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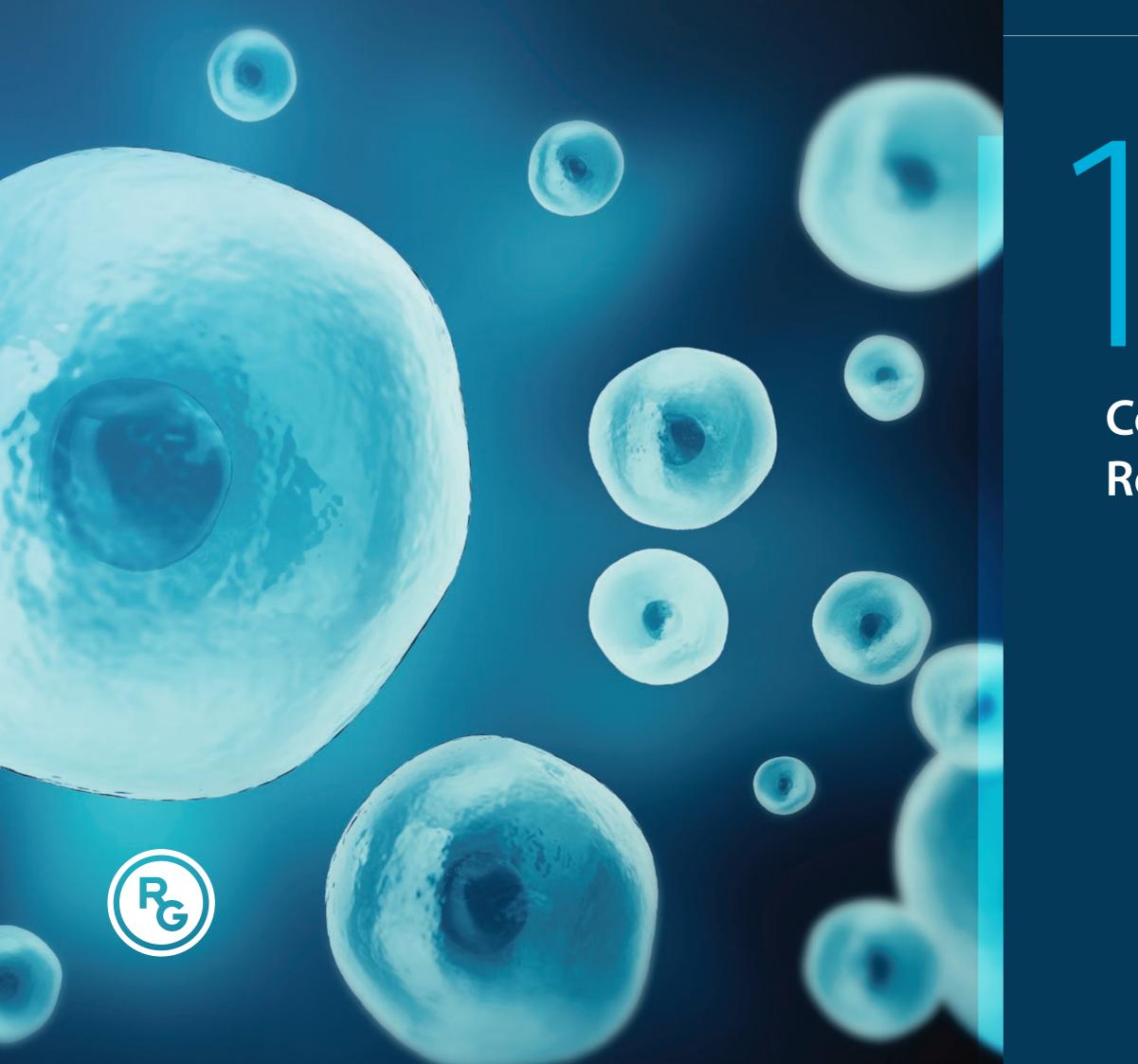
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# Corporate Review

Gedeon Richter Annual Report 2017

## 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
Phone	+36 1 431 5764
Fax	+36 1 261 2158
E-mail	investor.relations@richter.hu
Website	www.richter.hu



# 2. Financial Highlights

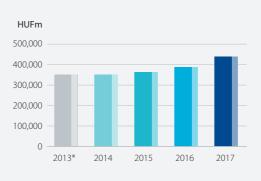
	2017	2016	Change	2017	2016	Change
	HUFm	HUFm	%	EURm	EURm	%
Total revenues	444,356	389,690	14.0	1,436.8	1,251.2	14.8
Profit from operations	20,711	54,616	(62.1)	67.0	175.4	(61.8)
Profit for the year	10,070	67,023	(85.0)	32.6	215.2	(84.9)
	2017	2016	Change	2017	2016	Change
	HUF	HUF	%	EUR	EUR	%
Earnings per share (EPS) <sup>(1)</sup>	48	356	(86.5)	0.15	1.14	(86.8)
Dividends per ordinary shares <sup>(2)</sup>	68	106	(35.9)	0.22	0.34	(35.3)

Notes:

<sup>(1)</sup> Earnings per share calculations were made considering the effect of treasury shares.

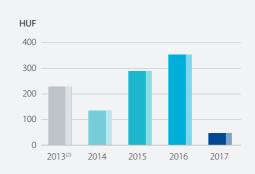
 $^{\scriptscriptstyle (2)}$  The amount of 2017 dividend per ordinary share is HUF 68 as proposed by the Board of Directors.

### Revenues



Note: \*Restated in respect of IFRS 11 standard.

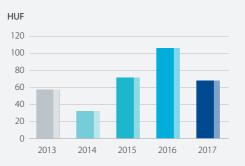
### Earnings per share(1)



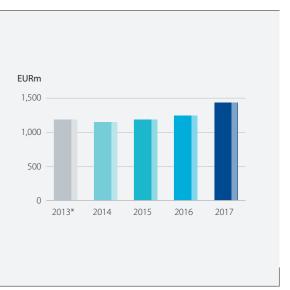
Notes:

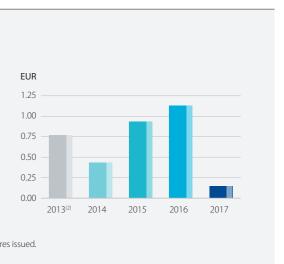
<sup>(1)</sup> Earnings per share calculations were based on the total number of shares issued. <sup>(2)</sup> Restated in respect of IFRS 11 standard.

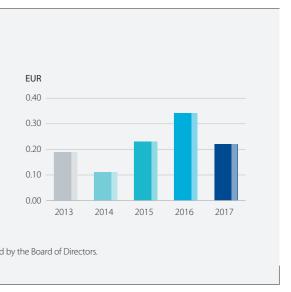
### Dividends per ordinary share\*



Note: \*The amount of 2017 dividend per ordinary share is HUF 68 as proposed by the Board of Directors.







Gedeon Richter Annual Report 2017



## 3. Chairman's Letter to the Shareholders

It is with great honour that I address the Shareholders of Gedeon Richter. Although its the twenty fourth occasion that I have done so, its the first time as Chairman and I would therefore briefly like to review the past quarter of a century that I have spent with Richter.

Having been appointed in 1992 as Managing Director of a relatively small, heavily indebted state-run pharmaceutical company which had just been through an unsuccessful privatization attempt I quickly realised that most of Richter's value was in a well established name with primary exposure to the markets of Central and Eastern Europe and the former Soviet Union. I was appointed to lead a long-lasting "product development process" targeting to become a pharmaceutical company which at the end of the day offers reliable drugs at affordable prices to patients, a respectable job to employees and sustainable resources to society at large.

The first successful privatization step introduced Richter to the stock exchange in November 1994. This exposed the management of the Company to the spotlight of the international financial environment and its demands for sustained shareholder value creation. Over the near quarter of a century, Richter has become, through organic growth, ongoing specialisation and a few selective acquisitions, one of the largest drug manufacturers in Central and Eastern Europe and has a worldwide exposure to Women's Healthcare, an original compound successfully launched in the USA through a fruitful partnership, and has completed the first steps in the highly demanding field of the future, i.e. drug manufacturing of biosimilar products.

Richter, initially a company with a portfolio consisting mainly of branded generic and certain original products has become over the years a respectable, middle sized player of the pharmaceutical universe, prepared to face new challenges. Richter addresses these challenges by putting even more emphasis on its high added value specialty activities. In my new role as an Executive Chairman I am responsible for Commercial, for Legal and Global Operations, for PR and Government Relations of the Company, whilst of course continuing to support the entire Board of Directors with the extensive business intelligence I have accumulated over the past decades.

I would like to express my gratitude to our Lifetime Honorary Chairman, Mr William de Gelsey KCSG for his consistent support of our Board with his valuable advice. I would also like to thank Mr Gábor Orbán for his contribution to the success of our company so far and welcome him in the responsible yet challenging CEO position, which he has held since 1 November 2017.

On behalf of the Board, I am proud to hand out this Annual Report to our distinguished shareholders and I would like to express at the same time my appreciation for their sustained support. I am convinced that the Management of the Company has taken the required steps in order to ensure the generation of long-term shareholders value.

Loga 1

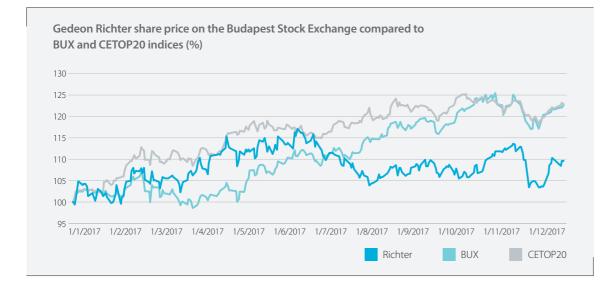
Erik Bogsch Executive Chairman

### 4. Investor Information

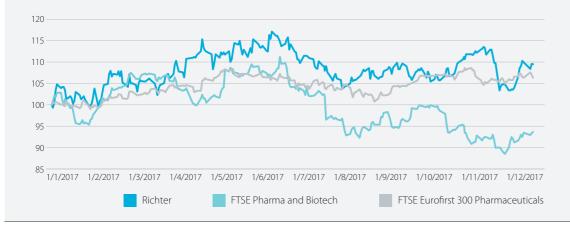
### a) Share Price and Market Capitalisation

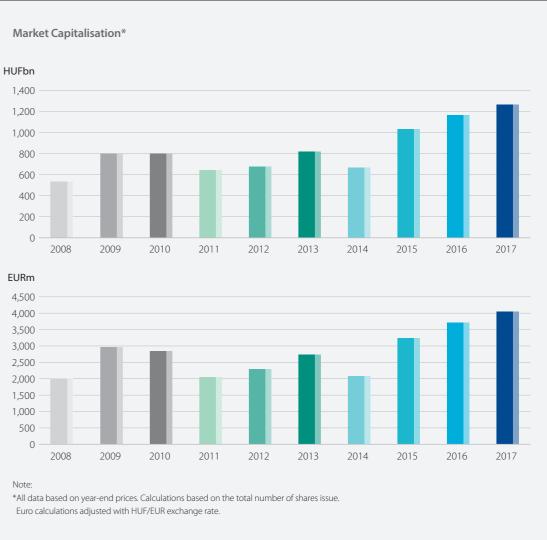
The Gedeon Richter Plc. share price on 2 January 2017 was HUF 6,191. Following a sustained increase, the price peaked at 7,250 in mid June. Losing about 11 percent from its peak value, the share price decreased to HUF 6,425 by early August. A standstill kept the shares trading around HUF 6,600 until mid November when noticeable growth brought it again just above the HUF 7,000 value. Having announced the commencement of an authority assessment of one of our flagship products in early December the shareprice declined to HUF 6,400 from which it increased again to reach its year closing value at HUF 6,780 on 29 December 2017.

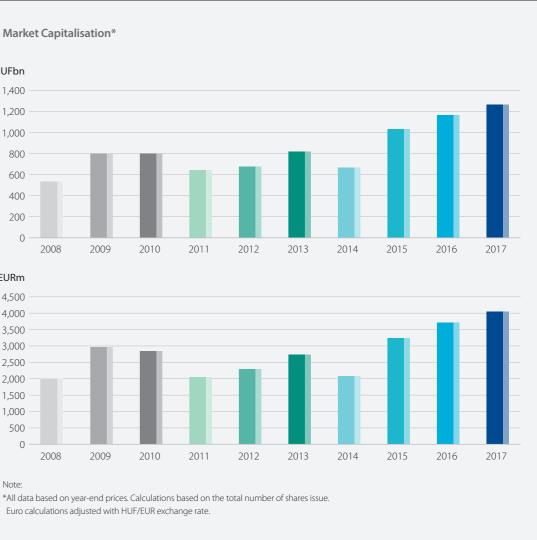
The Company's market capitalisation linked to the performance of its share price on the Budapest Stock Exchange at the end of 2017 was HUF 1,264 billion reflecting an about 9 percent increase, in HUF terms when compared to its value recorded on 30 December 2016. Market capitalisation on 29 December 2017 in Euro terms was EUR 4.07 billion, about 10 percent above the EUR 3.75 billion recorded on 31 December 2016.



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







### 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 15.00 on 25 April 2018 at Budapest 1143, Stefánia út 34.

### c) Dividend

In accordance with the dividend policy practised by the Company, the Board of Directors recommends the payment of 25 percent of Gedeon Richter Plc/s net consolidated profit adjusted with the impairment loss calculated according to International Financial Reporting Standards (IFRS) for 2017.

Dividends approved by the shareholders of Gedeon Richter Plc. at the Annual General Meeting held on 26 April 2017 totalled HUF 19.8 billion (EUR 63.4 million) in respect of 2016. The portion payable in relation to ordinary shares amounted to HUF 106 per share, 106 percent of the nominal share value. The record dates for these dividend payments were announced on 12 May 2017 with payments having commenced on 12 June 2017.

### 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 IR Department of Gedeon Richter Plc. participated at 2 international conferences and 4 additional investor roadshows in 2017. Gedeon Richter's management also held 17 meetings for approximately 22 fund managers and analysts at its headquarters where the Company's business progress and financial results were presented. Regular conference calls were organised during the year following publication of the quarterly reports of the Company and 21 additional conference calls were organised on request.

Conferences in 2017			
Concorde	"One on One Conference"	Budapest	5 April 2017
BAML	"Global Healthcare Conference"	London	13 September 2017

Investor roadshows in 2017	
London	7-9 February 2017
Paris	28 June 2017
London	12, 14 September 2017
London	16 November 2017

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

AEGON Assets Management	Ms Helena Naffa
Bank of America Merrill Lynch	Mr Jamie Clark
Concorde Securities Ltd.	Mr Attila Vágó
Erste Group Bank AG	Ms Vladimíra Urbánková
Goldman Sachs International	Ms Yulia Gerasimova
IPOPEMA Securities S.A.	Mr Michał Bugajski
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 2017 remained unchanged from the levels reported as at 31 December 2016.

### **Treasury Shares**

Treasury shares held by the Gro	oup				
	Reason of purchase	Number	Nominal value (HUF)	% as of share capital	Book value (HUF)
Opening balance		241,634	24,163,400	0.130	1,285,077,720
out of which owned by Parent Company		181,350	18,135,000	0.097	1,068,477,406
Purchased	Bonus, Remuneration, Programme approved by Emp.Sh.*	309,000	30,900,000	0.166	2,113,722,405
Shares repurchased (OTC)	Bonus, Remuneration, Programme approved by Emp.Sh.*	252,499	25,249,900	0.135	1,744,380,343
Repurchased through Programme approved by Emp.Sh.*	Programme approved by Emp.Sh.*	12,917	1,291,700	0.007	86,269,492
Total share purchased		574,416	57,441,600	0.308	3,944,372,240
Bonus, Professional Development Programme		72,904	7,290,400	0.039	428,238,096
Remuneration		431,800	43,180,000	0.232	2,849,808,481
Granted through Programme approved by Emp.Sh.*		245,163	24,516,300	0.132	1,696,326,296
Total utilization		749,867	74,986,700	0.403	4,974,372,873
Closing 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

Note: \*Employee share bonuses programme

As opposed with the practice of previous years we included in the table 'Treasury shares held by the Group' in respect of 2017 both the shares held by the Parent Company and by its subsidiaries. Share transactions that occurred between the Parent Company and any of its subsidiaries were similarly excluded from the consolidated amount.

The number of shares held by the Group in Treasury decreased during 2017.

The Company purchased 54,784 shares from its subsidiaries, 252,499 shares on the OTC market while a further 309,000 shares were acquired on the Budapest Stock Exchange.

Based on a decision of the Board of Directors of Gedeon Richter Plc., 504,704 shares held by the Company in Treasury were granted as bonuses during 2017 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 12,917 shares from employees who resigned from the Company during 2017.

