year due to higher sales levels of CAVINTON, including also pre-shipments, and to higher sales of emergency contraceptives.

With effect from 1 January 2018, the invoicing currency in China was replaced from EUR to the local currency (CNY). Sales in local currency terms totalled CNY 646.7 million in comparison with the turnover of CNY 597.6 million reported for the base year.

Latin America

Sales in Latin American countries amounted to USD 21.5 million (EUR 18.2 million), a decrease of USD 0.9 million (EUR 1.7 million) when compared with the base year, primarily due to lower ESMYA® sales and to the strengthening generic competition in the case of emergency contraceptives.

Rest of the World

In addition to sales in highlighted countries Richter's pharmaceuticals are marketed elsewhere, and the cumulative sales in these countries amounted to EUR 60.6 million (USD 71.6 million) in 2018. Turnover increased by EUR 5.6 million (USD 9.5 million) when compared with 2017. Vietnam, Switzerland and Australia contributed the most to the sales performance.

Women's Healthcare

In recognition of the strategic importance to the Company of this therapeutic area a detailed presentation of the Women's Healthcare (WHC) franchise is given below. This therapeutic area includes the following product groups and therapeutic indications: oral contraceptives (OC), emergency contraceptives (EC), contraceptive devices (CD); menopausal care, fertility, pregnancy care and obstetrics, gynaecological infections, and other gynaecological conditions, such as uterine fibroids.

Total sales recorded by Richter's WHC niche franchise at EUR 411.9 million declined by EUR 59.1 million, or 12.5 percent when compared to the previous year primarily as a consequence of the amendments to the initial label of ESMYA® as announced by the European Commission based on previous CHMP opinion. The decline experienced in the Euro denominated sales levels of WHC products in Russia also impacted negatively the turnover of this franchise.

When loss in sales suffered by ESMYA® during the reported year is excluded, Richter's WHC portfolio grew by EUR 8.0 million or 2.1 percent when compared to the previous year's performance.

Sales arising from the acquired OC portfolio amounted to EUR 43.1 million, having declined by EUR 0.8 million or 1.8 percent when compared to the performance achieved in the previous year.

Women's Healthcare sales by region

	2018 HUFm	2017 HUFm	Change HUFm	Change %	2018 EURm	2017 EURm	Change EURm	Change %
Hungary	**4,727**	**5,057**	**(330)**	**(6.5)**	**14.8**	**16.4**	**(1.6)**	**(9.8)**
EU*	**60,593**	**71,899**	**(11,306)**	**(15.7)**	**190.2**	**232.5**	**(42.3)**	**(18.2)**
EU12	14,965	13,055	1,910	14.6	47.0	42.2	4.8	11.4
Poland	5,365	3,816	1,549	40.6	16.8	12.3	4.5	36.6
Romania	2,097	2,001	96	4.8	6.6	6.5	0.1	1.5
EU 15	45,628	58,844	(13,216)	(22.5)	143.2	190.3	(47.1)	(24.8)
CIS	**32,535**	**35,057**	**(2,522)**	**(7.2)**	**102.1**	**113.3**	**(11.2)**	**(9.9)**
Russia	27,117	28,787	(1,670)	(5.8)	85.1	93.1	(8.0)	(8.6)
Ukraine	1,738	2,609	(871)	(33.4)	5.4	8.4	(3.0)	(35.7)
Other CIS republics	3,680	3,661	19	0.5	11.6	11.8	(0.2)	(1.7)
USA	**10,469**	**11,599**	**(1,130)**	**(9.7)**	**32.9**	**37.5**	**(4.6)**	**(12.3)**
China	**9,095**	**7,884**	**1,211**	**15.4**	**28.5**	**25.5**	**3.0**	**11.8**
Latin America	**4,457**	**4,878**	**(421)**	**(8.6)**	**14.0**	**15.7**	**(1.7)**	**(10.8)**
Rest of the World	**9,382**	**9,303**	**79**	**0.8**	**29.4**	**30.1**	**(0.7)**	**(2.3)**
Total	**131,258**	**145,677**	**(14,419)**	**(9.9)**	**411.9**	**471.0**	**(59.1)**	**(12.5)**

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

In Germany negative sentiments surrounding oral contraceptives prevailed during the reported period. Group sales declined by EUR 7.2 million primarily driven by lower sales levels of ESMYA®.

Sales reported in Spain decreased by EUR 7.7 million. Declining ESMYA® sales were only offset to a certain extent by higher sales levels of a range of oral contraceptives and BEMFOLA® during 2018.

Turnover in France declined by EUR 7.1 million primarily due to lower turnover of ESMYA® partly offset by a good performance of BEMFOLA® and a range of oral contraceptives.

In Italy Richter Group achieved WHC sales of EUR 20.4 million in the reported year, EUR 4.6 million below the levels reported in twelve months to December 2017. A better performance recorded by BEMFOLA® together with improving sales figures of the range of oral contraceptives could not offset lower turnover of ESMYA®.

Sales in the UK were GBP 14.2 million (EUR 16.2 million) lower. The significant decline in sales was caused primarily by lower sales levels of ESMYA®.

WHC sales to the CIS in 2018 totalled EUR 102.1 million representing a decline of EUR 11.2 million compared to the sales levels achieved in the previous year. The EUR denominated decline recorded in the CIS region originated primarily in Russia as a result of unfavourable exchange rate movements recorded by RUB both against the EUR and the HUF.

WHC sales to the USA in 2018 decreased by USD 3.5 million, (8.3 percent) as higher sales levels of finished form PLAN B / PLAN B ONE-STEP were more than offset by the decline suffered in the profit sharing proceedings and lower sales of certain steroid APIs.

WHC sales in the ROW countries reported a EUR 0.7 million decline when compared with the twelve months to December 2017 primarily due to lower sales of ESMYA®. BEMFOLA® sales increased by 5.9 percent during the reported year.

Lajos Kovács
Technical Director

f) Corporate 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.

All three of our main manufacturing sites in Hungary possess IPPC (Integrated Pollution Prevention and Control) licenses.

Due to the expansion of production capacities at our facility in Debrecen, it has become necessary to build an averaging pool to compensate for the quantitative / qualitative fluctuations of wastewater discharged, the plans of which have been prepared and a review of the IPPC license have been submitted.

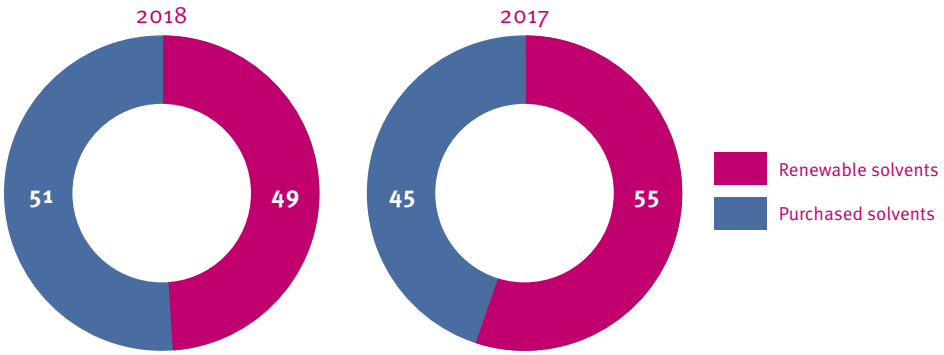
The Company's environmental management system complies with all requirements of ISO 14001: 2015. In accordance with the change of the standard, the entire documentation of our Environmental Management System (EMS) was reviewed and updated; the system has been certified by a successful supervisory audit in 2018 to meet the requirements of the renewed standard. Our subsidiary in Romania started to build an EMS system in accordance with the ISO 14001. The implementation is supported by the transfer of our documents and many years of system operation experience, as well as on-site consultation.

Review of the sewer networks, and their repair as needed, is in progress at both the Budapest and Dorog facilities. We will carry out remediation actions to eliminate groundwater contamination from the past, in accordance with current regulatory requirements. Significant reconstruction was carried out at Dorog in the biological wastewater treatment plant. We have begun preparing the reconstruction of the emergency reservoir planned for 2019 by renovating some reservoir pools and dismantling an unused pool. During the operation of the wastewater treatment plant, we attach great importance to eliminating odor and air pollution.

According to its environmental policy, the Company places great emphasis on the minimization of the environmental impacts of its activity. In line with the sustainable operation, the Company compiled the environmentally relevant indicators in accordance with the recommendations of the Global Reporting Initiative presented by the following diagrams.

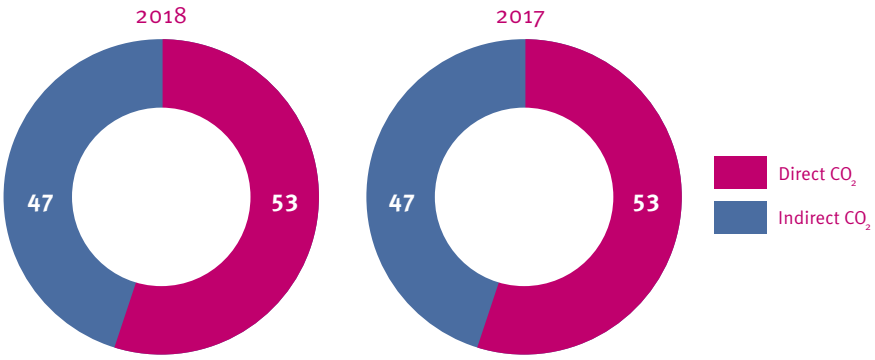
Environmental indicators

Materials used in 2017-2018*

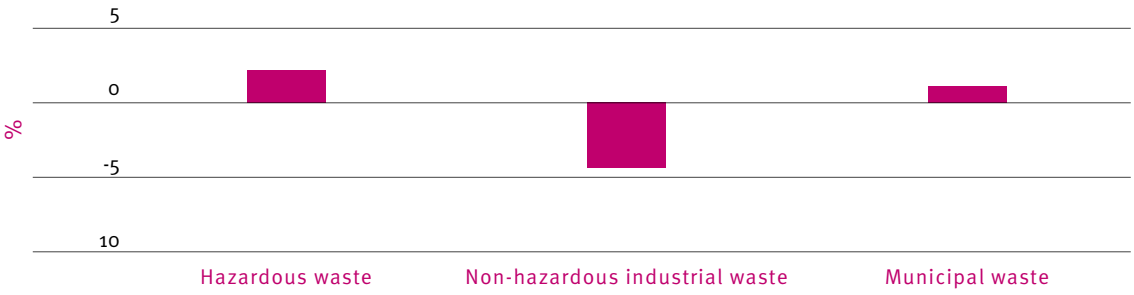


Note: * Materials used for manufacturing active ingredients and finished products.

CO_2 emission



Waste



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.

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.

Our Occupational Health and Safety Management System (OHSMS) in compliance with OHSAS 18001:1999 standard, was officially certified at the beginning of 2006, making Richter the first Hungarian pharmaceutical company to obtain this type of certification. Following a recent re-certifying audit in 2018, performed against the more stringent criteria of OHSAS 18001:2007, the Company was successfully certified for further three years. The new National

Accreditation Authority has chosen the Safety Laboratory to conduct the European Accreditation Authority's (EA) International Audit in 2018, and that the Authority did not issue any partial report or deviation during the EA audit.

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.

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. We apply a multi-tiered risk management process, with the most important action plans managed at project level, within a framework of systematic targets and programs identified in the Management System.

Risk management related to occupational health has been put on 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 order to meet the requirements (REACH and CLP) issued by the European Union relating to the registration and labelling of certain chemicals, a compliance strategic plan has been developed. 22 registration dossiers for chemicals were submitted during 2018 in accordance with REACH, in 8 cases as lead registrants.

Our fire protection policy places particular emphasis on prevention. This includes a network of fire alarm and detecting devices covering the total area of premises ensuring the early detection of any possible signs of fire that may nonetheless break out. Implementation of an independent extinguishing water network at the Dorog facility has been completed. In addition to state-of-the-art upgrades of the Domestic Distribution Warehouse in Budapest, a new 550 m^3 reservoir for fire extinguishing water has been built.

A specific 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".

No fatal accidents or other serious work related injuries occurred at any of our facilities in 2018.

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. 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 2018.

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 2 million) 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: 68 towns have benefited and around 170,000 people have participated, with their presence increasing Richter's initial donation by an extra HUF 201 million. Over the ten years some 68 hospitals have received a total of HUF 337 million financial assistance from Richter. During this period specialists have carried out more than 150,000 screenings, out of which approximately 35,000 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.