In a programme related to employee share bonuses, the Company granted a total of 245,163 shares in respect of 4,266 of its employees for 2017. The above shares in the value of HUF 1,696 million will be deposited at the employees' individual securities accounts at UniCredit Bank Hungary Zrt. until 1 January 2020.

On 2 January 2018, following the expiry of the lock-up period the Company was able to remove all restrictions on 350,694 Richter ordinary shares granted to its employees on 16 December 2015 according to its programme related to employee share bonuses, thereby enabling these shares to be traded.

On 31 December 2017 the Group's subsidiaries held a total of 5,500 ordinary Richter shares compared to a holding of 60,284 reported ordinary Richter shares, held on 31 December 2016.

The total number of Company shares at Group level held in Treasury at 31 December 2017 was 66,183.

### **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.

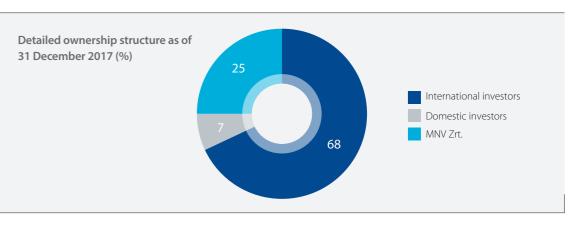
### **Registered Shareholders**

The shares held by the Hungarian State Holding Company (MNV Zrt.) remained at 25 percent, a level similar to that of 31 December 2016. The proportion held by domestic investors remained around approximately 7 percent while that of international investors remained at approximately 68 percent. The proportion of treasury shares including the above mentioned holding of subsidiaries was 0.04 percent at the end of 2017.

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 2017			
Ownership	Ordinary shares Number	Voting rights %	Share capita %
Domestic ownership	60,272,583	32.35	32.34
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	6,150,262	3.30	3.30
Retail investors	7,070,527	3.80	3.79
International ownership	126,025,320	67.64	67.61
Institutional investors	125,223,994	67.21	67.18
out of which Aberdeen Asset Mgmt. Plc.	18,243,530	9.79	9.79
out of which Black Rock, Inc.	9,628,286	5.17	5.17
out of which Harding Loevner LP	9,367,925	5.03	5.03
Retail investors	801,326	0.43	0.43
Treasury shares*	66,183	0.00	0.04
Undisclosed ownership	10,774	0.01	0.01
Share capital	186,374,860	100.00	100.00

Note: \*Treasury shares include the combined ownership of the parent company and subsidiaries.



	31 December 2017 Number of ordinary shares	31 December 2016 Number of ordinary shares
Board of Directors	51,374	46,172
Supervisory Committee	3,140	4,059
Executive Board	23,600	19,485
Total	78,114	69,716

Membership of the Company's Boards is shown on pages 20-23 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 offices of the Managing Director (CEO) and the Chairman of the Board of Directors were held by the same person from 1 January 2017 to 31 October 2017. With effect from 1 November 2017 the two offices were separated again, having a different Chief Executive Officer and a Chairman of the Board of Directors. 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. 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 ent 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 Managing Director.

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 auditors 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 from 1995 to April, 2017. Chairman of the Board between 1999 and 2016. Lifetime Honorary Chairman of the Company since January 2017.

### Mr Erik Bogsch (1947)

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

### 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 of Richter Gedeon Plc. 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 the CEO of Pénzintézeti Központ Rt. and later a member of the management team 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 of Richter in 2010.

### Mr Gábor Orbán (1979)

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

#### Dr Gábor Perjés (1941)

Medical doctor, urologist, nephrologist. Assistant at the Postgraduate Medical School between 1966-1970. Member of Parliament from 1990 to 1994. Currently practising as a physician, head of department with Gyógyír XI. Public Company responsible for medical services in district XI of Budapest. Has been a member of the Board since 1992.

### 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. Appointed by the Minister of National Development, Dr Szivek is the CEO and member of the Board of the Hungarian National Asset Management Inc. since 2015. 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 of Gedeon Richter Plc. in 2014.

### **Executive Board**

### 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 Gábor Orbán (1979)

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

### Dr 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, 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 the CEO of Pénzintézeti Központ Rt. and later a member of the management team 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.

### Mrs Tamásné Méhész (1948)

Chartered accountant, qualified tax expert. Also a certified public accountant. Managing director and owner of S&M Economix Ltd. Registered auditor of various companies. Joined the Supervisory Board in 2012. Member of the Audit Board.

### Mrs Klára Csikós Kovácsné (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 Kozsda Kovácsné (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 2017

At the Annual General Meeting on 26 April 2017, the following were reappointed to the Board of Directors for a 3 year period until the 2020 AGM: Mr Erik Bogsch, Mr János Csák, Dr Gábor Perjés, Prof Dr Szilveszter Vizi E., Dr Kriszta Zolnay, while Dr Ilona Hardy, Mr Gábor Orbán were appointed to the Board of Directors for a 3 year period until the 2020 AGM.

The membership of Mr William de Gelsey and Dr László Kovács in the Board of Directors expired on the date of at the AGM. With effect from 31 December 2017, Mr Christopher William Long resigned from his membership in the Company's Board of Directors.

## 7. Risk Management

Gedeon Richter Plc. is committed to creating long-term value for its customers, shareholders, employees and society at large. To achieve its corporate goals, the Company recognizes that risks are an integral part of its business and can feature opportunities, as well as threats and losses.

The effective management of risks plays an important role in the continued growth and success of Richter. The objective of risk management at Richter is not to eliminate risks, but rather to manage them in a way so as to provide that they remain within the predefined limits necessary for the Company to achieve its business objectives. Risk management at Richter is therefore about finding the right balance between risks and opportunities. By understanding and managing risk we endeavor to provide greater certainty for our shareholders, our employees, our customers and suppliers, and the communities in which we operate.

Richter views risk management as one of the tools for effective Corporate Governance. Our approach is to ensure that risks are identified in a timely manner, adequately understood, properly assessed and efficiently responded to by the Company.

### Our risk management approach involves the following aspects:

- A risk management process that provides insight to the risks that the company faces;
- A common risk language encompassing strategic, operational, compliance and financial risks to facilitate communications and decision-taking on risks;
- Respect of risk attitude;
- Periodic management review process to update the risk profile and monitor the effectiveness of risk management and internal controls;
- Accountability and governance structure in relation to risk management.

As part of a company-level risk assessment, relevant strategic, operational, compliance and financial risks have been identified, and evaluated by the management of the Company. The following risks proved to be the most typical in each category during the assessment.

	Description
Macroeconomic Factors	Changes in macroeconomic factors affecting the Company's markets: the Russian-Ukrainian conflict and the low level of oil price reults in decresing sales levels in CIS region and increases uncertainty
Competition and Pricing	The impact on the Company's market position and results of increasing generic competition and declining consumer prices in a competitive market
Healthcare Budget	The potential impact on the Company of changes and monetary restrictions in healthcar budgets and regulations (price reductions, increasing industry specific taxes, restrictions on reimbursement systems and delays in the acceptance of reimbursements applications)

	Description
Original and	The risk relating to the success of original
biosimilar R&D,	research, manufacturing and sales activitie
manufacture and	along with biosimilar development and
sales activities	manufacturing

The increasing complexity of Company activity, more diversified markets The risks relating to the increase of product sales level in respect of Women's Healthcare an Central Nervous System. The risks relating to the establishment of specialty sales network in Western Europe, in China and in Latin America

Qualified Workforce The risk relating to the retention of qualified employees in key positions and to the assurar and retention of blue-collar workforce

	Key risk management methods
	<ul> <li>Monitoring changes in major macroeconomic factors, incorporating their effects into the planning</li> </ul>
	• Restrictions in cost management and client relationship
	• Flexible utilization of local manufacturing capacities
	• Increasing market presence and turnover in the EU and in the USA
	• Identifying competitive advantages
	• Focusing on new original and value added products
е	• Introducing new generic products
	• Regularly performed industry and competitor evaluation effectiveness analysis
	• Regular analysis of market environment
re	• Monitoring changes in the legal and medical subsidy system
	• Communication with authorities
	• Adaptation in cost management

Ke	ey risk management methods
0	To focus on CNS R&D activity and Women's Healthcare development
0	To set up the milestones regarding the original and biosimilar R&D activity
0	Assessment of programs and decision-making with the involvement of advisory boards and international expert according to the international standards
0	Involving partners to minimise risk and to provide co- financing
0	To operate pharmacovigilance systems with respect to original products
o nd	Company level projects for the promotion of the new Women's Healthcare portfolio, the integration of Finox Group and coordinating the launch of BEMFOLA®
n o a	Stregthening market presence and sales network in Western Europe
0	Establish sales network in Latin America
0	Cooperation with our licence partner in respect if the launch of cariprazine in Europe
o nce	More frequent revision of HR strategy, salary increases adjusted to the labour market
0	Training plans, carrier/succession programs
0	Performance assessment system
0	To determine the optimal number of staff
0	Retention of employees performing high quality work

3. Compliance risks	3. Compliance risks					
	Description	Key risk management methods				
Health Authority Regulations, High quality requirements from customer side	The risk of compliance with Authority's regulations More frequent inspections due to original product launches Introduction of serialization (the unique identification of packed pharmaceutical products at unit level) is obligatory from 2019	<ul> <li>Implementing Quality systems and Standard Operational Processes (SOP)</li> <li>Monitoring the compliance with health authority regulations</li> <li>Separete projects to prepare for inspections</li> <li>A preparatory programme for the introduction of serialization</li> </ul>				
Intellectual Property, Patents and Litigations	The risk relating to patents and patent rights	<ul> <li>Continuous assessment and monitoring of intellectual property and patents</li> <li>Enforcement of patent rights</li> <li>Risk minimising agreements</li> </ul>				
Contracts and Liabilities	The risk relating to managing and enforcing contractual conditions and liabilities	<ul> <li>Centralised contracting processes</li> <li>Special treatment of unique contracts</li> <li>Introduction of global compliance program</li> </ul>				

4. Financial risks				
	Description	Key risk management methods		
Credit and Collections	Cash and receivable collection procedures Region specific customer risks	• Customer rating and establishing payment terms and credit limits		
		• Regular assesment of receivables		
		• Insurance on buyer's credits of CIS countries at MEHIB		
Foreign Exchange Rate	Managing exchange rate risks in a changed foreign currency structure	<ul> <li>Monitoring annual open FX positions and featured / key FX spot rates</li> </ul>		
Capital Structure,	Effective management of the Company's cash	• Developing and monitoring cash-flow plans		
Cash Management, Financial	demands and cash assets Maintenance of financing security beside	• To regulate the financial investments in order to handle the investment risk		
Investments Tax risks	aquisition expenses	• Cash-Pool system		
107 11313		• Preparing for the inspection of tax allowance		

# 8. Litigation Proceedings

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





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Gedeon Richter Annual Report 2017



# **Chief Executive Officer's Review**

I am delighted to present Richter's 2017 Annual Report to the general public as recently appointed CEO. I felt honoured to accept this nomination by the Board of Directors of Gedeon Richter, a Company with such strong foundations, glorious traditions and high ethical standards. I strongly hope that I will be able to live up to the high expectations set to the management team led by me.

First and foremost I would like to underline that I am fully committed to the well-established specialty pharma strategy of the Company. I strongly believe that the implementation of our specialty pharma model with a broad women's healthcare product portfolio and a demonstrated ability to bring original and biosimilar products to the market will guarantee the Company's sustained results in the future.

I am pleased to report that we had a series of positive news coming out of our cariprazine development programme last year. In mid-July the European Commission granted marketing authorization to REAGILA® for the treatment of schizo-phrenia. Subsequently our partner, Recordati commenced the compilation of application files to include REAGILA® to the lists of reimbursed drugs in most of the Western European countries. Another milestone on the road of develop-ing cariprazine was further expanding its therapeutic reach by the successful completion of a second phase III trial in patients suffering from bipolar I depression. Based on the promising results of both pivotal studies a potential attempt to further extend the label is also under consideration in order to include adjunctive treatment for major depressive disorder in adults. While we were able to broadcast some good news from the US and Europe, our Japanese partner, MitsubishiTanabe Pharma decided in the fourth quarter 2017 to cancel the clinical development programme of cariprazine and as a consequence a new agreement was settled in respect of the clinical and regulatory status of cariprazine in the Asian countries.

Our key specialty area, nonetheless, remains Women's Healthcare, where we provide one of the broadest range of products available to women of all age groups. 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. In order to pursue these objectives, as a very promising addition to our current Women's Healthcare portfolio in 2017 we signed an exclusive license and distribution agreement with Prima-Temp, a USA based company, to commercialize its innovative medical device, PriyaRing globally, except for the USA and Canada. Additionally, we agreed with the Sweden based company, Pharmanest on the commercialization of its SHACT (Short Acting Lidocaine) technology in Europe, in Latin America and in certain other markets.

In parallel to the progress achieved in 2017 on the way of execution of our corporate strategy, we had to face serious challenges, too regarding one of our flagship products, ESMYA®. Towards the end of last year, the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) initiated a review procedure of drug induced liver injury potentially related to our product. In addition to the above in early 2018 PRAC initiated the implementation of certain temporary precautionary measures, which require that new patients may not be started on ESMYA® until the end of the review procedure and the liver function must be regularly monitored in women who are on the treatment. We are determined to work with PRAC and provide the necessary information to allow them the completion of a fair assessment in a timely manner. We continue to believe that all the available data for ESMYA® support a favourable benefit-risk profile and is committed to providing this unique treatment option to women suffering from uterine fibroids.

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.

Therefore I am very pleased to report that in 2017 the European Commission (EC) granted marketing authorization for our biosimilar teriparatide, TERROSA for the treatment of osteoporosis. Being our first biosimilar regulatory approval, it is considered as a major milestone for the Company as we implement our specialty pharma strategy. As far as our other microbial biosimilar product is concerned in early March 2018 the EMA accepted our resubmission for pegfilgrastim. This resubmission follows the successful completion of an additional clinical study, which provided data demonstrating biosimilarity of both the pharmacokinetics and pharmacodynamics of the proposed biosimilar and NEULASTA<sup>®</sup>.

Our Group reported EUR 1,436.8 million consolidated sales in 2017, representing a 15 percent increase when compared with 2016.

Given the expected negative impact on business of the temporary measures imposed by PRAC (for details please refer to Women's Healthcare section on ESMYA® on page 38) the Management accounted for an impairment loss with regard to the intangible asset and goodwill linked to Esmya. Having included this impairment loss among Other expenses the profit from operations (amounting to EUR 67.0 million by the end of the reported year) declined by 62 percent when compared with 2016.

Owing to the above mentioned strong sales growth and partly also some other one-off items, profit from operations adjusted for the above impairment loss would increase by 28 percent amounting to EUR 224.6 million in 2017.

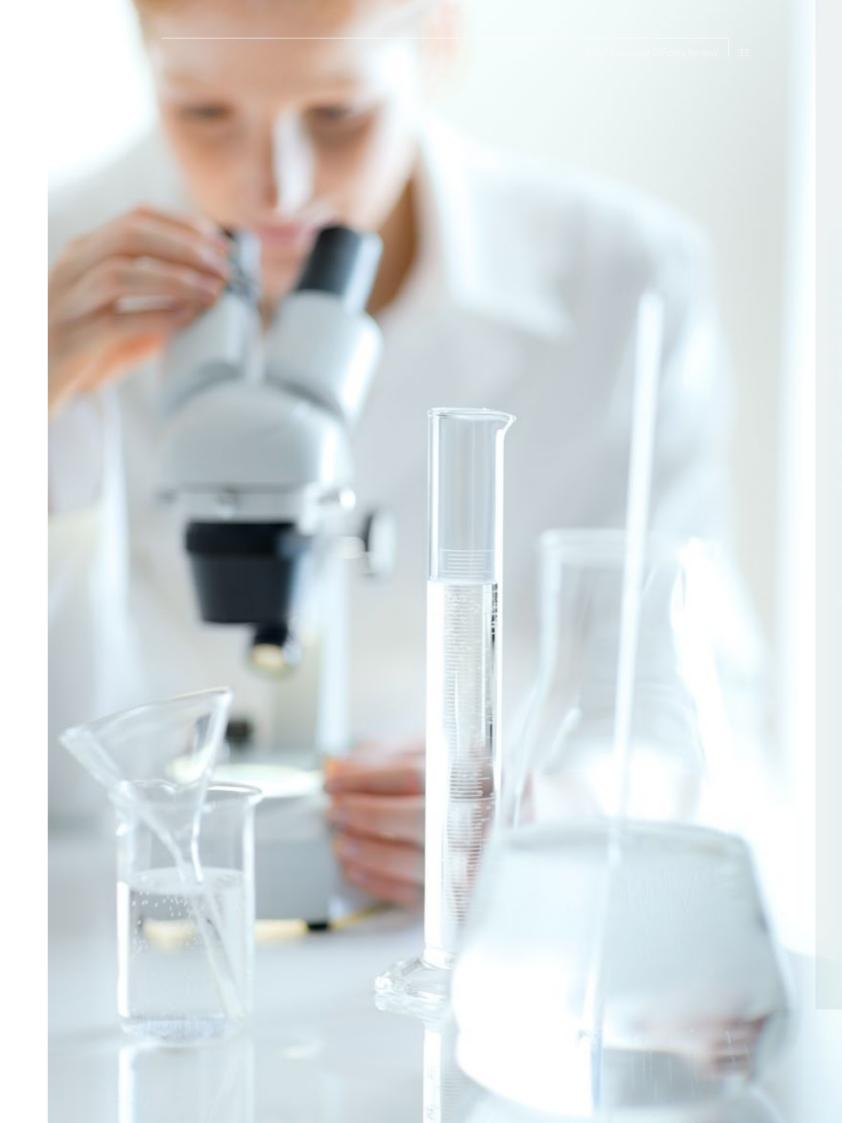
The impairment loss presented above was partly offset by a change in the corresponding deferred tax items, leaving the net impact of the write-off at EUR 137.7 million (HUF 42.6 billion). Profit for the year attributable to owners of the parent, therefore, decreased by 87 percent in 2017 to a total of EUR 28.8 million, which also includes a negative financial result coming from currency revaluations.

Adjusting the profit for the year attributable to owners of the parent with the net amount of the above impairment loss it would have declined by 22 percent amounting to EUR 166.5 million in 2017.

The progress we made in 2017 in executing our strategy highlights the investments we have made in the Group over the last several years to build scale and sustainability as well as develop new products. I expect the Group to make continued progress in 2018 and, as we are in a new period of leadership for the company, I am grateful to the Board of Directors for their guidance and support through this transition. I believe Richter is well positioned to deliver a steady long-term performance for shareholders. I also want to thank all of our Richter colleagues for keeping their focus on the important work to be done amid continuing changes inside and outside the company. Though the challenges are multiplying, we believe we are well positioned to successfully overcome them, thanks to our ongoing investment into our future.

Gábor Orbán

Chief Executive Officer





# Specialty Pharma

Gedeon Richter Annual Report 2017

### **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 of national healthcare budgets, aging populations and substantial changes in the lifestyle of the urbanized Western societies) Richter's management decided to implement a high added value driven specialty pharma business model with a primary focus on organic growth strategy complemented with selected acquisitions primarily in 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 preoperative 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.

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.

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**

Following its approval for the long term management of uterine fibroids, ESMYA® was granted reimbursed status in Lithuania during the first quarter 2017, in Belgium during the third quarter 2017 and in the fourth quarter 2017 in Norway.

Following its marketing authorization in the first quarter 2017, ESMYA<sup>®</sup> was launched in Argentina during the third quarter. The product was also granted marketing authorization in the second quarter in Guatemala and in the fourth quarter 2017 in Trinidad and Tobago. In addition it reached the market during the third quarter 2017 in Suriname and in El Salvador.

ESMYA® reported total sales were EUR 93.0 million in 2017, compared to the EUR 69.0 million turnover recorded in the previous year.

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 the PRAC has initiated the implementation of temporary precautionary measures as a part of its review procedure on drug induced liver injury potentially related to ESMYA®. PRAC considers that until a thorough assessment of the available data is performed within the ongoing review, temporary measures are needed to minimise potential risks to patients.

The PRAC has recommended regular liver monitoring for women taking ESMYA® for uterine fibroids. The PRAC is also recommending that no new patients should be started on ESMYA® and no patients who have completed a course of treatment should start another one. Treatments commenced prior to this decision are allowed to be completed. PRAC recommendations are temporary measures to protect patients' health. The final decision depends on the conclusion of the review of ESMYA® and is expected to be completed before end of May 2018.

Richter is determined to work with PRAC and provide the necessary information to allow them to complete a fair assessment in a timely manner.

Richter takes patient safety seriously. Richter continues to believe that all the available data for ESMYA® support a favourable benefit-risk profile and is committed to providing this unique treatment option to women suffering from uterine fibroids.

In October 2017 the U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) filing for ulipristal acetate for the treatment of abnormal uterine bleeding in women with uterine fibroids.

In connection with the ongoing PRAC assessment the US FDA recently notified our partner, Allergan, that the review of the New Drug Application (NDA) for ulipristal acetate will be extended. The Prescription Drug User Fee Act (PDUFA) target action date has been extended to August 2018 to provide time for a full review of the file.

### **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

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.

BEMFOLA® was granted marketing authorization both for Kosovo and Macedonia in the three months to March 2017 period. Following the completion of the marketing authorization transfer sales activities were taken over by Richter during 2017 in Poland, in the Czech Republic, in Slovakia, in Bulgaria, in Slovenia, in Romania, in Croatia and in Hungary.

Sales of BEMFOLA® recorded during 2017 amounted to EUR 34.6 million (US\$ 39.1 million). First sales of BEMFOLA® were recorded in the last quarter of 2016 following the acquisition of Finox Holding in June 2016.

As a very promising addition to our current Women's Healthcare portfolio 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 device currently is under registration, the expected launch date in the US is first quarter 2018, while in Europe third quarter 2018.

### 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<sup>®</sup> was licensed-in from Allergan in January 2017 for Western and Northern European countries. The product had been earlier launched by Allergan in a number of these countries. Based on an agreement established in 2011 with Uteron Pharma, Richter had also previously marketed LEVOSERT<sup>®</sup> in many Central and Eastern European countries and thus subsequent to the agreement with Allergan it became a pan European distributor.

Following the completion of the marketing authorization transfer, the product was launched in the second quarter 2017 in Germany. Sales activities were taken over in the same quarter by Richter in Austria and in the third quarter 2017 in Switzerland, in Sweden and in the UK.

Total turnover achieved by this product in 2017 amounted to EUR 1.8 million.

(except for the USA) of the innovative biosimilar product BEMFOLA®.

### 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. Following its launch in a number of countries during 2016, LENZETTO® also reached the market by the end of December 2017 in the following countries: Estonia, Luxembourg, Slovenia, Sweden, Finland, Moldova, Spain, Italy and Denmark.

Turnover of LENZETTO® during 2017 amounted to EUR 2.4 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

According to an agreement signed with Uteron Pharma in 2011 for the marketing of its levonorgestrel containing Intrauterine System, LEVOSERT® for the treatment of menorrhagia the product was registered and launched in most Central and Eastern European countries during 2014. In 2016 a further agreement has been signed with Allergan for the commercialisation of LEVOSERT® as a contraceptive Intra Uterine System in Western Europe and in other European countries.

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.



Brand name	Active ingredients	Product type	Regions where launched <sup>(1)</sup>
Oral contraceptives (OC)			
/OLINA / MIDIANA / ARANKA / MAITALON 30 / ROSINA	DRP + 30 mcg EE	Fourth generation	Hungary; EU; CIS; RoW; Latin America
SYMICIA / DAYLETTE / VOLINA MITE / REZIA / MAITALON 20 / DARYLIA / DIMIA / LILADROS / ARANKELLE	DRP + 20 mcg EE	Fourth generation	Hungary; EU; CIS; RoW; Latin America
REGULON / DESORELLE / DESMIN 30	DSG + 30 mcg EE	Third generation	Hungary; EU; CIS; RoW; Latin America
NOVYNETTE / DESMIN 20 / FEMINA	DSG + 20 mcg EE	Third generation	Hungary; EU; CIS; RoW; Latin America
AZALIA / LACTINETTE	DSG	Third generation	Hungary; EU; CIS; RoW; Latin America
INDYNETTE 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 / PERLEAN	GST + 30/40 mcg EE	Third generation	Hungary; EU
/IOLETTA / VARIANTA	GST + 15 mcg EE	Third generation	EU
KLEODINA	LVG + 30 mcg EE	Second generation	EU
RIGEVIDON / MICROFEMIN	LVG + 30 mcg EE	Second generation	Hungary; EU; CIS; RoW; Latin America
FRI-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 (2x)		Hungary; EU; CIS; USA; RoW; China Latin America
ESCAPELLE / LEVONELLE ONE-STEP / POSTINOR 1 / PLAN B ONE-STEP / EVITTA	LVG (1x)		Hungary; EU; CIS; USA; RoW; Latin America; China
Contraceptive device (CD)			
GOLDLILY / SILVERLILY	Au + Cu, Ag + Cu	IUD	Hungary; EU; CIS; RoW
EVOSERT®(2)	levonorgestrel	IUD	Hungary; EU; RoW
Abbreviations used in the table: .VG: Levonorgestrel	EE: Ethynil estradiol CLM: Chlormadinone	DRP: Drospirenone GST: Gestodene	DSG: Desogestrel BCLM: Biphasic-chlormadinone

Brand name	Active ingredients	Product type	Regions where launched <sup>(1)</sup>	
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 <sup>(2)</sup>	tibolone	Hormone replacement therapy	EU	
ESTRIMAX	estradiol	Hormone replacement therapy	Hungary; EU	
LENZETTO®(2)	estradiol	Hormone replacement therapy (spray)	Hungary; EU; CIS	
OSSICA	ibandronate	Osteoporosis	Hungary; EU	
SEDRON / OSTALON / BEENOS	alendronate	Osteoporosis	Hungary; EU; CIS; RoW; Latin America	
CALCI-SEDRON-D / OSTALON CALCI D	alendronate + Ca, vitamin D	Osteoporosis	Hungary; CIS; RoW	
Pregnancy care and Obstetrics	5			
GRAVIDA <sup>(2)</sup>	vitamins	Pregnancy care	Hungary	
OXYTOCIN	oxytocine	Labour induction (injection)	Hungary; EU; CIS; RoW; Latin America	
BROMOCRIPTIN	bromocriptin mesilate	Prolactin inhibitor	Hungary; EU; CIS; RoW; China	
LORITAN <sup>(2)</sup>		Medical pad for the detection of potential leakage of the amniotic liquid	Hungary	
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 <sup>(2)</sup>	butoconazole nitrate	Antifungal (cream)	Hungary; EU; CIS; RoW	
KLION D	metronidazole + miconazole	Antifungal	Hungary; EU; CIS; RoW; Latin America	
FLUOMIZIN <sup>(2)</sup>	dequalinium chloride	Anti-infectiv, antiseptic	EU; CIS	
GYNOFLOR <sup>(2)</sup>	estriol + lactobacillus	Women's Healthcare, restoration of vaginal flora and atrophic vaginitis	EU	
Other Gynaecological condition	ons			
ESMYA®	ulipristal acetate	Uterine myoma	Hungary; EU; CIS; RoW; Latin America	
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 Ameri	

Notes: <sup>(1)</sup> Products are launched in certain countries of the given region. <sup>(2)</sup> 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 and experience and share 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 manicdepressive 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<sub>1A</sub> receptors and antagonist activity at serotonin 5-HT<sub>2A</sub> 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<sub>1A</sub> receptors. Cariprazine acts as an antagonist at 5-HT<sub>2B</sub> and 5-HT<sub>2A</sub> receptors with high and moderate binding affinity as well as it binds to the histamine H<sub>1</sub> receptors. Cariprazine shows lower binding affinity to the serotonin 5-HT<sub>2C</sub> and  $\alpha_{1A}$ -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.

Those interested in more information on this once daily option for the acute treatment of manic or mixed episodes associated with bipolar I disorder and for the treatment of schizophrenia in adults please visit www.VRAYLAR.com.

### **Recent developments**

In July 2017 the European Commission (EC) granted marketing authorization to REAGILA® (cariprazine) for the treatment of schizophrenia in adult patients. This decision follows positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) announced in May 2017. In August 2016 we signed an exclusive license agreement with Recordati to commercialize cariprazine in Western Europe, in Algeria, in Tunisia and in Turkey.

Following extensive discussions with FDA regarding the submission of an efficacy supplement to provide for the treatment of predominantly negative symptoms of schizophrenia (PNS), in September 2017 our US partner, Allergan received refusal to file letter from FDA for VRAYLAR<sup>™</sup> (cariprazine) supplemental New Drug Application (sNDA).

In November 2017 Allergan received approval from the U.S. Food and Drug Administration (FDA) in respect of its supplemental New Drug Application (sNDA) for VRAYLAR<sup>™</sup> (cariprazine) for the maintenance treatment of adults with schizophrenia.

In our endeavor to continue the development programme of cariprazine and widen its therapeutic fields Richter and Allergan initiated phase III clinical trial programme investigating the use of cariprazine as a treatment for bipolar I depression in 2016. In December 2017 we announced positive topline results from this study as the second positive pivotal trial of cariprazine for this investigational use.

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

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 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 2015, globally, seven of the top ten selling drugs were biopharmaceuticals. Biologics account for just under 50 percent of all products at clinical phases within development pipelines of pharmaceutical companies globally.

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. By 2020, it is projected that biosimilars have the potential to enter markets for a number of key biologics that have current sales of more than EUR 40 billion.

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 based in Hamburg, Germany, establishing with Helm AG a joint venture business with Richter as the majority shareholder. The site 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 complement a totally new manufacturing unit built in the industrial park of Debrecen in Eastern Hungary. This facility enables development in Budapest and manufacture in Debrecen of biological drugs based on mammalian cells.

When selecting candidate products Richter proceeded very carefully, focusing on two main therapeutic areas, notably Oncology and Immunology. Both 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**

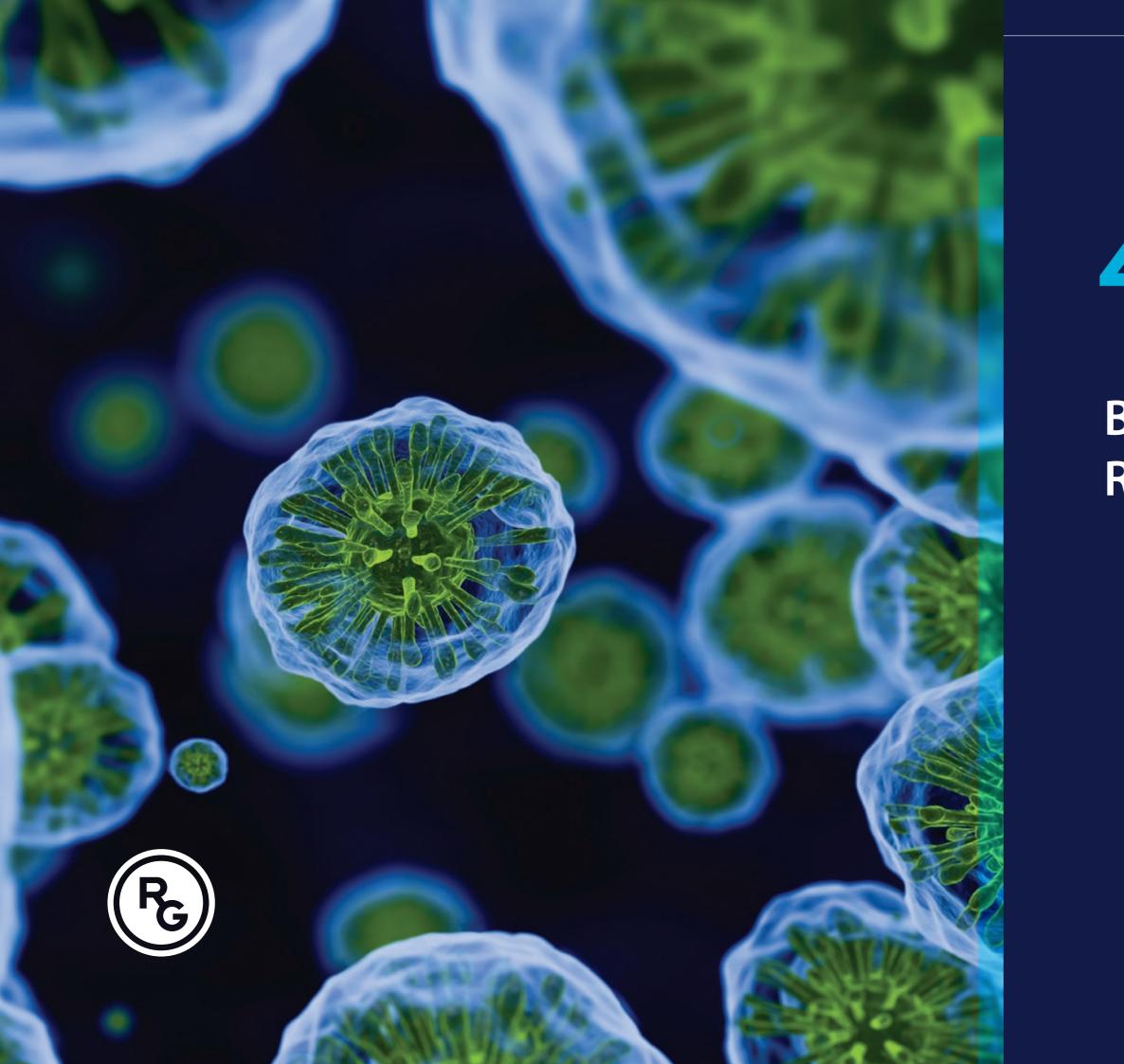
In January 2017 the European Commission (EC) granted marketing authorization for Richter's biosimilar teriparatide, TERROSA for the treatment of osteoporosis. This decision follows positive opinion issued in November 2016 from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and is applicable for all Member States in the European Union. The CHMP's positive opinion was based on data collected from analytical, pre- clinical and clinical studies related to the development program of the biosimilar teriparatide which demonstrated biosimilarity to Elli Lilly's FORSTEO.