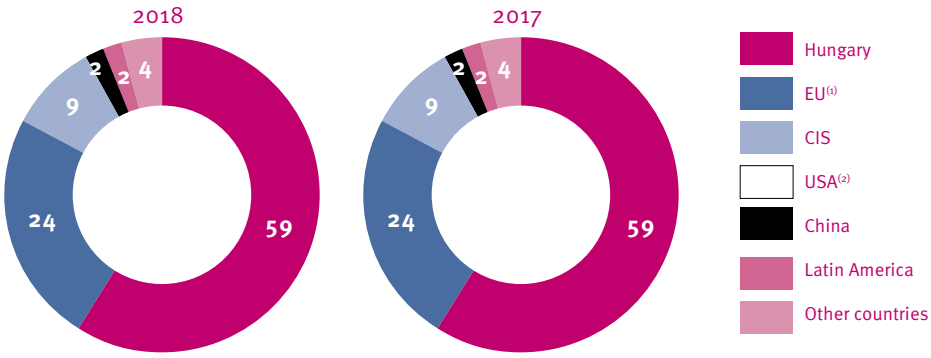
As a global pharmaceutical company, it has always been important for the Group to carry on its activity according to honesty, ethics and compliance and it is henceforward committed to operate legally and responsibly.

g) 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[3] by region (%)



Notes: (1) Excluding Hungary.
(2) As a result of the low rate of the number staff in the USA, the data is not displayed.
(3) As at 31 December 2017 and 31 December 2018.

In 2018 the Company reviewed its HR strategy relating to the mid-term business strategy in order to update and highlight the activities to facilitate the achievement of our business objectives in the current economic/market environment.

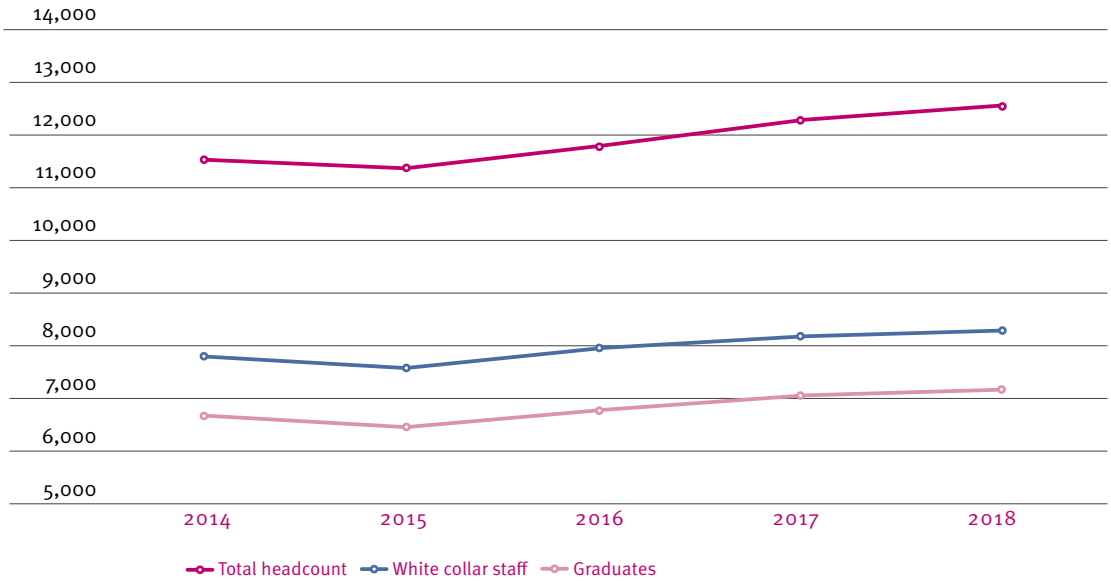
Successful and great companies are defined by people who embrace a shared sense of purpose, put extra energy and passion into their jobs and identify with common goals. That is the kind of engagement we aim for at Richter. We start from a foundation of respect; we passionately believe that a company 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

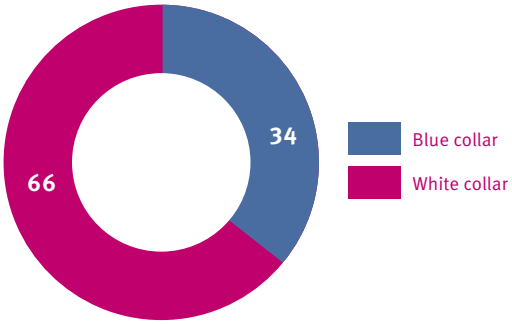
The total headcount for the Group was 12,667 at the end of 2018, a 2.4 percent (298) increase when compared to 2017. The growth was primarily due to the increasing number of personnel in manufacturing and in information technology.

The number of skilled employees at the Group increased to 7,216 at the end of 2018, from 7,081 reported in 2017. Graduate educated personnel represented 87 percent of white collar staff and 57 percent of the total number of employees at the Group.

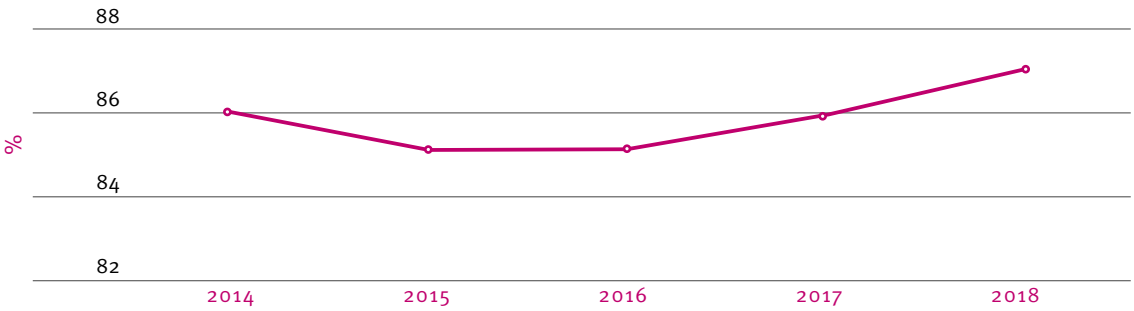
Number of staff



Proportion of blue and white collar staff (%)



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. 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 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 2018 including the 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 scientific and professional education and advanced training. Accordingly, during 2018 more than 700 employees participated in Hungarian scientific conferences and professional seminars. During 2018 we paid particular attention to training programmes also in the field of basic IT skills.