The biosimilar teriparatide has been developed by Richter-Helm BioTec GmbH & Co. KG. According to the relevant license agreements, it is expected to be launched under both Richter and STADA labels in geographical Europe following the patent expiry of the original product.

In December 2016 Richter announced that it has withdrawn its Marketing Authorization Application (MAA) from the European Medicines Agency (EMA) for its biosimilar pegfilgrastim because the data provided did not allow the Committee to conclude a positive benefit risk assessment. On 2 March 2018 the Company revealed that the EMA has accepted Richter's regulatory resubmission for its proposed biosimilar to Amgen's NEULASTA® (pegfilgrastim). This resubmission follows the successful completion of an additional clinical study, which provided data demonstrating biosimilarity of both the pharmacokinetics and pharmacodynamics of the proposed biosimilar and NEULASTA®. The biosimilar pegfilgrastim of Richter is currently under review by the EMA for the same indications as the reference product.

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, which will be further developed and commercialised in certain territories.

The current and future portfolio of mammalian cell fermentation products will fill capacities at the Company's Debrecen facilities, which in 2018 are undergoing capacity extension projects in order to cope with future demand and in order to provide further state-of-the-art biotechnology manufacturing capabilities.





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# Business Review

Gedeon Richter Annual Report 2017



Dr György Thaler Development Directo

Dr István Greiner Research 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.

Cariprazine related activities have been very much the focus for the everyday work of individual departments within the Research Directorate, notably the registration procedure of cariprazine. This was initiated in March 2016 and in the Company's history is the first centralized procedure in respect of a new chemical entity under review at the European Medicines Agency. Following the issue of the Committee for Medicinal Products for Human Use (CHMP) positive opinion, in July 2017, the European Commission (EC) granted marketing authorization to REAGILA® (cariprazine) for the treatment of schizophrenia in adult patients. The preparation of the application files for the reimbursement of REAGILA® on individual European markets was commenced during the second half of 2017. In certain countries, such as Lithuania and Latvia, the product is already available for patients suffering from schizophrenia. The execution of cariprazine related post approval commitments, including preclinical and clinical studies, are also considered to be of paramount importance for the Research Directorate.

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, conducting Phase III clinical trials with cariprazine in the treatment of bipolar depression and potentially as adjunctive therapy in major depression. In December 2017 Richter and Allergan announced positive topline results for a phase III study of cariprazine for the treatment of bipolar I depression. This is the second positive pivotal trial of cariprazine for this investigational use. The topline results of the third ongoing clinical trial are expected to be released during the first half of 2018.

In September 2017 our partner, Allergan, announced that it had received a Refusal to File (RTF) letter from the U.S. Food and Drug Administration (FDA) regarding its Supplemental New Drug Application (sNDA) for cariprazine (VRAYLAR™) for treatment of negative symptoms associated with schizophrenia, in adult patients.

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

Progress has been also made in the Women's Healthcare field during the year under review. Based on two successful phase III clinical trials, in 2017 Allergan initiated the registration of ulipristal acetate for the treatment of abnormal uterine bleeding in women with uterine fibroids at the FDA. The product has been already marketed since 2013 in Canada under the brand name, FIBRISTAL<sup>™</sup>.

On the other hand in December 2017 the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) initiated an Article 20 review process of drug induced liver injury potentially related to ESMYA<sup>®</sup>. As a part of this review procedure in February 2018 PRAC initiated the implementation of temporary precautionary measures. These entail

Business Review

regular liver monitoring for women taking ESMYA® and required that no new patients should be started on the product. In connection with the ongoing PRAC assessment the US FDA recently notified our partner, Allergan, that the review of the New Drug Application (NDA) for ulipristal acetate will be extended. The Prescription Drug User Fee Act (PDUFA) target action date has been extended to August 2018 to provide time for a full review of the file.

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

At the end of 2017, in addition to cariprazine the Company has a research portfolio of 10 ongoing projects, two of which are in their early clinical phase with the remainder in preclinical research phase.

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 early January 2017 the European Commission (EC) granted a marketing authorization for our biosimilar teriparatide, TERROSA for the treatment of osteoporosis. Being our first biosimilar regulatory approval, it is considered to be a major milestone for the Company executing on its specialty pharma strategy.

In December 2016 we withdrew our Marketing Authorization Application (MAA) from the EMA for our biosimilar pegfilgrastim, following a CHMP (Committee for Medicinal Products for Human Use) meeting, according to which it was indicated that the data provided did not allow the Committee to conclude a positive benefit risk assessment. In March 2018 the European Medicines Agency (EMA) accepted our regulatory resubmission for our proposed biosimilar to Amgen's NEU-LASTA® (pegfilgrastim). This resubmission follows the successful completion of an additional clinical study, which provided data demonstrating biosimilarity of both the pharmacokinetics and pharmacodynamics of the proposed biosimilar and NEULASTA®. Our biosimilar pegfilgrastim is currently under review by the EMA for the same indications as the reference product.

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 2017. 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 below highlights all products which were either developed in-house, acquired or licensed- in during 2017:

Brand name	Active ingredient	Therapeutic area	Country
Own-Developed products / Ac	quired		
AMBROXOL SYRUP	ambroxol	Respiratory	Russia
AMLODIPIN-PERINDOPRIL	amlodipine + perindopril	Cardiovascular, antihypertensive	Armenia
AMLODIPIN-VALSARTAN RICHTER	amlodipine + valsartan	Cardiovascular, antihypertensive	Russia
AZALIA	desogestrel	Women's Healthcare, oral contraceptive	Serbia, Chile, Peru
BELARA	chlormadinone + 30 mcg EE*	Women's Healthcare, oral contraceptive	Vietnam
BEMFOLA®	follitropin alfa	Women's Healthcare, fertility	Baltic States, Bulgaria, Czech Republic, Poland, Slovakia, Slovenia, Switzerland
CALYPSOL	ketamine	Central Nervous System, analgetic	Iraq
CURIDOL	tramadol + paracetamol	Central Nervous System, analgetic	Hungary
DAYLLA	drospirenone + 20 mcg EE*	Women's Healthcare, oral contraceptive	Croatia
EPISTAT	fenspiride	Respiratory, antiasthmatic	Romania
ESCAPELLE	LVG (1x)	Women's Healthcare, emergency contraceptive	Luxemburg
GOLDAR tibolone		Women's Healthcare, hormone replacement therapy	Italy
INDAPAMID LONG RICHTER	indapamid	Cardiovascular, cardiac therapy	Russia
JOLIAN	drospirenone + 20 mcg EE*	Women's Healthcare, oral contraceptive	Bolivia, Chile, Colombia

Note: \* Ethynil estradiol

Brand name	Active ingredient	Therapeutic area	Country
Own-Developed p	roducts / Acquired		
MIDIANA	drospirenone + 30 mcg EE*	Women's Healthcare, oral contraceptive	Croatia
NOVYNETTE	DSG + 20 mcg EE*	Women's Healthcare, oral contraceptive	South Africa, Peru
POSTINOR-1	levonorgestrel	Women's Healthcare, emergency contraceptive	Slovakia
PROMATERN	vitamins	Women's Healthcare, pregnancy care	Romania
RAENOM	ivabradin	Cardiovascular, cardiac therapy	Baltic States, Bulgaria, Czech Republic, Poland, Hungary, Romania, Slovakia
REGULON	desogestrel + 30 mcg EE*	Women's Healthcare, oral contraceptive	Peru
ROSINA	drospirenone + 30 mcg EE*	Women's Healthcare, oral contraceptive	Bolivia
SIBILLA	dienogest + 30 mcg EE*	Women's Healthcare, oral contraceptive	Bolivia, Colombia, Peru, Uruguay
SINGLON	montelucast	Respiratory, antiashmatic	Mongolia
VIOLETTA	gestodene + 15 mcg EE*	Women's Healthcare, oral contraceptive	Poland

Note: \* Ethynil estradiol

Brand name Active ingredient Therapeutic ar		Therapeutic area	Country
Licensed-in products			
AFLAMIL	aceclofenac	Non-steroid anti-inflammatory	Mongolia
FLUOMIZIN	dequalinium-chloride	Women's Healthcare, anti-infective, antiseptic	Luxemburg, Russia
GYNOFLOR / GYNOFORT	estriol + lactobacillus	Women's Healthcare, restoration of vaginal flora and atrophic vaginitis	Belgium, Luxemburg, Montenegro
GYNOSITOL	inozitol	Women's Healthcare, nutritional supplement	Hungary
LENZETTO®	estradiol	Women's Healthcare, hormone replacement therapy (spray)	Denmark, Finland, Luxemburg, Sweden, Slovenia, Russia, Moldova
LEVOSERT®	levonorgestrel	Women's Healthcare, other contraceptive method, IUS	Austria, Germany

The Group reported 2017 spending of HUF 39,903 million (EUR 128.5 million) on research and development, representing a year on year increase 13.0 percent in HUF terms (13.8 percent in EUR terms) and 8.9 percent of 2017 consolidated sales.





András Radó Director, Production and Logistics

### b) Manufacturing and Supply

### Our focus

Having paid special attention to offer reliable and modern products at affordable prices manufacturing remains at the centre of management interest. Our key objective is to be in position to satisfy market demand by providing sufficient quantities of quality products in a timely and a cost efficient manner. Continuous cost optimization and the operation of an integrated supply process system across all the manufacturing subsidiaries of the Group help us to maintain cost efficiency of products and technologies.

In 2017 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 increased slightly by 1.4 percent in 2017, compared to the levels reported in 2016. Volumes of finished products manufactured at the parent company showed a flat performance with increasing quantities of injectables and ointments offset almost completely by a decline in the number of solid dosage forms. In respect of our manufacturing subsidiaries produced volumes of finished products increased by 18 percent in Russia, while they declined marginally, by 1 percent in Poland and by 4 percent in Romania.

The volumes of API manufacturing in Hungary increased by 11.2 percent when compared to the levels recorded in the previous year. Steroid API volumes increased by 2.8 percent primarily due to higher levels of demand for ESMYA<sup>®</sup>. As far as the share of production is concerned our site in Dorog provides approximately two thirds of API manufacturing.

### Investments

Capital expenditure for the Group including payments for intangible assets totalled HUF 39,929 million in the twelve months to December 2017.

The expansion and improvement of manufacturing capacities of steroid intermediates, and preparative chromatographic units, which is another capital expenditure project with a runtime of multiple years has reached near to completion.

Research and development activity, an area of focus of our specialty pharma strategy, incurred important amounts within the capital expenditure reported for 2017. The included acquisition of different items of high value, sophisticated laboratory instruments at our Budapest research centre, and the building up and fitting of a molecular biology laboratory unit located in Debrecen at our biosimilar business unit.

A complex program approved at the end of 2017 and expected to be carried out over the next three years aims towards the modernization of our Indian subsidiary. In addition, a number of small scale investments have been carried out to ensure or maintain the quality of production and environmental protection facilities and improve certain controlling and monitoring activities both at our Hungarian sites as well as 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 legislation, 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.). With regard to our extensive product portfolio and commercial relations with more than 80 countries, operating a comprehensive quality program entails multi-faceted and extremely complex regulatory adherence by the Total Quality Management Directorate.

Gedeon Richter Plc. has developed, implemented and is running a comprehensively designed, fully documented and regularly monitored Quality Management System, meant to give basic 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.

In its corporate quality policy issued in 1999, the senior management of Richter committed itself to continuous quality improvement. The objective of Richter's quality program is to safeguard the superior quality of its products, safety and efficiency in accordance with strict regulations. All corporate units in charge of quality assurance play a major role in quality planning and implementation, since product quality depends not only on the materials used in the manufacturing process, but also on the equipment and condition of the production lines, the environment as well as the qualifications, professional experience and general health of the staff.

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 honorable 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 2017 we successfully passed customer audits conducted by 13 partners and completed 5 inspections at our Budapest, Dorog and Debrecen sites. Audits confirmed our high-level GMP compliance and reliability. At our Budapest site US, Russian and Kazakh Authorities also conducted inspections during the reported period. FDA carried out a comprehensive inspection including our API and finished products manufacturing, which were passed without observation contributing to the Company's positive status. The Agency for Management System Certification, Moscow, extended our ISO9001 certificate following their inspection. As a result of the Kazakh Authority inspection, Richter was granted the Kazakh GMP certificate for three years. The National Institute of Pharmacy and Nutrition carried out a GLP inspection at our Budapest site, while in Debrecen it extended our GMP certificate and inspected the quality control laboratory to supplement our manufacturing license.

### d) Products

Richter recognises that currently it is considered primarily to be a branded generic pharmaceutical manufacturer. Whilst the dominant part of its turnover originates from generic drugs the Group also manufactures and markets steroid based pharmaceuticals which represent a specialised, higher margin group of products. Over the last decade this niche portfolio has contributed substantially to both the increase in sales and to the margins achieved by the Group. It has been a priority for Richter management to further strengthen this therapeutic area of special knowledge traditionally possessed in-house. The acquired ex-Grünenthal oral contraceptive portfolio represented a strategic fit for Richter to both strengthen its presence in Western European markets and expand its oral contraceptive portfolio. Additionally, the acquisition of PregLem increased Richter's exposure to specialty pharma and complemented its existing Women's Healthcare franchise. Furthermore, the acquisition of Finox Holding allowed Richter to establish its presence in the female fertility therapeutic area – a major growth market. In this Annual Report the separate section on Women's Healthcare describes our gynaecological products in detail.

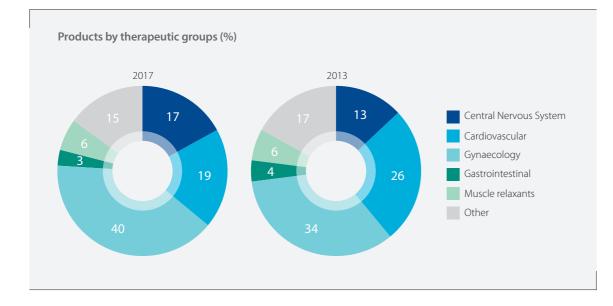
Richter also markets as part of its portfolio original products and continues to carry out intensive research activities to treat diseases of the Central Nervous System. It is management's opinion that it is important for the longer term success of the Group that it continues to research own developed compounds.

Richter is a regional mid-sized pharma company with a vertically integrated structure. This is based on a good market position with geographic and therapeutic niches supported by continuous enhancement through the supply of specialties partly via licensing agreements. Licensing-in has become an important route for the Group to renew its product portfolio. This is accomplished partly as an expansion of our existing generic product line and partly via providing high added value products including original compounds in the field of Women's Healthcare or in other therapeutic areas.

Main licencing-in partners of Richter					
Country	Product	Therapeutic area			
Australia	LENZETTO*	Women's healthcare			
Ireland	Several products	Gastrointestinal, Urology, Women's Healthcare, Central nervous system			
Spain	AFLAMIN	Non-steroid antiinflammatory			
Japan	SUPRAX	Antibiotic			
USA	EVE-112, EVE-116	Women's healthcare			
Germany	FENTANYL patch	Oncology			
Belgium	Several products	Central nervous system, Antifungal, Antibacterial			
Switzerland	FLUOMIZIN, GYNOFLOR	Women's healthcare, gynaecological infections			
Sweden	SHACT	Women's healthcare, topical analgesic (gel)			
USA	PriyaRing	Women's healthcare, fertility			
United Kingdom	LUNALDIN	Oncology			
Italy	REAGILA®	Central nervous system, antipsychotic			
France	TARIVID	Antibiotic			
	Country Australia Australia Ireland Spain Japan USA Germany Belgium Switzerland Sweden USA USA United Kingdom Italy	CountryProductAustraliaLENZETTO®IrelandSeveral productsSpainAFLAMINJapanSUPRAXUSAEVE-112, EVE-116GermanyFENTANYL patchBelgiumSeveral productsSwitzerlandFLUOMIZIN, GYNOFLORUSASHACTUSAPriyaRingUnited KingdomLUNALDINItalyREAGILA®			

Richter's management continues to endeavour to provide greater focus and improved shape to the product portfolio. With this background it is understandable that most of the top ten products in 2017 originated from the three largest therapeutic categories. Products belonging to the therapeutic areas of Gynaecological, Cardiovascular and Central Nervous System together generated 76 percent of total pharmaceutical sales.

Cardiovascular drugs showed a 9.1 percent sales increase in 2017, accounting for 19 percent of total pharmaceutical sales. The cardiac therapy PANANGIN (asparaginates) the leading product in this therapeutic area, increased by 27.7 percent in 2017 as sales increased in Russia, the main market for this product as a result of a price increase, an efficient marketing campaign and the positive impact of exchange rate. The sales of VEROSPIRON (spironolactone) increased during the reported year, whilst the turnover of ACE inhibitors (DIROTON / LISOPRESS / EDNYT) declined.



Central Nervous System related drugs contributed altogether 17 percent of total pharmaceutical sales and showed an increase of 25.9 percent compared to 2016. Royalty income related to our original product, the cariprazine containing VRAYLAR™, contributed substantially to the sales growth reported in this therapeutic group. Turnover of CAVINTON (vinpocetine), our leading original CNS drug increased by 7.2 percent compared with the previous year primarily due to higher sales levels in China.

Muscle relaxant drugs amounted to 6 percent of total pharmaceutical revenue of the Group in 2017. Sales of the original product MYDETON / MYDOCALM (tolperisone) increased by 13.6 percent in the reported period due to higher sales levels achieved primarily in the CIS region, being however impacted by the appreciation of the Rouble.

Gastrointestinal products represented 3 percent of total pharmaceutical sales led by the H,-blocker QUAMATEL (famotidine) in 2017.

TOP 10 product	ts					
			2017	2016	Change	
Brand name	Active ingredient	Therapeutic area	HUFm	HUFm	HUFm	%
Oral contraceptives	hormones	Women's Healthcare, oral contraceptives	90,576	87,002	3,574	4.1
CAVINTON	vinpocetine	Central nervous system, nootropic	30,832	28,760	2,072	7.2
ESMYA®	ulipristal acetate	Women's Healthcare, uterine myoma	28,757	21,504	7,253	33.7
MYDETON	DETON tolperisone Muscle relaxant		20,042	17,647	2,395	13.6
PANANGIN	asparaginates	Cardiovascular, cardiac therapy	16,799	13,150	3,649	27.7
VRAYLAR™	cariprazine	Central nervous system, antipsychotic	13,986	4,980	9,006	180.8
VEROSPIRON	spironolactone	Cardiovascular, diuretic	12,925	12,239	686	5.6
BEMFOLA®	follitropin alfa	Women's Healthcare, fertility	10,706	3,292	7,414	225.2
LISOPRESS	lisinopril	Cardiovascular, antihypertensive	9,557	9,654	(97)	(1.0)
GROPRINOSIN	inosine pranobex	Antiviral	8,355	9,108	(753)	(8.3)
Subtotal			242,535	207,336	35,199	17.0
Other			122,305	116,503	5,802	5.0
Total			364,840	323,839	41,001	12.7
Share of the TOP	Share of the TOP 10 products			64.0%		

In line with Group strategy the product portfolio successfully enhanced in 2016 has been under continuous renewal during the reported year, too. Focusing on specialty therapeutic areas we have withdrawn the low volume and low margin products while we kept introducing new products with improved profitability. Modernisation of the product portfolio proved to be successful in 2017, too.



Tibor Horváth

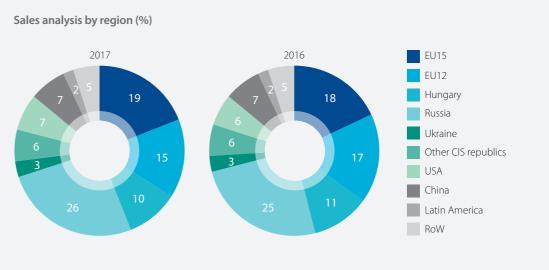
### e) Sales by Markets

Sales in the Pharmaceutical segment in 2017 totalled HUF 364,840 million (EUR 1,179.7 million), representing an increase of 12.7 percent (13.5 percent in EUR terms) compared to the same period of last year.

Sales by region								
	2017	2016	Cha	inge	2017	2016	Cha	nge
	HUFm	HUFm	HUFm	%	EURm	EURm	EURm	%
Hungary	35,417	34,979	438	1.3	114.5	112.3	2.2	2.0
EU <sup>(1)</sup>	125,719	114,631	11,088	9.7	406.5	368.0	38.5	10.5
EU 12 <sup>(2)</sup>	56,759	55,651	1,108	2.0	183.5	178.6	4.9	2.7
Poland	23,060	22,220	840	3.8	74.6	71.3	3.3	4.6
Romania	10,054	9,606	448	4.7	32.5	30.8	1.7	5.5
EU 15	68,960	58,980	9,980	16.9	223.0	189.4	33.6	17.7
CIS	129,089	111,598	17,491	15.7	417.4	358.3	59.1	16.5
Russia	95,732	80,240	15,492	19.3	309.5	257.6	51.9	20.1
Ukraine	10,769	9,216	1,553	16.9	34.8	29.6	5.2	17.6
Other CIS republics	22,588	22,142	446	2.0	73.1	71.1	2.0	2.8
USA	27,472	18,813	8,659	46.0	88.8	60.4	28.4	47.0
China	24,004	21,616	2,388	11.0	77.6	69.4	8.2	11.8
Latin America	6,134	5,819	315	5.4	19.9	18.7	1.2	6.4
Rest of the World	17,005	16,383	622	3.8	55.0	52.6	2.4	4.6
Total	364,840	323,839	41,001	12.7	1,179.7	1,039.7	140.0	13.5

#### Notes:

<sup>(1)</sup> All Member States of the European Union, except for Hungary. <sup>(2)</sup> EU12 now includes sales figures for both Poland and Romania. Base period figures were adjusted.



### Hungary

In Hungary sales totalled HUF 35,417 million (EUR 114.5 million) in 2017, a slight increase of 1.3 percent (2.0 percent in EUR terms) compared to 2016.

Based on the latest available market audit (IMS) data for the twelve months to December 2017 the pharmaceutical market increased by 5.3 percent year-on-year. Retail sales of Richter products increased by 0.9 percent compared to 2016 and the Company is now the fourth player on the Hungarian pharmaceutical market with a 5.1 percent share. When considering only the market for retail prescription drugs, Richter qualifies for second place with a market share of 7.4 percent.

### Hungarian Regulatory Environment

The Hungarian market has stabilised, albeit at significantly lower levels than a few years ago. In accordance with the regulations extraordinary taxes levied on the pharmaceutical industry and payable in 2017 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 that Richter exceeded the stated levels it has been exempted from the payment of this extraordinary tax from the second quarter.

Marginal changes to the price regulation system did not impact materially the Group's overall performance in the reported period. However, a tender system first introduced in 2011 aiming towards semestral price adjustments adversely affected several major Richter brands. Price cuts applied with effect from 1 October 2017 are expected to amount to an annual revenue loss of approximately HUF 16 million.

New products launched in Hungary during 2017				
Brand name	Active ingredient	Therapeutic area	Launch date	
RAENOM	ivabradin	Cardiovascular, cardiac therapy	Q1 2017	
CURIDOL	tramadol + paracetamol	Central Nervous System, analgetic	Q2 2017	
GYNOSITOL*	inozitol	Women's Healthcare, nutritional supplement	Q2 2017	

Note: \*Licenced-in product.

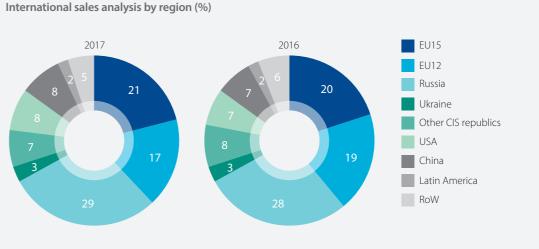
### Top 10 products in Hungary

			2017	2016	Change	
Brand name	Active ingredient	Therapeutic area	HUFm	HUFm	HUFm	%
Oral contraceptives	hormones	Women's Healthcare, oral contraceptive	2,964	3,076	(112)	(3.6)
CAVINTON	vinpocetine	Central nervous system, nootropic	1,955	2,046	(91)	(4.4)
QUAMATEL	famotidine	Gastrointestinal, antiulcer	1,704	1,661	43	2.6
XETER	rosuvastatin	Cardiovascular, cholesterol-lowering	1,440	1,568	(128)	(8.2)
PANANGIN	asparaginates	Cardiovascular, cardiac therapy	1,229	1,085	144	13.3
TANYDON	telmisartan + hydrochlorothiazide	Cardiovascular, antihypertensive	1,154	1,001	153	15.3
LAMOLEP	lamotrigine	Central nervous system, antiepileptic	1,048	1,040	8	0.8
AKTIL*	amoxicillin + clavulanic acid	Antibiotic	992	1,006	(14)	(1.4)
ESMYA®	ulipristal acetate	Women's Healthcare, uterine myoma	971	906	65	7.2
LISONORM	lisinopril + amlodipine	Cardiovascular, antihypertensive	926	956	(30)	(3.1)
Subtotal			14,383	14,345	38	0.3
Other			21,034	20,634	400	1.9
Total			35,417	34,979	438	1.3
Share of the TOP 10	products in Hungary		40.6%	41.0%		

Note: \*Licenced-in product.

### International Sales

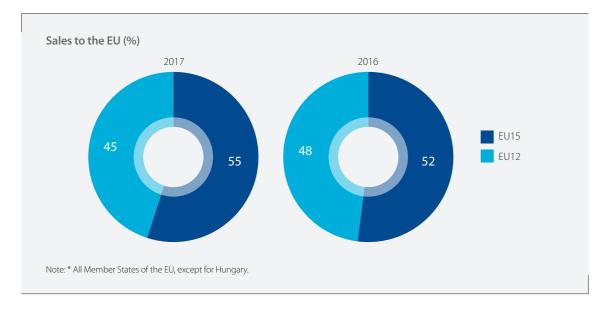
Sales to TOP 10 international markets	
Russia	
USA	
China	
Poland	
Germany	
Ukraine	
United Kingdom	
Romania	
France	
Spain	
Subtotal	
Total international sales	
Share of the TOP 10 international markets	



20	017	2016	C	hange
EU	Rm	EURm	EURm	%
30	09.5	257.6	51.9	20.1
ł	88.8	60.4	28.4	47.0
-	77.6	69.4	8.2	11.8
-	74.6	71.3	3.3	4.6
6	60.6	63.7	(3.1)	(4.9)
:	34.8	29.6	5.2	17.6
:	33.2	21.1	12.1	57.3
:	32.5	30.8	1.7	5.5
:	31.9	22.7	9.2	40.5
:	31.5	23.3	8.2	35.2
77	75.0	649.9	125.1	19.2
1,06	55.2	927.4	137.8	14.9
69.	<b>.9</b> %	70.1%		

### **European Union**

Sales in the European Union, excluding Hungary, amounted to EUR 406.5 million in 2017, EUR 38.5 million (10.5 percent) higher than the levels recorded in 2016.



In the EU12 region (which now includes sales figures for both Poland and Romania with base period figures readjusted accordingly) sales totalled EUR 183.5 million in 2017, EUR 4.9 million higher when compared to previous year. This region represented 45 percent of total EU sales of the Group's pharmaceutical segment.

New products launched in EU12 countries during 2017					
Brand name	Active ingredient	Therapeutic area	Launch date		
BEMFOLA®	follitropin alfa	Women's Healthcare, fertility	Q1 2017		
PROMATERN	vitamines	Women's Healthcare, pregnancy care	Q1 2017		
RAENOM	ivabradin	Cardiovascular, cardiac therapy	Q1 2017		
DAYLLA	drospirenone + 20 mcg EE <sup>(2)</sup>	Women's Healthcare, oral contraceptive	Q2 2017		
LENZETTO®(1)	estradiol	Women's Healthcare, hormone replacement therapy (spray)	Q2 2017		
MIDIANA	drospirenone + 30 mcg EE <sup>(2)</sup>	Women's Healthcare, oral contraceptive	Q2 2017		
VIOLETTA	gestodene + 15 mcg EE <sup>(2)</sup>	Women's Healthcare, oral contraceptive	Q2 2017		
EPISTAT	fenspiride	Respiratory, antiashmatic	Q3 2017		
POSTINOR-1	levonorgestrel	Women's Healthcare, emergency contraceptive	Q3 2017		

Notes: (1) Licenced-in products.

(2) Ethynil estradiol.

In Poland the Group recorded sales of PLN 317.5 million (EUR 74.6 million) in 2017, an increase of PLN 6.1 million (EUR 3.3 million) compared to 2016. 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 4.6 percent in 2017 according to the preliminary estimate by 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.

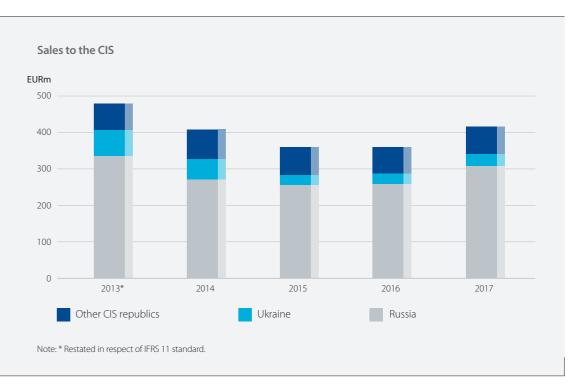
In Romania sales amounted to RON 148.6 million (EUR 32.5 million) in 2017, an increase of RON 10.0 million (EUR 1.7 million) when compared with the previous year. As a consequence of substantial price decreases implemented by the Government in recent years, a number of original products were withdrawn from the market, which in turn provided sales opportunities for some generic products. The implementation of a revised price list has been further delayed and it is expected to enter into force with effect from 1 April 2018.

Romania's GDP continued to grow by 7.0 percent in 2017, driven by strong domestic consumption. Nevertheless the government is facing a crucial challenge keeping the budget deficit under control.

In the EU15 region sales amounted to EUR 223.0 million in 2017, EUR 33.6 million higher than in the previous year. This region contributed 55 percent of total EU pharmaceutical sales.

### CIS

Sales to the CIS in 2017 totalled EUR 417.4 million, a significant increase of EUR 59.1 million (16.5 percent) compared to the sales levels achieved in the previous year. As a result of an improving overall economic and FX environment higher sales levels were recorded in Russia, in Ukraine and in the Other CIS republics.



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 requirements 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. Sales totalled RUB 20,325.3 million in 2017, RUB 1,174.9 million (6.1 percent) higher when compared to the previous year. The increased sales achieved resulted from an improving product mix, particularly a higher share of the Women's Healthcare franchise and certain, limited price increases implemented at the end of 2016. The improving (11.7 percent) year-on-year average exchange rate of the Rouble against the Euro contributed significantly to our sales performance in Russia when reported in Euro. Sales levels during the reported period at EUR 309.5 million increased by EUR 51.9 million when compared with the turnover reported in 2016.

Sales to Ukraine amounted to US\$ 39.3 million (EUR 34.8 million) in 2017, an increase of US\$ 6.5 million (EUR 5.2 million) compared to the turnover reported for 2016, although still from a low base and partly due to certain pre-shipments made during the reported year. The Ukrainian economy has stabilized to some extent, with purchasing power having slightly increased. By the end of the reported year, the local currency, UAH, had devalued year-on-year against the US\$ by 4.2 percent.

Sales in Other CIS republics totalled EUR 73.1 million (US\$ 82.5 million) in 2017, representing an increase of EUR 2.0 million (US\$ 3.8 million) compared to 2016. Oil and natural gas prices stabilised and currency appreciations in certain countries have positively impacted the overall performance of this region.

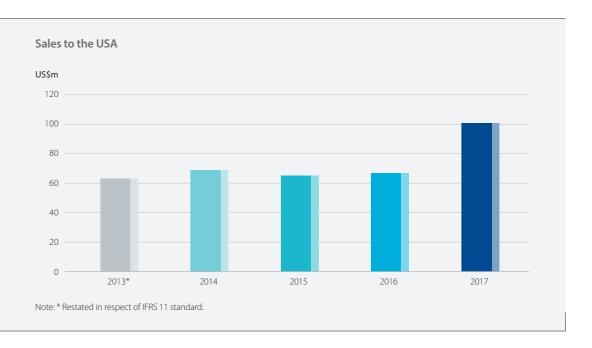
New products launched in the CIS republics during 2017						
Brand name	Active ingredient	Therapeutic area	Launch date			
AMBROXOL SYRUP	ambroxol	Respiratory	Q1 2017			
AMLODIPIN-PERINDOPRIL	amlodipine+perindopril	Cardiovascular, antihypertensive	Q2 2017			
INDAPAMID LONG RICHTER	indapamid	Cardiovascular, cardiac therapy	Q2 2017			
LENZETTO®*	estradiol	Women's Healthcare, hormone replacement therapy (spray)	Q2 2017			
AMLODIPIN-VALSARTAN RICHTER	amlodipine + valsartan	Cardiovascular, antihypertensive	Q4 2017			
FLUOMIZIN*	dequalinium-chloride	Women's Healthcare, anti-infective, antiseptic	Q4 2017			

Note: \* Licenced-in product.