To support innovation and knowledge sharing within our Group in 2018 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 2018. 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.

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 gradually implement 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 set up business aligned objectives for 2019 were already recorded in this system.

We focus on the health factors that enable employees to perform at the highest level by sustaining energy and engagement. Similar to earlier years, a new two-year employee health programme wholly financed by the Company was initiated in 2018. All employees could participate in this 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 visit 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.

We are also paying special attention to mental health protection for our colleagues. As an integral part of any work place risk assessment, all of our sites and departments perform an evaluation of risks to mental health. Furthermore we provide training programmes for our employees which assist them in stress-management.

Dr Gábor Gulácsi
Chief Financial Officer

2. Wholesale and Retail

Richter Group is active in two major business segments, primarily Pharmaceuticals comprising the research and development, manufacturing and marketing of pharmaceutical products and also engaged in the Wholesale and Retail of those products. These latter activities are mainly focused in Romania although the Group has also built up retail and wholesale businesses in certain CIS republics. In addition, the Latin American reporting region includes our Jamaican businesses that belong to Wholesale and Retail.

Pharmafarm is the Romanian wholesaler belonging to Richter Group. Gedeon Richter Farmacia is our major retail operation. Altogether 92 pharmacy units support the promotion and sale of Richter products in Romania.

Sales

The principal aim of the Wholesale and Retail companies is to support the sales levels of our products on the Group's selected traditional markets.

Sales amounted to EUR 278.1 million in 2018, a EUR 7.9 million decrease compared to the base period. The decline resulted from the temporary suspension of the license to operate of the Group's Romanian wholesaler subsidiary, Pharmafarm on 21 June 2018. Most of the warehousing facilities of the Romanian wholesaler subsidiary had resumed operations by 19 September 2018.

Romanian subsidiaries of the Group (both wholesale and retail) realised around 79 percent of the turnover in the Wholesale and Retail segment (RON 1,016.1 million), with the remainder primarily being invoiced by our subsidiaries in the CIS region. The sales performance in Romania declined by 2.4 percent in RON terms during the twelve months to December 2018.

Wholesale and retail sales

	2018 HUFm	2017 HUFm	Change %	2018 EURm	2017 EURm	Change %
Romania	69,571	70,438	(1.2)	218.4	227.7	(4.1)
Other CIS republics	14,797	13,992	5.8	46.4	45.2	2.7
Latin America	4,230	4,031	4.9	13.3	13.1	1.5
Total	**88,598**	**88,461**	**0.2**	**278.1**	**286.0**	**(2.8)**

3. Group Figures

The activities of Richter Group are presented in this Annual Report along three operating segments. Those subsidiaries of the Group that are engaged in the core activities of research and development together with manufacturing and sale of pharmaceutical products have been classified as the Pharmaceutical segment. The performance of those distributor and retail subsidiaries that represent the distribution chain in some of our markets and facilitate our products reaching final buyers are presented under the Wholesale and Retail segment. Finally, the Other segment relates to the business of those group members that do not belong to any of the above segments. These companies provide services to group members belonging to the Pharmaceutical segment.

a) Business Segment Information

Business segment information

	Pharmaceuticals HUFm		Wholesale and retail HUFm		Other HUFm		Eliminations HUFm		Group total HUFm	
	2018	**2017**	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**	**2018**	**2017**
Total revenues	**364,731**	**364,840**	**88,598**	**88,461**	**6,255**	**5,395**	**(14,100)**	**(14,340)**	**445,484**	**444,356**
Gross profit	**245,465**	**244,245**	**7,509**	**8,241**	**676**	**647**	**186**	**(55)**	**253,836**	**253,078**
Profit from operations	44,631	18,617	(97)	1,777	331	391	175	(74)	45,040	20,711
Share of profit of associates and joint ventures	(431)	60	1,428	1,466	27	58	31	(56)	1,055	1,528
Number of employees at period end	**10,739**	**10,488**	**1,487**	**1,465**	**441**	**416**	**-**	**-**	**12,667**	**12,369**

b) Consolidated Turnover

Sales by region

	2018 HUFm	2017 HUFm	Change HUFm	Change %	2018 EURm	2017 EURm	Change EURm	Change %
Hungary	**39,472**	**36,040**	**3,432**	**9.5**	**123.9**	**116.6**	**7.3**	**6.3**
EU*	**181,766**	**190,720**	**(8,954)**	**(4.7)**	**570.5**	**616.6**	**(46.1)**	**(7.5)**
EU12	123,615	121,745	1,870	1.5	388.0	393.6	(5.6)	(1.4)
Poland	24,204	23,060	1,144	5.0	76.0	74.6	1.4	1.9
Romania	75,343	75,040	303	0.4	236.5	242.6	(6.1)	(2.5)
EU 15	58,151	68,975	(10,824)	(15.7)	182.5	223.0	(40.5)	(18.2)
CIS	**133,356**	**139,689**	**(6,333)**	**(4.5)**	**418.5**	**451.7**	**(33.2)**	**(7.4)**
Russia	92,404	95,734	(3,330)	(3.5)	290.0	309.6	(19.6)	(6.3)
Ukraine	8,380	10,824	(2,444)	(22.6)	26.3	35.0	(8.7)	(24.9)
Other CIS republics	32,572	33,131	(559)	(1.7)	102.2	107.1	(4.9)	(4.6)
USA	**35,985**	**27,472**	**8,513**	**31.0**	**113.0**	**88.8**	**24.2**	**27.3**
China	**26,384**	**24,004**	**2,380**	**9.9**	**82.8**	**77.6**	**5.2**	**6.7**
Latin America	**9,207**	**9,418**	**(211)**	**(2.2)**	**28.9**	**30.5**	**(1.6)**	**(5.2)**
Rest of the World	**19,314**	**17,013**	**2,301**	**13.5**	**60.6**	**55.0**	**5.6**	**10.2**
Total	**445,484**	**444,356**	**1,128**	**0.3**	**1,398.2**	**1,436.8**	**(38.6)**	**(2.7)**