### USA

Sales in the USA totalled US\$ 100.4 million (EUR 88.8 million) in 2017, an increase of US\$ 33.5 million (EUR 28.4 million) compared to the previous year. The significant year-on-year growth was mainly due to cariprazine (VRAYLAR™) royalty income. Higher API sales also contributed to the sales growth achieved during the reported period.

With effect from 1 January 2017 the Group reports cariprazine related royalty income, US\$ 51.0 million (EUR 45.1 million), based on sales estimations made for the same period by Richter's US partner, Allergan.



### China

Sales to China amounted to EUR 77.6 million in 2017, an increase of EUR 8.2 million when compared with the previous year.

### Latin America

Sales in Latin American countries amounted to US\$ 22.4 million in 2017, an increase of US\$ 1.7 million when compared with 2016 primarily due to higher sales levels of ESMYA<sup>®</sup>.

### **Rest of the World**

Sales in these countries amounted to EUR 55.0 million (US\$ 62.1 million) in 2017 resulting primarily from a better performance achieved by core Women's Healthcare products. Turnover increased by EUR 2.4 million (US\$ 3.8 million) when compared with the same period in 2016.

### Women's Healthcare

In recognition of the strategic importance to the Company of this therapeutic area a detailed presentation of the Women's Healthcare (WH) 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 WH niche franchise at EUR 469.4 million experienced notable growth of EUR 69.3 million, or 17.3 percent when compared to the previous year.

The key driver of the growth was the EU15 region led by the UK, France and Spain. As far as the product portfolio is concerned growth resulted primarily from higher sales levels of ESMYA® and of recently acquired BEMFOLA®.

Sales arising from the OC portfolio acquired in 2010 amounted to EUR 43.9 million, having declined by EUR 2.7 million when compared to the performance achieved in the previous year.

Women's Healthcare sales by region									
	2017	2016	Change		2017	2016 Ch		hange	
	HUFm	HUFm	HUFm	%	EURm	EURm	EURm	%	
Hungary	5,057	5,064	(7)	(0.1)	16.4	16.3	0.1	0.6	
EU <sup>(1)</sup>	71,407	60,428	10,979	18.2	230.9	194.0	36.9	19.0	
EU12 <sup>(2)</sup>	12,563	12,402	161	1.3	40.6	39.8	0.8	2.0	
Poland	3,324	2,931	393	13.4	10.7	9.4	1.3	13.8	
Romania	2,001	2,220	(219)	(9.9)	6.5	7.1	(0.6)	(8.5)	
EU 15	58,844	48,026	10,818	22.5	190.3	154.2	36.1	23.4	
CIS	35,048	27,751	7,297	26.3	113.3	89.1	24.2	27.2	
Russia	28,780	22,326	6,454	28.9	93.1	71.7	21.4	29.8	
Ukraine	2,609	1,824	785	43.0	8.4	5.9	2.5	42.4	
Other CIS republics	3,659	3,601	58	1.6	11.8	11.5	0.3	2.6	
USA	11,599	11,997	(398)	(3.3)	37.5	38.5	(1.0)	(2.6)	
China	7,884	6,569	1,315	20.0	25.5	21.1	4.4	20.9	
Latin America	4,878	4,772	106	2.2	15.7	15.3	0.4	2.6	
Rest of the World	9,303	8,018	1,285	16.0	30.1	25.8	4.3	16.7	
Total	145,176	124,599	20,577	16.5	469.4	400.1	69.3	17.3	

Notes: <sup>(1)</sup> All Member States of the European Union, except for Hungary.

<sup>(2)</sup> EU12 now includes sales figures for both Poland and Romania. Base period figures were readjusted.

In Germany, Richter's contraceptives franchise has been hit by negative media campaigns linked to potential side effects of OCs in general and certain novel APIs in particular, to which Richter has a broader exposure. In-market sales of ESMYA<sup>®</sup> according to IMS statistics grew by 11.8 percent in 2017 when compared to the previous year. Group sales, however were negatively impacted by parallel imports.

Sales in the UK were GBP 11.6 million (EUR 12.1 million) higher, although from a very low base. The timing of shipments in respect of certain oral contraceptives had a positive impact on the figure reported. ESMYA® also contributed to the higher turnover achieved during 2017.

Sales reported in Spain increased by EUR 8.8 million primarily due to the good performance of BEMFOLA®. During the reported year ESMYA® also contributed substantially to the sales growth achieved.

Turnover in France increased by EUR 10.1 million due to the good performance of both BEMFOLA® and ESMYA®. Richter is conducting negotiations with French Authorities on the reimbursement level of ESMYA® and its claw-back related issues. According to current regulations the reimbursed sales ceiling was set to a level which significantly falls behind patient needs. All turnover exceeding this level is subject to a claw-back payment to the authorities. The ongoing negotiations are expected to establish more appropriate conditions in respect of both the sales cap and price levels.

In Italy Richter Group achieved Women's Healthcare sales of EUR 25.0 million in the reported year, EUR 5.4 million above the levels reported in 2016. ESMYA® and BEMFOLA® contributed primarily to the sales growth achieved.

WH sales to the CIS in 2017 totalled EUR 113.3 million representing an increase of EUR 24.2 million compared to the sales levels achieved in the previous year. Growth recorded in the CIS region originated primarily in Russia. In RUB terms sales to Russia reached RUB 6,110.4 million, an increase of RUB 782.1 million or 14.7 percent due to the positive impact of higher sales of a range of oral contraceptives. The Group's Women's Healthcare franchise performed at a higher growth rate than its overall product portfolio in each of the four quarters reported in 2017.

WH sales to the USA in 2017 decreased marginally by US\$ 0.2 million, 0.5 percent as the decline in turnover of finished form PLAN B / PLAN B ONE-STEP more than offset the increase recorded in the sales of steroid APIs.

WH sales in the ROW countries reported a healthy, 16.7 percent growth in EUR terms when compared with the previous year primarily due to the combined result of BEMFOLA® sales recorded in Australia, in Norway and in Israel, which were recently included in the consolidation. Sales recorded in Switzerland contributed significantly to turnover realised in this region.

7.



Lajos Kovács **Technical Director** 

# f) Corporate Social Responsibility

Conducting our business in a responsible manner is central to our strategy and how we conduct our business is just as important to us as the financial results we achieve. Developing innovative products and maximising access to them provides direct benefit to patients and consumers. If we do this successfully, we will deliver profitable and sustainable business performance. In turn it allows us to generate value and to reinvest in the business. Beyond this it provides wider society benefits, since healthy people and communities are essential to building strong, sustainable societies. We also contribute significant value by making direct and indirect economic contributions in the countries and communities where we operate through our employment of more than 12,000 people, tax payments and charitable support.

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

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

- managing our business responsibly, with high levels of corporate governance;
- creating high-guality, 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 a part of our care as is treating illness. As a pharmaceutical manufacturing company, we take an active role towards limiting the environmental impact of our operations; we follow a systematic approach that ensures the sustainability of our business.

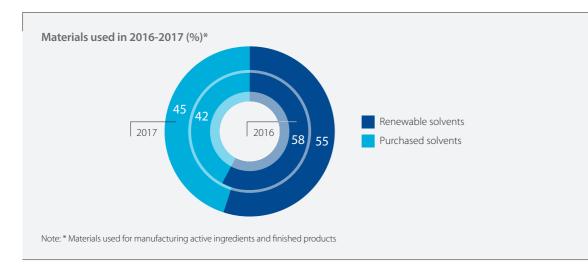
Pharmaceutical manufacturing carries a number of risks. In the course of pursuing our investments and development projects, we pay particular attention to ensuring that the environmental protection tasks related to our operations are carried out responsibly by using the best available technology (BAT)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

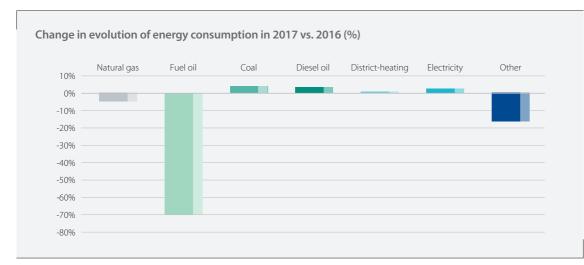
All three of our main manufacturing sites in Hungary possess IPPC (Integrated Pollution Prevention and Control) permits.

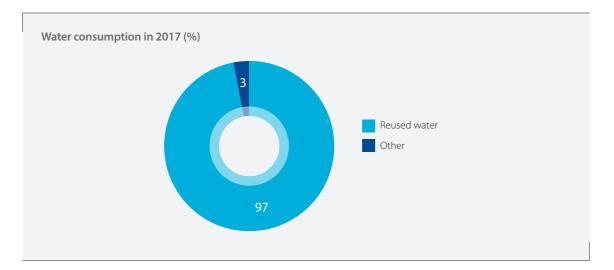
Environmental Management Systems at the Company meet all requirements of ISO 14001:2004 standards. We are pleased to report that as a result of the audit held in 2013 the Company was successfully re-certified for a further three year period. The integration of the Debrecen site was initiated in 2014, the related testing commenced in 2015. Following the successful completion of the testing procedure, the renewed certification has been extended to our Debrecen plant in 2016.

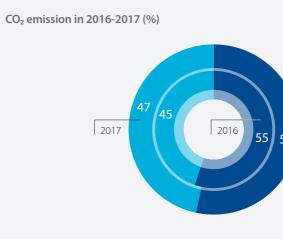
In accordance with the effective water rights operating permit, a cyclical maintenance programme, initiated and carried out earlier at the Company aimed at technical checks and troubleshooting of the sewage system at both Budapest and Dorog sites continued in 2017. The elimination of ground water contamination required by the relevant authorities continued in 2017 at our Vecsés warehouse site. Following evaluation of the required documents, a pilot test was executed in 2017, necessary for the implementation of the intervention plan at our Budapest site. The intervention plan, aimed at the elimination of ground water contamination, will be submitted in the first half of 2018. The continuous upgrade of our facilities treating waste water disposal at the Dorog site was ongoing in 2017.

The following diagrams present the environmentally substantial and relevant indicators in respect of 2016 and 2017.









Change in evolution of the amount of waste in 2017 vs.



# 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

53 Direct CO <sub>2</sub> Indirect CO <sub>2</sub>		
5. 2016 (%)		
industrial waste	Municipal waste	

this type of certification. Following a recent audit, performed against the more stringent criteria of OHSAS 18001:2007, the Company was successfully re-certified in 2012 and subsequently in 2015 for a further three years. The audit has again been successfully implemented in 2017.

Following modernisation of equipment in the Safety Laboratories both in Budapest and in Dorog, an audit held by the National Accreditation Body in 2015 confirmed that both Laboratories met the relevant standard (EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories). The two laboratories were merged into one single organization in 2016.

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 to the prevention of occupational injuries and illnesses. It is the responsibility of work supervisors to familiarise themselves with the risks of any given workplace and to manage and control workplace tasks accordingly. It is both the right and obligation of workers to demand safe working conditions and to comply with the health and safety at work regulations.

The representation of employees' interests with respect to occupational health and safety is performed by elected safety representatives who are also members 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 workplace exposure of our employees to risks, and accordingly we do our best 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' competencies have been identified by personalised risk assessments.

In order to meet the requirements established by European Union legislation (REACH and CLP) related to the registration and labelling of chemicals used in manufacturing processes, a compliance strategic plan has been developed. In 2017, 16 REACH registration dossiers for chemicals were submitted, of which in two cases the company had the role of lead registrant.

Our fire protection policy places particular emphasis on prevention. This includes a network of fire alarm and detecting devices covering the entire premises ensuring the early detection of any possible signs of fire that may nonetheless break out. We have worked out an implementation plan for a separate fire-water network at our Dorog site. The first two phases of the construction was completed in 2015 and in 2016. According to the established plans the project is expected to be completed in 2018.

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

An assessment for industrial major accident hazards for the Budapest site was submitted in 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 rerated as "Under Tier".

No fatal accidents or other serious work related injuries occurred at any of our facilities during 2017.

#### **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 2017.

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: 61 towns have benefited and around 140,000 people have participated, with their presence increasingRichter's initial donation by an extra HUF 174.7 million. Over the nine years some 61 hospitals have received a total of HUF 296.7 million financial assistance from Richter. During this period specialists have carried out more than 136,000 screenings, out of which approximately 31,000 returned with health warnings. Screened patients, when needed, have received prompt advice about further treatment options.

We are very pleased to report that the "Randstad Award", which is a recognition of the most attractive employer, was granted to Richter in 2017 for the fourth consecutive year since the award was initiated.

#### **Ethical guidelines**

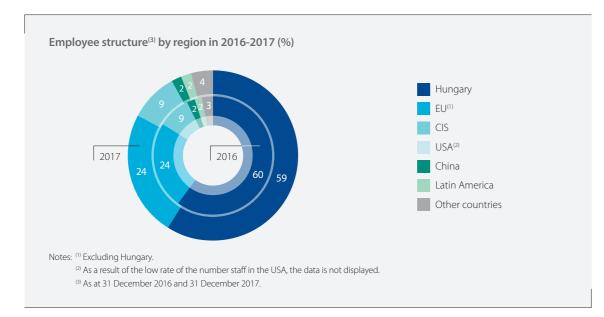
The Group introduced its Global Compliance Programme in 2016, including the norms that are consistent with the values and objectives of Richter Group, specifying the behaviour expected from its employees. A Compliance Handbook was issued in the framework of the programme consisting of eight regulations. 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 is henceforward committed to operate legally and responsibly in accordance with its strict ethical guidelines.

# 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.



The Human Resources Directorate has undergone a significant organisational transformation to be able to serve more efficiently the Company's new and innovative business model. The transformation of the Company both at the level of technology and product portfolio, as well as the dynamically changing environment made it necessary to reform the Directorate both structurally and operatively to continuously support the efficient operation of the Company.

The organisation development of the Human Resources Directorate was completed in 2017. As a result of the transformation, the organisation will support the Company's business activity with a renewed structure and operation from 2018. A number of leaders at the Directorate will retire in the near future and this provided an opportunity to systematically and thoroughly review both the scopes of activities and the workflows linked to the change of the current generation.

#### As an outcome:

- service-type and administrative activities were focused in the organisational structure,
- remuneration was connected to training and
- a business partner department was established.

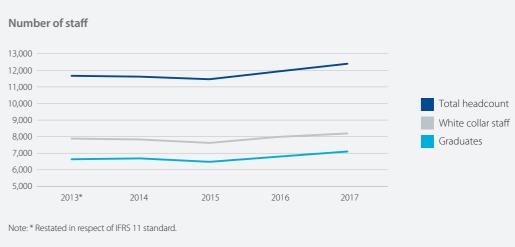
The professionally well-trained and sufficiently experienced new leaders are properly motivated to overcome the future challenges. We believe that our new and modern HR organisation will provide an appropriate framework in the future for a long-term and efficient operation.

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.

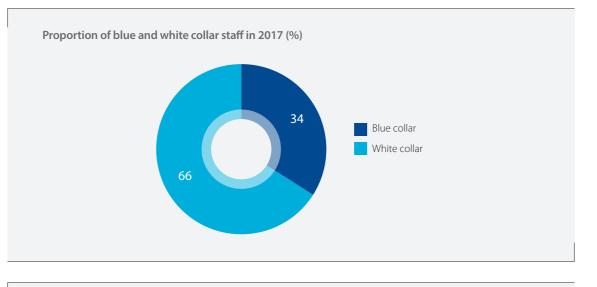
#### Employees

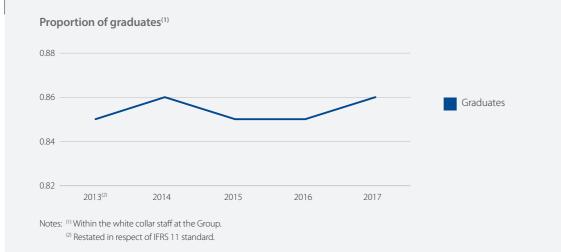
The total headcount for the Group was 12,369 at the end of 2017, a 4.0 percent (477) increase when compared to 2016. The year on year increase resulted primarily from a higher level of staff in our Western European and Latin American subsidiaries' sales and marketing networks.