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

c) Key Financial Data

Key financial data

	2018 HUFm	2017 HUFm	Change %	2018 EURm	2017 EURm	Change %
Total revenues	445,484	444,356	0.3	1,398.2	1,436.8	(2.7)
Gross profit	253,836	253,078	0.3	796.7	818.3	(2.6)
Gross margin %	**57.0**	**57.0**		**57.0**	**57.0**	
Profit from operations	45,040	20,711	117.5	141.4	67.0	111.0
Operating margin %	**10.1**	**4.7**		**10.1**	**4.7**	
Profit before income tax	43,953	13,901	216.2	137.9	44.9	207.1
Profit for the year	36,193	10,070	259.4	113.5	32.6	248.2
Net margin %	**8.1**	**2.3**		**8.1**	**2.3**	
EPS (HUF, EUR)[1]	190	48	295.8	0.60	0.15	300.0
Total assets and total equity and liabilities	797,883	760,865	4.9	2,481.8	2,453.3	1.2
Capital and reserves[2]	685,745	664,019	3.3	2,132.9	2,141.0	(0.4)
Capital expenditure	58,055	39,929	45.4	182.2	129.1	41.1
Number of employees at year-end	12,667	12,369	2.4			

Notes: [1] EPS calculations were based on the total number of shares issued.
[2] Includes minority interest.

d) Profit and Loss Items

Sales amounted to HUF 445,484 million (EUR 1,398.2 million) in 2018, virtually unchanged (grew by 0.3 percent) in HUF terms and declined by 2.7 percent in EUR terms when compared with the previous year. A positive performance was recorded primarily in the USA, Hungary and China with HUF denominated turnover having declined mostly in the EU15 region, in Russia and in Ukraine.

Cost of sales amounted to HUF 191,648 million (EUR 601.5 million) in 2018, almost unchanged (increased by 0.2 percent or HUF 370 million) and declined by (2.7 percent or EUR 17.0 million when compared to 2017. Amortization of the acquired intangible asset ESMYA amounted to HUF 2,166 million while amortization of another intangible asset BEMFOLA was HUF 2,061 million in 2018.

Gross margin in 2018 remained at 57.0 percent, at the same level as reported for the previous year. The significant increase in Royalty income received from Allergan in respect of VRAYLAR® and the expanding share in the turnover of the relatively high margin Chinese businesses lifted the gross margin. In addition, gross profitability of BEMFOLA® also increased significantly as sales levels increased and the negative impact of inventories valued at the time of the acquisition disappeared. Restricted sales of ESMYA®, weakening average exchange rates of RUB, price erosion experienced on our traditional markets, increasing labour costs in our manufacturing subsidiaries located in the CEE countries, costs of suspending and resuming our Romanian wholesale activities and an increase of costs related to serialization negatively impacted our gross margin. A volatility of the gross margin experienced throughout the year was mostly the consequence of the disruption in our Romanian wholesaling business. While the absence of low margin turnover pushed the ratio higher in the second and third quarter 2018, the sharp boost to sales in the last quarter 2018 led to a sharp reversal.

Sales and marketing expenses amounted to HUF 115,584 million (EUR 362.8 million) in 2018, a near flat performance (increase of 0.6 percent in HUF terms), a decline of 2.3 percent in EUR terms when compared with 2017. Somewhat higher marketing costs related to growing promotion costs incurred on the Chinese market were partly offset by a slight decrease of promotion costs incurred in Russia at weakening RUB exchange rates. The proportion of S&M expenses to sales was 25.9 percent in the reported period, unchanged when compared to 2017.

Amortisation of the marketing and intellectual property rights of the OC portfolio acquired from Grünenthal in the amount of HUF 4,388 million represented 1.0 percent of sales achieved in the reported year. After adjustment for this amortization, S&M expenses represented 24.9 percent of turnover.

The annual registration fee payable in respect of medical representatives in Hungary amounted to HUF 221 million (EUR 0.7 million) in 2018. In accordance with the regulations tax payable in 2018 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 that Richter exceeded these stated levels it was exempted from the payment of this extraordinary tax from the second quarter.

Administration and general expenses totalled HUF 24,070 million (EUR 75.5 million) in 2018, representing a 3.0 percent increase in HUF terms (near flat, or 0.1 percent decrease in EUR terms) when compared with the level recorded in the previous year. These expenses grew primarily due to higher employee costs, IT related expenses together with increased insurance, legal assistance and other advisory fees.

Research and development expenses represented 9.1 percent of sales and after an increase of 1.6 percent in HUF terms and a decline of 1.3 percent in EUR terms they amounted to HUF 40,545 million or EUR 127.3 million during the reported year. These expenses include the ongoing clinical trials being carried out in the field of biotechnology together with those managed in co-operation with Allergan. R&D expenses of the Group also include such costs at the operations of GR Polska and GR Romania.

The net Impairment recognised on financial and contract assets in accordance with in IFRS 9 was HUF 407 million in 2018. In the comparative these are presented as Other income and other expenses (net) or Net financial (loss)/income.

Other income and other expenses (net) decreased to an expense of HUF 29,004 million (EUR 91.0 million) in 2018 when compared to an expense of HUF 54,208 million (EUR 175.3 million) recorded in the previous year.

Most important one-off expenses included an impairment loss amounting to HUF 24,270 million (EUR 76.2 million) with regard to related ESMYA items accounted for at the execution of the year-end mandatory impairment tests on Intangible asset and Goodwill. During the reported year Other income and expenses also comprised liabilities amounting to HUF 4,784 million (EUR 14.0 million) in respect of the claw-back regimes effective in Romania, Germany, France, Spain, Portugal, Belgium, Italy, Bulgaria, Austria, Poland, Latvia, Slovenia, Croatia and UK. The latter expenses declined by HUF 1.917 million (EUR 7.8 million) primarily as a result of the sales restrictions applied to ESMYA®.

In 2018 an expense of HUF 432 million (EUR 1.4 million) 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. Given that Richter exceeded these stated levels it was exempted from the payment of this extraordinary tax from the second quarter.

One-off incomes included payments received from Recordati in respect of the amended license agreement subsequent to the European authorization of REAGILA® entering into force, in respect of the gradual launch of REAGILA® in the EU15 region and connected to the successful clinical trial of cariprazine in the indication of bipolar depression and the reception by FDA of the sNDA submitted by Allergan in respect of the label extension of VRAYLAR®. These milestones amounted altogether to HUF 8,429 million (EUR 26.5 million).

Profit from operations increased by 117.5 percent in HUF terms (111.0 percent in EUR terms) and amounted to HUF 45,040 million (EUR 141.4 million) in 2018 primarily due to a significantly lower amount of ESMYA related impairment loss accounted for among Other income and expenses for the reported year when compared to 2017, which in turn impacted less on profit from operations in 2018. Sales and gross margins did not change materially during the reported year. The consolidated operating margin increased to 10.1 percent from the 4.7 percent reported in 2017.

When adjusting for the balance of Other income and expenses with milestones received and ESMYA impairment loss accounted for during the reported year, consolidated operating margin was 13.7%

Financial loss of HUF 2,142 million (EUR 6.8 million) was driven by Unrealised financial items, resulting primarily from the revaluation of Trade receivables and trade payables. Realised financial items resulted from Interest income and Foreign exchange gains on conversion of cash, while Exchangeable bonds sold and accounted for among Other financial items resulted in a financial loss. Reassessment gains were a consequence of the period end appreciation of USD and EUR against HUF, while the depreciation of the RUB partly offset the above. For more detailed information on the Net financial result please refer to the table on page 88.

Share of profit of associates and joint ventures amounted to HUF 1,055 million (EUR 3.3 million) in 2018.

Profit before income tax amounted to HUF 43,953 million (EUR 137.9 million) in 2018, an increase of HUF 30,052 million (EUR 93.0 million) compared with 2017.

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.

Having examined the tax liability foreseeably due in the next coming years the Management concluded that most of the deferred tax assets accounted for in the previous years at the Parent cannot be realised, therefore these have to be derecognised in accordance with IFRS regulations.

Tax allowance linked to intensive R&D activities of the Parent together with increasing proceeds from cariprazine related royalties reached such a level, that most of the above mentioned deferred tax assets cannot be realised as they can be adopted for a related tax carry loss forward within a maximum period of five years. The derecognition of deferred tax assets from the balance sheet of the Parent won't impact the cash flow of the Company, but the amount of deferred tax assets diminishes by HUF 4,049 million (EUR 12.7 million) with Income and deferred tax expense increasing by the same amount.

In 2018 the Group recorded HUF 1,978 million (EUR 6.2 million) in respect of corporate tax expense and HUF 1,720 million (EUR 5.4 million) deferred tax expense resulting in HUF 3,698 million (EUR 11.6 million) tax expense. Local business tax and contribution fee amounted to HUF 4,062 million (EUR 12.8 million) during the reported year.

Profit for the year was HUF 36,193 million (EUR 113.5 million), HUF 26,123 million (EUR 80.9 million) higher than the profit for the year realised in 2017.

Profit for the year attributable to owners of the parent increased by 297.8 percent in HUF (285.1 percent in EUR) terms in 2018 to a total of HUF 35,348 million (EUR 110.9 million).

e) Balance Sheet Items

Total assets and total shareholders' equity and liabilities of the Group amounted to HUF 797,883 million on 31 December 2018, HUF 37,018 million, or 4.9 percent above the levels reported at 31 December 2017.

Non-current assets amounted to HUF 439,812 million in the reported year, HUF 16,522 million (or 3.6 percent) below from the reference figure. Lower levels of Other intangible assets resulted from a decline in the fair value of Richter's investment in the Russian wholesaler and retail Group, Protek and the sale of non-current bonds exchangeable into Richter shares and the conversion of non-current other sovereign bonds to current assets. An impairment loss was accounted for in respect of intangible asset ESMYA which resulted in lower amounts of Goodwill and Other intangible assets the latter being partly offset by the acquisition of the combined oral contraceptive developed by Mithra.

The levels of Deferred tax assets declined primarily as a result of the derecognition of Deferred tax assets accounted for at the Parent.

As stipulated by IFRS the amount of government subsidies which Richter qualifies for and are expected to be received shall be included among Long term receivables. In practice it means that beginning with the reported year this condition is met as soon as the capital expenditure and R&D related subsidy contracts are signed consequently these amounts are accounted for both as Long term receivables and as Non-current liabilities.
Higher levels of Property, plant and equipment (installation and putting into operation of manufacturing and packaging production lines) also impacted positively the Non-current assets.

Current assets amounted to HUF 358,071 million and increased by HUF 53,540 million or 17.6 percent when compared to the level reported on 31 December 2017. Cash and cash equivalents increased as a result of both the Government repurchase of the bonds exchangeable into Richter shares and the positive net cash flow from operating activities of the Group. Other sovereign bonds owned became current during the reported year. Higher levels of Inventories and Trade receivables also contributed to the growth.

Capital and reserves of the Group increased by 3.3 percent and amounted to HUF 685,745 million when compared to the balance as at 31 December 2017. Retained earnings increased by HUF 23,456 million and amounted to

HUF 626,052 million. A higher translation difference of HUF 4,327 million included in Foreign currency translation reserve also contributed to the above increase.

Non-current liabilities of the Group on 31 December 2018 at HUF 19,987 million were HUF 4,327 million higher than the levels as at the end of the previous year. As stipulated by IFRS the amount of government subsidies that Richter qualifies for and are expected to be received shall be included among Non-current liabilities. In practice it means that beginning with the reported year this condition is met as soon as the capital expenditure and R&D related subsidy contracts are signed consequently these amounts are accounted for both as Non-current liabilities and as Long term receivables.

Current liabilities of the Group at HUF 92,151 million on 31 December 2018 were HUF 10,965 million higher than their level reported on 31 December 2017. The increase resulted from higher amounts of Trade payables and Other current liabilities and accruals.

f) Cash flow

As indicated by the cash flow statement, the Group generated net cash from operating activities of HUF 101,244 million during 2018. Cash from operating activities exceeded the levels reported for the previous year mainly as a result of an Increase in payables and other liabilities. Not insignificant amounts of cash were directed towards capital expenditure and payment of dividends. Overall, during 2018 cash increased by HUF 36,980 million primarily due to higher Proceeds on sale/redemption on maturity of financial assets.

Cash flow

	2018 HUFm	2017 HUFm
Net cash flow		
From operating activities	101,244	83,747
From investing activities	(45,275)	(46,457)
From financing activities	(16,326)	(60,196)
Effect of foreign exchange rate changes	(2,663)	2,894
Increase/(Decrease) in cash and cash equivalents	**36,980**	**(20,012)**

g) 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 2018 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 no open forward contracts recorded by the Group as of 31 December 2018.