The number of skilled employees at the Group increased to 7,081 at the end of 2017, from 6,806 reported in 2016. Graduate educated personnel represented 86 percent of white collar staff and 57 percent of the total number of employees at the Group.









#### Recruitment and Individual Development

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

Generally we pursue a personnel policy that focuses on long-term employee support creating loyalty to the Group and carrying out those personnel changes that are required for sustainable development. In the recruiting process we pay high attention to the selection of those candidates whose professional skills and experiences are expected to contribute the most to Richter's success and whose career plans and attitudes are expected to fit with the Company's corporate culture. We implemented a behavioural 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.

A Welcome Programme for young Employees aims at giving an insight into the organisation of Richter, its activities, company culture and values.

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.

We encourage and support all our people in fully developing their capabilities with a range of high quality learning and development opportunities. We offer training programmes, including coaching, languages and other courses to ensure employees have the skills needed in our business. The Company makes special efforts to assist scientific and professional education and postgraduate training. To encourage personal development the Company continued during 2017 to support employees to participate in university education, including PhD courses. During 2017 we paid particular attention to training programmes in the field of biotechnological product development as it is considered as a key strategic initiative for the Group.

To support innovation and knowledge sharing within our Group in 2017 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. Currently we have three leadership programs running:

• Well established management training programmes involving all managers of the Company both at middle and senior levels were ongoing in 2017. Based on the results of the Leadership Competence Assessment programme, all managers designed their personal coaching programme and identified the key areas for further improvement.

- Our career development program, started in 2006, which focuses on further development of high potential management talent continued in 2017. 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.

A system which presents professional development opportunities within the Company offering future career opportunities for new entrants and existing employees alike was expanded across the whole Company during 2016. The programme continued in 2017.

#### **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.

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

We focus on the health factors that enable employees to perform at the highest level by sustaining energy and engagement. Similar to earlier years, a new two-year employee health programme wholly financed by the Company was initiated in 2016. All employees could participate in this wide-ranging medical programme which aims to minimise illness by early diagnosis.

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.

With the aim of improving the efficiency of Human Resources activities within the Group, special meetings were organized by the Human Resources Department at individual subsidiaries. The main topics of these meetings included the review of the current HR policies of the Group and identification of those areas which may require further development.

We are very proud to report that in 2017 Richter was selected as the most desired workplace in the pharmaceutical and chemical industry sector winning the "Randstad Award" for the fourth time. Such recognition confirms that Richter's values are very much appreciated by employees in Hungary.





Dr Gábor Gulácsi Chief Financial Director

# 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 94 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 286.0 million in 2017, a EUR 46.9 million increase compared to the previous year.

Our Romanian subsidiaries realised 80 percent (RON 1,040.9 million) of the turnover in the Wholesale and Retail segment, with the remainder primarily being invoiced by our subsidiaries in the CIS region. The sales increase in Romania was RON 222.0 million (27.1 percent) in 2017. A significant reduction in payment delays occurred on the Romanian pharma market during the reported year, while the amount of outstanding receivables also decreased.

Wholesale and retail sales						
	2017	2016	Change	2017	2016	Change
	HUFm	HUFm	%	EURm	EURm	%
Hungary	-	121	(100.0)	_	0.4	(100.0)
Romania	70,438	56,758	24.1	227.7	182.3	24.9
Other CIS republics	13,992	13,523	3.5	45.2	43.4	4.1
Latin America	4,031	4,062	(0.8)	13.1	13.0	0.8
Total	88,461	74,464	18.8	286.0	239.1	19.6

# 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 Segme	nt Informati	on									
	Pharmaceuticals W HUFm		Wholesale and retail HUFm		-	Other HUFm		Eliminations HUFm		Group total HUFm	
	2017 Audited	2016 Audited		2016 Audited	2017 Audited	2016 Audited	2017 Audited	2016 Audited	2017 Audited	2016 Audited	
Total revenues	364,840	323,839	88,461	74,464	5,395	4,603	(14,340)	(13,216)	444,356	389,690	
Gross profit	244,245	217,283	8,241	7,629	647	571	(55)	205	253,078	225,688	
Profit from operations	18,617	55,204	1,777	1,158	391	151	(74)	(1,897)	20,711	54,616	
Share of profit of associates	60	(835)	1,466	2,566	58	41	(56)	26	1,528	1,798	
Number of employees at period end	10,488	10,073	1,465	1,475	425	344	-	-	12,378	11,892	

# b) Consolidated Turnover

Sales by region								
	2017	2016	Cha	inge	2017	2016	Cha	nge
	HUFm	HUFm	HUFm	%	EURm	EURm	EURm	%
Hungary	36,040	35,776	264	0.7	116.6	114.9	1.7	1.5
EU <sup>(1)</sup>	190,720	166,167	24,553	14.8	616.6	533.5	83.1	15.6
EU12 <sup>(2)</sup>	121,745	107,159	14,586	13.6	393.6	344.0	49.6	14.4
Poland	23,060	22,220	840	3.8	74.6	71.3	3.3	4.6
Romania	75,040	61,114	13,926	22.8	242.6	196.2	46.4	23.6
EU 15	68,975	59,008	9,967	16.9	223.0	189.5	33.5	17.7
CIS	139,689	121,736	17,953	14.7	451.7	390.9	60.8	15.6
Russia	95,734	80,243	15,491	19.3	309.6	257.6	52.0	20.2
Ukraine	10,824	9,269	1,555	16.8	35.0	29.8	5.2	17.4
Other CIS republics	33,131	32,224	907	2.8	107.1	103.5	3.6	3.5
USA	27,472	18,813	8,659	46.0	88.8	60.4	28.4	47.0
China	24,004	21,616	2,388	11.0	77.6	69.4	8.2	11.8
Latin America	9,418	9,187	231	2.5	30.5	29.5	1.0	3.4
Rest of the World	17,013	16,395	618	3.8	55.0	52.6	2.4	4.6
Total	444,356	389,690	54,666	14.0	1,436.8	1,251.2	185.6	14.8

Notes: <sup>(1)</sup> All Member States of the European Union, except for Hungary. <sup>(2)</sup> EU12 now includes sales figures for both Poland and Romania. Base period figures were readjusted.

# c) Key Financial Data

Key Financial Data						
	2017	2016	Change	2017	2016	Change
	HUFm	HUFm	%	EURm	EURm	%
Total revenues	444,356	389,690	14.0	1,436.8	1,251.2	14.8
Gross profit	253,078	225,688	12,1	818,3	724.6	12.9
Gross margin %	57.0	57.9		57.0	57.9	
Profit from operations	20,711	54,616	(62.1)	67.0	175.4	(61.8)
Operating margin %	4.7	14.0		4.7	14.0	
Profit before income tax	13,901	68,226	(79.6)	44.9	219.1	(79.5)
Profit for the year	10,070	67,023	(85.0)	32.6	215.2	(84.9)
Net margin %	2.3	17.2		2.3	17.2	
EPS (HUF, EUR) <sup>(1)</sup>	48	356	(86.5)	0.15	1.14	(86.8)
Total assets and total equity and liabilities	760,865	813,877	(6.5)	2,453.3	2,616.8	(6.2)
Capital and reserves <sup>(2)</sup>	664,019	681,873	(2.6)	2,141.0	2,192.4	(2.3)
Capital expenditure	39,929	36,453	9.5	129.1	117.0	10.3
Number of employees at year-end	12,378	11,892	4.1			

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

# d) Profit and Loss Items

Sales amounted to HUF 444,356 million (EUR 1,436.8 million) in 2017, representing a 14.0 percent increase in HUF and 14.8 percent in EUR terms when compared with the previous year. A positive performance was recorded in most markets of the Group.

Cost of sales amounted to HUF 191,278 million (EUR 618.5 million) in 2017, an increase of HUF 27,276 million (EUR 91.9 million) when compared to 2016. Amortization of the acquired intangible asset Esmya amounted to HUF 2,774 million while amortization of another intangible asset Bemfola was HUF 2,002 million in 2017. Following the acquisition of the Finox Group a reassessment was made of the fair value of Bemfola inventories and given that the sale of these inventories was carried over to 2017 it had the impact of increasing costs.

Gross margin in 2017 at 57.0 percent declined from the 57.9 percent level reported for the previous year. Price erosion experienced on our traditional markets, an increase of costs related to tightening regulatory measures, together with the amortization of Esmya and Bemfola impacted negatively on the gross margin. Furthermore, the share of turnover of the lower margin Wholesale and Retail segment in Romania increased which also negatively impacted gross margin. All the above were only partly offset by royalty income received from Allergan in respect of VRAYLAR™ and the appreciation of the average exchange rate of the Rouble experienced during the reported period both against HUF and EUR.

Sales and marketing expenses amounted to HUF 114,882 million (EUR 371.4 million) in 2017, an increase of 6.8 percent in HUF terms (7.6 percent in EUR terms) when compared with 2016. Higher marketing costs incurred on the EU15, on the Chinese and on the Latin American markets and the consolidation of Finox Group, which further increased such costs. In addition an increase of such expenses in Russia, in Ukraine and in Other CIS region was reported together with an appreciation on a year-on-year basis of the Rouble and some of the currencies of Other CIS region countries. The proportion of S&M expenses to sales was 25.9 percent in the reported period. Amortisation of the marketing and intellectual property rights of the OC portfolio acquired from Grünenthal in the amount of HUF 4,430 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 213 million (EUR 0.7 million) in 2017. In accordance with the regulations tax payable in 2017 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 23,374 million (EUR 75.6 million) in 2017, representing a 14.9 percent increase in HUF terms (15.8 percent in EUR terms) when compared with the level recorded in the previous year. These expenses grew primarily due to the inclusion of the Finox group and to some extent as a result of higher employee costs, legal assistance and other advisory fees.

Research and development expenses represented 9.0 percent of sales and after an increase of 13.5 percent in HUF terms and 14.3 percent in EUR terms they amounted to HUF 39,903 million or EUR 129.0 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 cooperation with Allergan. R&D expenses of the Group also include such costs at the operations of GR Polska and GR Romania. Other income and other expenses (net) decreased to an expense of HUF 54,208 million (EUR 175.3 million) in 2017 when compared to an expense of HUF 8,016 million (EUR 25.7 million) recorded in the previous year. Having taken into account the expected negative impact on business of the temporary measures imposed by PRAC (for details see Women's Healthcare section on ESMYA® on page 38) the Management accounted for an impairment loss with regard to intangible asset and goodwill linked to Esmya amounting altogether to HUF 48,733 million (EUR 157.6 million). This amount was included among Other expenses.

The 2016 figure included one-off income amounting to HUF 3,453 million (EUR 11.1 million) recorded in connection with the 100 percent acquisition of the joint venture Gedeon Richter Rxmidas JV Co. Ltd. engaged in the trading of OTC products on the Chinese market. Other expenses incurred in 2016 also include an impairment loss of intangible assets amounting to HUF 2,405 million (EUR 7.7 million) and a HUF 849 million (EUR 2.7 million) inventory write-off both connected to the market withdrawal of LISVY<sup>®</sup>. Similarly Richter accounted in the third quarter 2016 for a one-off income paid by Recordati as an upfront payment, amounting to HUF 3,112 million (EUR 10.0 million) as stipulated in the concluded agreement relating to future European sales and marketing of cariprazine.

Settlement of accounts were made and contracts terminated during 2017 in respect of the market withdrawal of LISVY® and as a result thereof Richter accounted for other income amounting to HUF 2,147 (EUR 6.9 million). In addition we have accounted for a one-off milestone received upon the reception of an NDA filing of ESMYA® in the USA and the commencement of the registration of cariprazine in South Korea.

In 2017 an expense of HUF 399 million (EUR 1.3 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 in 2017 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.

During the reported year Other income and expenses include expenses of HUF 6,701 million (EUR 21.8 million) in respect of the claw-back regimes effective in Romania, Germany, France, Spain, Portugal, Belgium, Italy, Bulgaria, Austria, Poland and Latvia.

Profit from operations decreased by 62.1 percent in HUF terms (61.8 percent in EUR terms) and amounted to HUF 20,711 million (EUR 67.0 million) in 2017 mainly as a result of the impairment loss accounted for in respect of ESMYA<sup>®</sup>.

As a result of the impairment loss accounted for in respect of ESMYA® operating profit fell significantly behind the amounts published in the report presented to the Budapest Stock Exchange in February 2018, containing figures for the 12 months to December 2017 period.

When adjusted for the above change, operating profit grew by 27.1 percent and amounted to HUF 69,444. In EUR terms it increased by 28.1 percent and reached EUR 224.6 million.

Subsequent to the impairment loss accounted for during the reported year the consolidated operating margin dropped to 4.7 percent from the 14.0 percent reported in 2016. Underlying operating margin would have been 15.6 percent.

A substantial financial loss of HUF 8,338 million (EUR 27.0 million) was driven partly by unrealised financial items, mainly by the revaluation at period end weaker CHF, RUB and US\$ exchange rates on foreign currency loans receivables. Weaker average RUB and US\$ exchange rates for the year, however, also caused financial loss among the realised items, most notably on trade payables and receivables. For a more detailed information on Net financial result please refer to the table on page 96.

Share of profit of associates and joint ventures amounted to HUF 1,528 million (EUR 4.9 million) in 2017.

Profit before income tax amounted to HUF 13,901 million (EUR 44.9 million) in 2017, a decrease of HUF 54,325 million (EUR 174.2 million) compared with 2016.

By virtue of Hungarian Tax Regulations, the base income of the Parent Company of the Group (incorporated in Hungary) 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. In addition, the Parent Company is also entitled to a tax allowance in respect of the capital expenditure programme carried out at the Debrecen biosimilar manufacturing site. Other members of the Group are subject to customary tax regulations effective in their respective countries of incorporation.

During 2017 the Group recorded HUF 2,110 million (EUR 6.8 million) in respect of corporate tax expense and HUF 2,983 million (EUR 9.7 million) deferred tax gain resulting in HUF 873 million (EUR 2.9 million) tax income. The above mentioned deferred tax income resulted from the utilisation of losses incurred and accrued in previous years at our Swiss affiliates having been offset by the tax income linked to the impairment loss accounted for in respect of Esmya. Local business tax and contribution fee amounted to HUF 4,704 million (EUR 15.2 million) during the reported year.

Profit for the year was HUF 10,070 million (EUR 32.6 million), HUF 56,953 million (EUR 182.6 million) lower than the profit for the year realised in 2016.

The impairment loss presented above was partly offset by a change in the corresponding deferred tax items, leaving the net impact of the write-off at HUF 42,610 million (EUR 137.7 million). Profit for the year attributable to owners of the parent, therefore, decreased by 86.5 percent in HUF (86.6 percent in EUR) terms in 2017 to a total of HUF 8,885 million (EUR 28.8 million), an amount which also includes a negative financial result coming from currency revaluations.

Adjusting the profit for the year attributable to owners of the parent with the net amount of the above impairment loss it would have declined by 22.2 percent in HUF (21.7 percent in EUR) terms amounting to HUF 51,495 million (EUR 166.5 million) in 2017.

### e) Balance Sheet Items

Total assets and total shareholders' equity and liabilities of the Group amounted to HUF 760,865 million on 31 December 2017, HUF 53,012 million, or 6.5 percent lower than that reported at 31 December 2016.

Non-current assets amounted to HUF 456,334 million in the reported period, HUF 47,597 million (or 9.4 percent) below from the reference figure. In consideration of the expected negative business impact of the PRAC's temporary measures regarding Esmya, Executive Board has revised and lowered its long-term Esmya sales forecasts for the EU and Latin

American markets. The impairments of Goodwill and intangible asset reported are the effect of the revised forecast. Other intangibles assets were HUF 37,719 million (or 19.6 percent) lower year-on-year mainly as a result of the revised forecast mentioned above and the depreciation and year-end currency related restatement of Esmya and Bemfola. The HUF 24,255 million (or 35.3 percent) decrease in Goodwill is the result of the revised forecast mentioned above too and the revaluation of goodwill on acquisitions in previous years.

Current assets amounted to HUF 304,531 million decreased by HUF 5,415 million or 1.7 percent when compared to the level reported on 31 December 2016. Cash and cash equivalents decreased as a result of having repaid the entire outstanding loan (EUR 117 million) to the EIB. The impact of this on Current assets was partly offset by a higher year end level of Trade receivables and Other current assets as non-current loans were converted to current loans.

Capital and reserves of the Group decreased by 2.6 percent and amounted to HUF 664,019 million when compared to the balance as at 31 December 2016. Retained earnings decreased by HUF 12,061 million and amounted to HUF 602,596 million. Translation difference impacting on Foreign currency translation reserve also decreased by HUF 8,623 million.