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 certain 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.

h) Capital Expenditure

Capital expenditure for the Group, including payments for intangible assets, totaled HUF 58,055 million in 2018 surpassing the prior year by HUF 18,126 million. The increase is largely due to the acquisition of licence and supply rights for a combined novel contraceptive under development by Mithra Pharmaceuticals. In this context, we made an upfront payment of HUF 11,365 million (EUR 35.0 million) in the third quarter. Intellectual property rights for the USA acquired in respect of BEMFOLA® also increased the amount of capital expenditure by HUF 1,389 million (CHF 5.0 million)

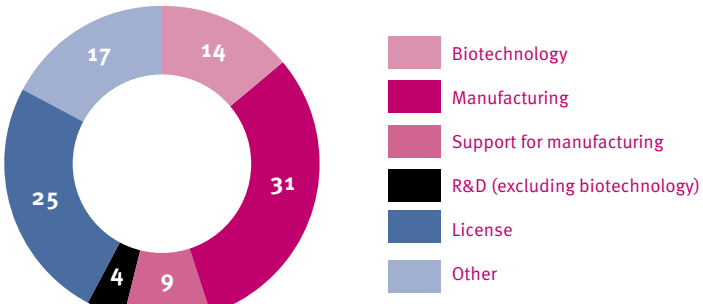
Preparation for serialization represented the most important challenge in the area of manufacturing of finished drugs during 2018. In order to comply with EU regulations the Company had to invest substantial time, effort and financial means to implement the required new technology to the existing packaging lines.

In 2018 the construction of a molecular biology laboratory in Debrecen was completed and similarly the expansion and improvement of manufacturing capacities of steroid intermediates and preparative chromatographic units at our Dorog facility, another multiple year project has been concluded and inaugurated.

Important amounts were directed during 2018 to the Research and development activity supporting our specialty pharma strategy by acquiring laboratory equipment at Richter's Budapest research centre, and at the new molecular biology laboratory opened in Debrecen.

In addition to a complex program approved at the end of 2017 aiming at the modernization of our API manufacturing subsidiary in India, a number of small scale investments have also been carried out to ensure or maintain the quality of the production, environmental protection and improve certain controlling and monitoring activities both at our Hungarian sites as well as at our subsidiaries abroad.

Capital expenditure analysed by function in 2018 (%)



Disclosures

I, the undersigned declare, that Gedeon Richter Plc. takes full responsibility, that this annual report, which contains the Group's 2018 results is prepared in accordance with the applicable accounting standards and according to the best of our knowledge. The report above provides a true and fair view of the financial position of Gedeon Richter Plc., comprises the subsidiaries included in the consolidation, it presents the major risks and factors of uncertainty and it also contains an explanation of material events and transactions that have taken place during the reported year and their impact on the financial position of Gedeon Richter Plc. and its subsidiaries included in the consolidation.

Gábor Orbán
Chief Executive Officer

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Appendices

Consolidated Financial Record

Net financial results

for the year ended 31 December	2018 HUFm	2017 HUFm	Change HUFm	2018 EURm	2017 EURm	Change EURm
Unrealised financial items	**(2,106)**	**(3,660)**	**1,554**	**(6.6)**	**(11.8)**	**5.2**
Exchange (loss)/gain on trade receivables and trade payables	(3,259)	156	(3,415)	(10.2)	0.5	(10.7)
Gain/(loss) on foreign currency loans receivable	1,276	(4,276)	5,552	4.0	(13.8)	17.8
Year-end foreign exchange translation difference of borrowings	-	65	(65)	-	0.2	(0.2)
Exchange (loss)/gain on other currency related items	(96)	369	(465)	(0.3)	1.3	(1.6)
Result of unrealised forward exchange contracts	(27)	26	(53)	(0.1)	0.0	(0.1)
Realised financial items	**(36)**	**(4,678)**	**4,642**	**(0.1)**	**(15.2)**	**15.1**
Exchange gain/(loss) realised on trade receivables and trade payables	316	(5,411)	5,727	1.0	(17.6)	18.6
Foreign exchange difference on conversion of cash	1,305	(966)	2,271	4.1	(3.1)	7.2
Dividend income	15	675	(660)	0.0	2.2	(2.2)
Interest income	1,349	1,563	(214)	4.2	5.0	(0.8)
Interest expense	(2)	(990)	988	0.0	(3.2)	3.2
Other financial items	(3,019)	451	(3,470)	(9.4)	1.5	(10.9)
Net financial loss	**(2,142)**	**(8,338)**	**6,196**	**(6.7)**	**(27.0)**	**20.3**

Consolidated Balance Sheet

at 31 December	2018 HUFm	2017 HUFm
ASSETS	**797,883**	**760,865**
Non-current assets	**439,812**	**456,334**
Property, plant and equipment	214,880	196,990
Investment property	135	-
Goodwill	35,386	44,377
Other intangible assets	151,648	154,958
Investments in associates and joint ventures	11,755	11,847
Other financial assets	9,452	35,482
Deferred tax assets	7,895	10,548
Loans receivable	2,626	2,132
Long term receivables	6,035	-
Current assets	**358,071**	**304,531**
Inventories	92,687	84,474
Trade receivables	129,006	123,023
Contract asset	1,425	-
Other current assets	16,187	20,180
Investments in securities	4,728	18
Current tax assets	1,017	795
Cash and cash equivalents	113,021	76,041

EQUITY AND LIABILITIES	**797,883**	**760,865**
Capital and reserves	**685,745**	**664,019**
Share capital	18,638	18,638
Treasury shares	(2,186)	(415)
Share premium	15,214	15,214
Capital reserves	3,475	3,475
Foreign currency translation reserve	14,182	9,855
Revaluation reserve for available for sale investments	-	9,964
Revaluation reserve for securities at FVOCI	4,810	-
Retained earnings	626,052	602,596
Non-controlling interest	5,560	4,692
Non-current liabilities	**19,987**	**15,660**
Borrowings	2	3
Deferred tax liability	7,176	8,005
Other non-current liabilities and accruals	9,255	4,347
Provisions	3,554	3,305
Current liabilities	**92,151**	**81,186**
Borrowings	-	-
Trade payables	54,549	47,495
Contract liabilities	85	-
Current tax liabilities	438	703
Other payables and accruals	33,664	30,515
Provisions	3,415	2,473

Prepared in accordance with IAS 34 Interim Financial Reporting.