Non-current liabilities of the Group on 31 December 2017 at HUF 15,660 million were HUF 27,132 million lower than the levels as at the end of the previous year. The decline recorded resulted from the entire outstanding loan (EUR 92 million) having been repaid to the EIB.

Current liabilities of the Group at HUF 81,186 million on 31 December 2017 were HUF 8,026 million lower than their level reported on 31 December 2016. They declined primarily as a consequence of having repaid the entire outstanding loan (EUR 25 million) to the EIB.

# f) Cash Flow

As indicated by the cash flow statement, the Group generated net cash from operating activities of HUF 83,747 million during 2017. Cash from operating activities exceeded the levels reported for the previous year mainly as a result of an increase in impairment recognized on intangible assets. Not insignificant amounts of cash were directed towards capital expenditure and payment of dividends. Overall, during 2017 cash decreased by HUF 22,906 million primarily as a result of higher net cash outflow on repayment of borrowings.

### Cash flow

# Net cash flow From operating activities From investing activities From financing activities Effect of foreign exchange rate changes Decrease in cash and cash equivalents

2017	2016
HUFm	HUFm
83,747	77,419
(46,457)	(91,001)
(60,196)	(22,134)
2,894	(605)
(22,906)	(35,716)

# 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 2017 the Group did not apply any hedge accounting rules under IAS39 in respect of these transactions. The management of FX risk is periodically reviewed by the Board of Directors. There were no open hedging contracts recorded by the Group as of 31 December 2017 (only a few short dated forward contracts, made for daily liquidity management purposes, were open at this date).

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.

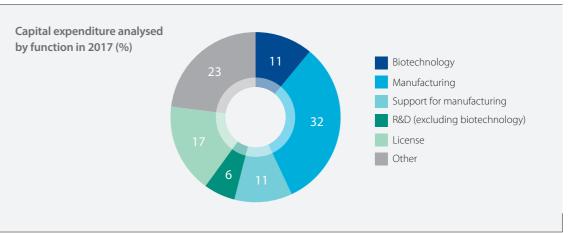
As the Group markets its products in several countries which could be considered to be medium-to high-risk, the sovereign and counterparty risk can affect profitability. The Group use credit insurance products in certain regions to partially mitigate its risk exposure. Management of receivables and impairment 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 totalled HUF 39,929 million in the twelve months to December 2017 when compared to HUF 36,453 million reported for 2016.

The manufacturing capacities of steroid intermediates and preparative chromatographic units at our Dorog site which have been undergoing a several years long expansion and improvement project have reached near completion. Important amounts were directed towards the acquisition of different high value, sophisticated analytical instruments at our Budapest research centre, while at our biosimilar business unit located in Debrecen a molecular biology laboratory was built and fitted with equipment. During 2017 Richter also began within the framework of a centrally coordinated project to install equipments needed for the Serialization Project as required by the Authorities. The project was launched at all of the sites of the Group where finished form products are being manufactured. The first equipments have arrived and were put in operation while others are expected to become operational during 2018.

A complex program of modernizing our Indian subsidiary was approved by the end of 2017 and it is expected to be carried out during the next three years. A number of additional small scale investments have been carried out to ensure or maintain the quality of the production and environmental protection facilities and improve certain controlling and monitoring activities both at our Hungarian sites as well as at our subsidiaries abroad. The manufacturing area was reorganised at our Romanian subsidiary in Marosvásárhely in order to prepare it for future capacity increasing investments and at our Russian plant we have installed a packing line for bottles. During 2017 a tablet packaging unit was also put in operation at our Polish subsidiary.

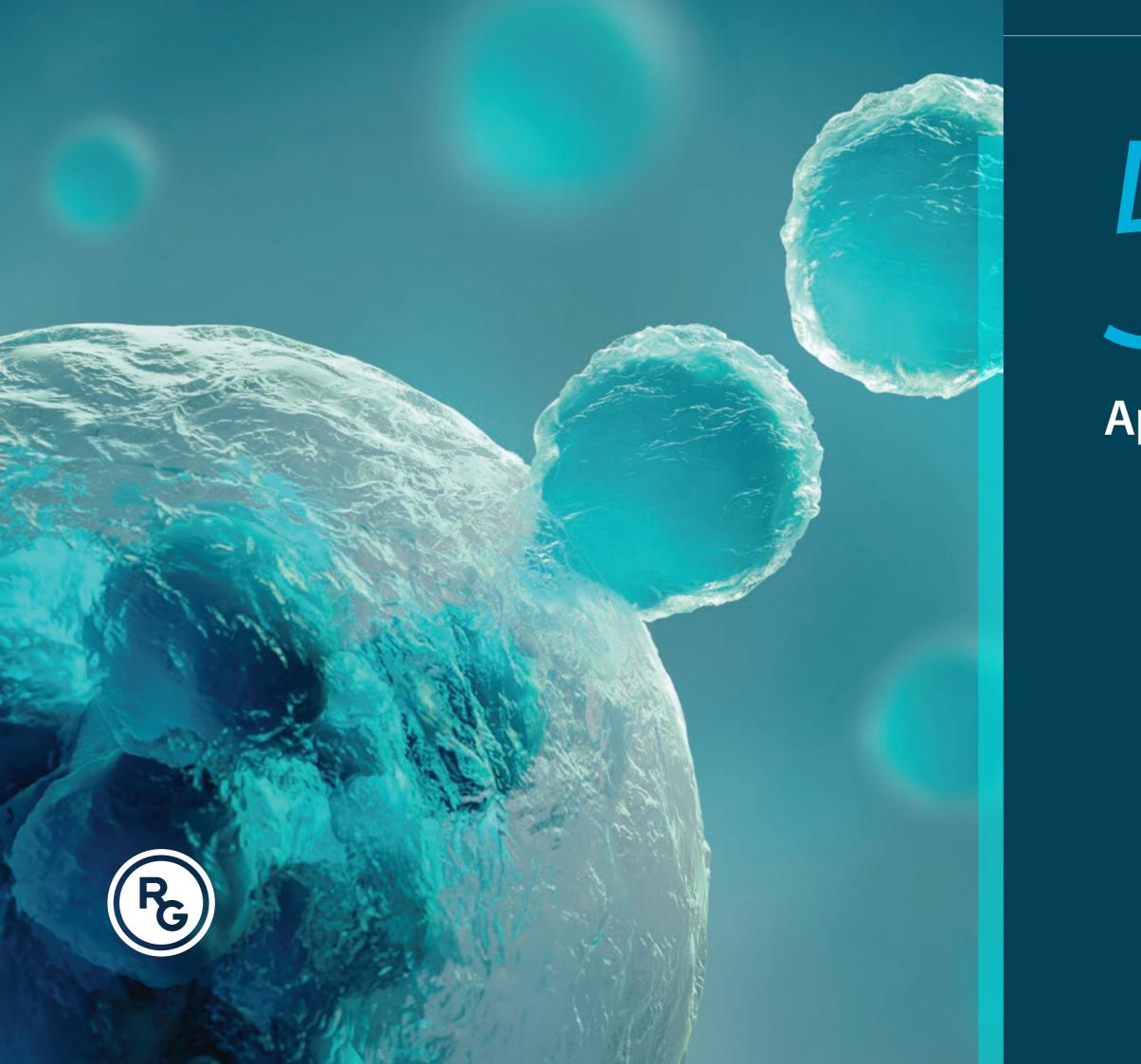


### Disclosures

I, the undersigned declare, that Gedeon Richter Plc. takes full responsibility that the management report, which contains the Group's 2017 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., comprising the subsidiaries included in the consolidation, and 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





Gedeon Richter Annual Report 2017

# **Consolidated Financial Record**

Net Financial Income						
	2017	2016	Change	2017	2016	Change
	HUFm	HUFm	HUFm	EURm	EURm	EURm
Unrealised financial items	(3,660)	4,679	(8,339)	(11.8)	15.0	(26.8)
Exchange gain on trade receivables and trade payables	156	3,658	(3,502)	0.5	11.7	(11.2)
Loss on foreign currency loans receivable	(4,276)	(148)	(4,128)	(13.8)	(0.5)	(13.3)
Year-end foreign exchange translation difference of borrowings	65	245	(180)	0.2	0.8	(0.6)
Exchange gain on other currency related items	369	1,939	(1,570)	1.3	6.3	(5.0)
Unwinding of discounted value related to contingent-deferred purchase price liabilities	-	(948)	948	-	(3.0)	3.0
Result of unrealised forward exchange contracts	26	(4)	30	-	(0.1)	0.1
Impairment loss on investments	-	(63)	63	-	(0.2)	0.2
Realised financial items	(4,678)	7,133	(11,811)	(15.2)	22.9	(38.1)
Exchange (loss)/gain realised on trade receivables and trade payables	(5,411)	2,670	(8,081)	(17.6)	8.6	(26.2)
Foreign exchange difference on conversion of cash	(966)	218	(1,184)	(3.1)	0.7	(3.8)
Dividend income	675	2,792	(2,117)	2.2	9.0	(6.8)
Interest income	1,563	2,566	(1,003)	5.0	8.2	(3.2)
Interest expense	(990)	(827)	(163)	(3.2)	(2.7)	(0.5)
Other financial items	451	(286)	737	1.5	(0.9)	2.4
Net financial (loss)/income	(8,338)	11,812	(20,150)	(27.0)	37.9	(64.9)

31 Dece	mber
SETS	
on-curre	nt assets
Property,	plant and equipment
Goodwill	
Other int	angible assets
Investme	nts in associates and joint ventures
Other fina	ancial assets
Deferred	tax assets
Loans rec	eivable
urrent as	sets
Inventori	es
Trade rec	eivables
Other cu	rrent assets
Investme	nts in securities
Current ta	ax asset
Cash and	cash equivalents
QUITY AI	ND LIABILITIES
apital an	d reserves
Share cap	vital
Treasury	shares
Share pre	mium
Capital re	iserve
Foreign c	urrency translation reserve
Revaluati	on reserve for available for sale investments
Retained	earnings
Non-con	trolling interest
on-curre	nt liabilities
Borrowin	gs
Deferred	tax liability
Other no	n-current liabilities and accruals
Provision	S
urrent lia	bilities
Borrowin	gs
Trade pay	/ables
Current ta	ax liabilities
Othor pa	yables and accruals

2017	2016
HUFm	HUFm
760,865	813,877
456,334	503,931
196,990	191,002
44,377	68,632
154,958	192,677
11,847	8,541
35,482	32,864
10,548	5,416
2,132	4,799
304,531	309,946
84,474	81,246
123,023	116,223
20,180	14,991
18	751
795	682
76,041	96,053
760,865	813,877
664,019	681,873
18,638	18,638
(415)	(1,285)
15,214	15,214
3,475	3,475
9,855	18,478
9,964	8,825
602,596	614,657
4,692	3,871
15,660	42,792
3	28,874
8,005	5,962
4,347	4,448
3,305	3,508
81,186	89,212
-	7,776
47,495	45,926
703	655
30,515	32,929
2,473	1,926

Consolidated Income Statement		
for the year ended 31 December	2017	2016
	HUFm	HUFm
Revenue	444,356	389,690
Cost of sales	(191,278)	(164,002)
Gross profit	253,078	225,688
Sales and marketing expenses	(114,882)	(107,564)
Administration and general expenses	(23,374)	(20,339)
Research and development expenses	(39,903)	(35,153)
Other income and other expenses (net)	(54,208)	(8,016)
Profit from operations	20,711	54,616
Finance income	14,957	26,600
Finance cost	(23,295)	(14,788)
Net financial (loss)/income	(8,338)	11,812
Share of profit of associates and joint ventures	1,528	1,798
Profit before income tax	13,901	68,226
Income tax	(3,831)	(1,203)
Profit for the year	10,070	67,023
Profit attributable to:		
Owners of the parent	8,885	66,200
Non-controlling interest	1,185	823
Consolidated Statement of Comprehensive Income		
Profit for the year	10,070	67,023
Actuarial (loss) on retirement defined benefit plans	(82)	(44)
Items that will not be reclassified to profit or loss	(82)	(44)
Exchange differences arising on translation of foreign operations	(8,890)	1,546
Exchange differences arising on translation of associates and joint ventures	17	34
Revaluation for available for sale investments	1,139	5,502
Items that may be subsequently reclassified to profit or loss	(7,734)	7,082
Other comprehensive income for the year	(7,816)	7,038
Total comprehensive income for the year	2,254	74,061
Attributable to:		
Owners of the parent	1,299	73,203
Non-controlling interest	955	858
Earnings per share (EPS)	HUF	HUF
Basic	48	356
Diluted	48	356

for the ve	ar ended 31 December
Revenue	
Cost of s	ales
Gross pro	fit
Sales and	d marketing expenses
Adminis	ration and general expenses
Research	and development expenses
Other in	come and other expenses (net)
Profit fror	n operations
Finance	ncome
Finance	cost
Net finan	cial (loss)/income
Share of	profit of associates and joint ventures
Profit bef	ore income tax
Income	ax
Profit for	the year
Profit attrik	butable to:
Owners	of the parent
Non-cor	trolling interest
Average e	kchange rate (EURHUF)
Consolida	ted Statement of Comprehensive Income
Profit for	the year
Actuaria	(loss) on retirement defined benefit plans
Items tha	t will not be reclassified to profit or loss
Exchang	e differences arising on translation of foreign operations
Exchang	e differences arising on translation of associates and joint ven
Revaluat	ion for available for sale investments
Items tha	t may be subsequently reclassified to profit or loss
Other cor	nprehensive income for the year
Total com	prehensive income for the year
Attributab	le to:
Owners	of the parent
Non-cor	trolling interest
Earnings	oer share (EPS)
Basic	
Diluted	

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2017	2016
EURm	EURm
1,436.8	1,251.2
(618.5)	(526.6)
818.3	724.6
(371.4)	(345.3)
(75.6)	(65.3)
(129.0)	(112.9)
(175.3)	(25.7)
67.0	175.4
48.3	85.4
(75.3)	(47.5)
(27.0)	37.9
4.9	5.8
44.9	219.1
(12.3)	(3.9)
32.6	215.2
28.8	212.6
3.8	2.6
309.28	311.46

	32.6	215.2
	(0.3)	(0.1)
	(0.3)	(0.1)
	(28.8)	5.0
entures	0.1	0.1
	3.7	17.6
	(25.0)	22.7
	(25.3)	22.6
	7.3	237.8

235.0	4.3	
2.8	3.0	
EUR	EUR	
1.14	0.15	
1.14	0.15	

Consolidated Cash flow Statement		
for the year ended 31 December	2017	2016
	HUFm	HUFm
Operating activities		
Profit before income tax	13,901	68,226
Depreciation and amortisation	34,747	32,895
Non cash items accounted through Total Comprehensive Income	(1,347)	(6,725)
Year-end foreign exchange translation difference of borrowings	(65)	(245)
Net interest and dividend income	(1,248)	(4,531)
Changes in provision for defined benefit plans	(220)	(15)
Decrease/(increase) on changes of property, plant and equipment and intangible assets	1,141	(461)
Impairment recognised on intangible assets and goodwill	49,184	3,873
Impairment on investments	-	63
Expense recognised in respect of equity-settled share based payments	3,640	4,724
Movements in working capital		
Increase in trade and other receivables	(12,519)	(18,095)
Increase in inventories	(3,228)	(11,446)
Increase in payables and other liabilities	7,631	16,358
Interest expense	(990)	(827)
Income tax paid	(6,880)	(6,375)
Net cash flow from operating activities	83,747	77,419
Cash flow from investing activities		
Payments for property, plant and equipment	(30,328)	(30,551)
Payments for intangible assets	(9,601)	(5,902)
Proceeds from disposal of property, plant and equipment	957	401
Payments to acquire financial assets	(1,745)	(88)
Proceeds on sale or redemption on maturity of financial assets	733	3,950
Disbursement of loans net	(666)	(614)
Interest income	1,563	2,566
 Dividend income	675	2,792
Net cash outflow on acquisition of subsidiaries	(8,045)	(63,555)
Net cash flow to investing activities	(46,457)	(91,001)
Cash flow from financing activities		. , ,
Purchase of treasury shares	(3,858)	(1,758)
Dividend paid	(19,756)	(13,563)
Repayment of borrowings	(36,585)	(6,813)
Proceeds from borrowings	3	(0,013)
Net cash flow to financing activities	(60,196)	(22,134)
Net decrease in cash and cash equivalents	(22,906)	(35,716)
· · · · · · · · · · · · · · · · · · ·	96,053	132,374
Cash and cash equivalents at beginning of year		
Cash and cash equivalents at beginning of year Effect of foreign exchange rate changes on the balances held in foreign currencies	2,894	(605)

Notes

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