Consolidated Income Statement

for the year ended 31 December	2018 HUFm	2017 HUFm
Total revenues	**445,484**	**444,356**
Cost of sales	(191,648)	(191,278)
Gross profit	**253,836**	**253,078**
Sales and marketing expenses	(115,584)	(114,882)
Administration and general expenses	(24,070)	(23,374)
Research and development expenses	(40,545)	(39,903)
Other income and other expenses (net)	(29,004)	(54,208)
Net impairment losses on financial and contract assets	407	-
Profit from operations	**45,040**	**20,711**
Finance income	19,285	14,957
Finance cost	(21,427)	(23,295)
Net financial (loss)	**(2,142)**	**(8,338)**
Share of profit of associates and joint ventures	1,055	1,528
Profit before income tax	**43,953**	**13,901**
Income tax	(7,760)	(3,831)
Profit for the year	**36,193**	**10,070**
Profit attributable to:		
Owners of the parent	**35,348**	**8,885**
Non-controlling interest	845	1,185

Consolidated Statement of Comprehensive Income

	2018 HUFm	2017 HUFm
Profit for the year	**36,193**	**10,070**
Actuarial loss on retirement defined benefit plans	(353)	(82)
Changes in the fair value of equity investments at fair value through other comprehensive income	(5,154)	-
Items that will not be reclassified to profit or loss (net of tax)	**(5,507)**	**(82)**
Exchange differences arising on translation of foreign operations	4,609	(8,890)
Exchange differences arising on translation of associates and joint ventures	(95)	17
Revaluation of available for sale investments	-	1,139
Items that may be subsequently reclassified to profit or loss (net of tax)	**4,514**	**(7,734)**
Other comprehensive income for the year	**(993)**	**(7,816)**
Total comprehensive income for the year	**35,200**	**2,254**
Attributable to:		
Owners of the parent	**34,168**	**1,299**
Non-controlling interest	1,032	955
Earnings per share (EPS)	**HUF**	**HUF**
Basic	190	48
Diluted	190	48

Consolidated Income Statement

for the year ended 31 December	2018 EURm	2017 EURm
Total revenues	**1,398.2**	**1,436.8**
Cost of sales	(601.5)	(618.5)
Gross profit	**796.7**	**818.3**
Sales and marketing expenses	(362.8)	(371.4)
Administration and general expenses	(75.5)	(75.6)
Research and development expenses	(127.3)	(129.0)
Other income and other expenses (net)	(91.0)	(175.3)
Net impairment losses on financial and contract assets	1.3	0
Profit from operations	**141.4**	**67.0**
Finance income	60.5	48.3
Finance cost	(67.3)	(75.3)
Net financial (loss)	**(6.8)**	**(27.0)**
Share of profit of associates and joint ventures	3.3	4.9
Profit before income tax	**137.9**	**44.9**
Income tax	(24.4)	(12.3)
Profit for the year	**113.5**	**32.6**
Profit attributable to:		
Owners of the parent	**110.9**	**28.8**
Non-controlling interest	2.7	3.8
Average exchange rate (EURHUF)	318.61	309.28

Consolidated Statement of Comprehensive Income

	2018 EURm	2017 EURm
Profit for the year	**113.5**	**32.6**
Actuarial loss on retirement defined benefit plans	(1.1)	(0.3)
Changes in the fair value of equity investments at fair value through other comprehensive income	(16.2)	-
Items that will not be reclassified to profit or loss (net of tax)	**(17.3)**	**(0.3)**
Exchange differences arising on translation of foreign operations	14.5	(28.8)
Exchange differences arising on translation of associates and joint ventures	(0.3)	0.1
Revaluation of available for sale investments	-	3.7
Items that may be subsequently reclassified to profit or loss (net of tax)	**14.2**	**(25.0)**
Other comprehensive income for the year	**(3.1)**	**(25.3)**
Total comprehensive income for the year	**110.4**	**7.3**
Attributable to:		
Owners of the parent	**107.3**	**4.3**
Non-controlling interest	3.2	3.0
Earnings per share (EPS)	**EUR**	**EUR**
Basic	0.60	0.15
Diluted	0.60	0.15

Consolidated Cash flow Statement

for the year ended 31 December	2018 HUFm	2017 HUFm
Operating activities		
Profit before income tax	43,953	13,901
Depreciation and amortisation	34,907	34,747
Non-cash items accounted through Total Comprehensive Income	2,130	(1,347)
Year-end foreign exchange translation difference of borrowings	-	(65)
Net interest and dividend income	(1,362)	(1,248)
Changes in provision for defined benefit plans	249	(220)
Reclass of results on changes of property, plant and equipment and intangible assets	312	1,141
Impairment recognised on intangible assets and goodwill	24,680	49,184
Expense recognised in respect of equity-settled share-based payments	1,743	3,640
Movements in working capital		
Increase in trade and other receivables	(5,899)	(12,519)
Increase in inventories	(8,772)	(3,228)
Increase in payables and other liabilities	15,483	7,631
Interest paid	(2)	(990)
Income tax paid	(6,178)	(6,880)
Net cash flow from operating activities	**101,244**	**83,747**
Cash flow from investing activities		
Payments for property, plant and equipment	(39,073)	(30,328)
Payments for intangible assets	(18,982)	(9,601)
Proceeds from disposal of property, plant and equipment	736	957
Payments to acquire financial assets	(3,291)	(1,745)
Proceeds on sale or redemption on maturity of financial assets	17,498	733
Disbursement of loans net	(646)	(666)
Interest received	1,349	1,563
Dividend received	15	675
Net cash outflow on purchase of group of assets	(2,881)	-
Net cash outflow on acquisition of subsidiaries	-	(8,045)
Net cash flow to investing activities	**(45,275)**	**(46,457)**
Cash flow from financing activities		
Purchase of treasury shares	(3,653)	(3,858)
Dividend paid	(12,673)	(19,756)
Repayment of borrowings (-)	-	(36,585)
Proceeds from borrowings (+)	-	3
Net cash flow to financing activities	**(16,326)**	**(60,196)**
Net increase/(decrease) in cash and cash equivalents	**39,643**	**(22,906)**
Cash and cash equivalents at beginning of year	**76,041**	**96,053**
Effect of foreign exchange rate changes on the balances held in foreign currencies	(2,663)	2,894
Cash and cash equivalents at end of year	**113,021**	**76,041**

Notes

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