# GEDEON RICHTER

ANNUAL REPORT 2016

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# Richter – Corporate Review

# 1 Fact Sheet

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

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

## Parent Company Data

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

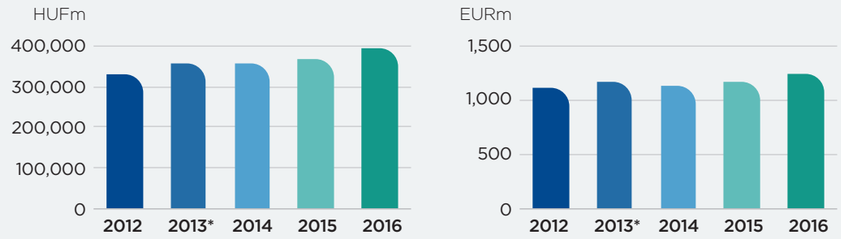
# 2 Financial Highlights

## Consolidated financial highlights

| | 2016 | 2015[3] | Change | 2016 | 2015[3] | Change |
|---|---|---|---|---|---|---|
| | HUFm | HUFm | % | EURm | EURm | % |
| **Revenues** | 389,690 | 365,220 | 6.7 | 1,251.2 | 1,179.4 | 6.1 |
| **Profit from operations** | 54,616 | 66,682 | (18.1) | 175.4 | 215.4 | (18.6) |
| **Profit for the year** | 67,023 | 53,863 | 24.4 | 215.2 | 173.9 | 23.7 |
| | 2016 | 2015[3] | Change | 2016 | 2015[3] | Change |
| | HUF | HUF | % | EUR | EUR | % |
| **Earnings per share (EPS)[1]** | 356 | 291 | 22.3 | 1.14 | 0.94 | 21.3 |
| **Dividends per ordinary shares[2]** | 106 | 72 | 47.2 | 0.34 | 0.23 | 47.8 |

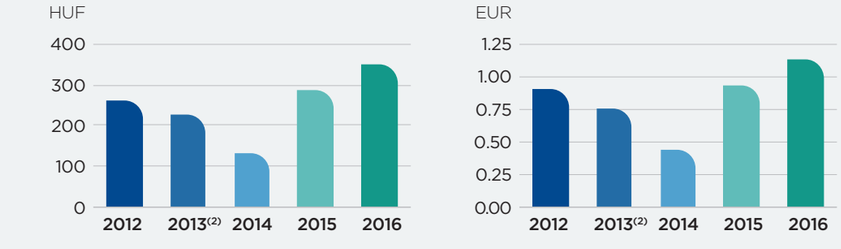
Notes:
[1] Earnings per share calculations were based on the total number of shares issued.
[2] The amount of 2016 dividend per ordinary share is HUF 106 as proposed by the Board of Directors.
[3] Restated. For details see Explanatory note on page 104.

## Revenues



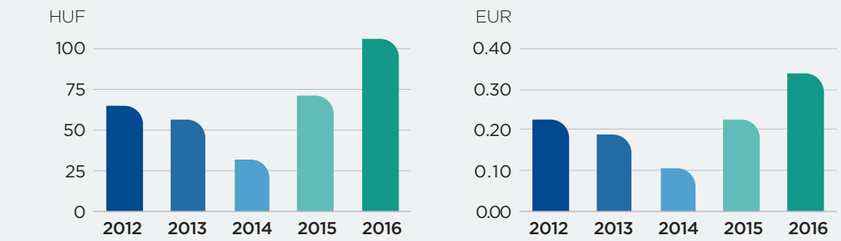

Note:
*Restated in respect of IFRS 11 standard.

## Earnings per share[1]




Notes:
[1] Earnings per share calculations were based on the total number of shares issued.
[2] Restated in respect of IFRS 11 standard.

## Dividends per ordinary share*




Note:
*The amount of 2016 dividend per ordinary share is HUF 106 as proposed by the Board of Directors.

William de Gelsey KCSG, Chairman

# 3 Chairman's Letter to the Shareholders

I have the honour to address the Shareholders of Gedeon Richter on the eighteenth occasion as Chairman and may I therefore "walk down Memory Lane" with you and briefly review the past eighteen years.

Turnover has grown by more than 5 fold, approaching HUF 390 billion by the end of 2016, while EPS has increased by nearly 3 times from HUF 89.6 or US$ 0.38 per share (adjusted to reflect the impact of share split implemented in 2013), to reach HUF 356 or US$ 1.27 at the end of the reported year. The Group, while maintaining a generic focus on its traditional markets, has successfully expanded its activities into new geographic regions including Western Europe, China and Latin America. Importantly, by the end of the reported year, Richter accomplished its first marketing authorization of teriparatide, a leading edge biosimilar project. I am also pleased to see initial proceeds from cariprazine, the Company's first original molecule approved in the USA. As a result of the sustained efforts by both the Management and employees, Women's Healthcare, the Group's core business, reached 38 percent of Pharmaceutical sales reported for 2016, a global recognition of leading performance.

I am pleased to present the Annual Report for 2016 which overall was a successful year for the Group. Many ambitious targets were met in most of the key specialty areas although adverse events were also experienced:

i) Cariprazine, an original compound discovered by Richter's scientists and co-developed through subsequent clinical trials jointly with Allergan (earlier Forest / Actavis), was launched on the US market in mid March 2016. In addition, following the submission for a marketing authorization approval in the EU, evaluation of the file is currently ongoing.

ii) Women's Healthcare, the Company's core specialty area, showed encouraging results in 2016. Sales proceeds from ESMYA®, our original product for the treatment of uterine fibroids grew satisfactorily. Product launches in Latin American markets continued during the reported year in line with the established schedule. In January 2017 Richter and Allergan notified investors of the successful completion of the second Phase III trial of ESMYA® conducted in the USA, making imminent the filing of this unique therapy with the FDA. Focusing on the meaningful widening of its core Women's Healthcare portfolio, Richter acquired during 2016 the global rights (except for the USA) of the innovative biosimilar product BEMFOLA®, addressing female fertility. In January 2017 a levonorgestrel releasing Intrauterine System (IUS), LEVOSERT® was licensed-in from Allergan for Western and Northern European countries. Notwithstanding the successful widening of its core portfolio as described above, in October 2016 Richter initiated the voluntary withdrawal of LISVY® a transdermal contraceptive patch. The decision followed a notification received from Bayer HealthCare, the licensor and supplier of the product, that according to certain stability tests carried out under specific conditions the product resulted in out-of specification results.

iii) The strategic initiative on the development of sophisticated biosimilar products also achieved an important milestone during the reported year. In November 2016 Richter received a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency recommending that marketing authorization be granted for its biosimilar teriparatide, TERROSA and based on that, the European Commission granted approval for this product in January 2017. In December 2016, however, Richter had to withdraw its Marketing Authorization Application from the European Medicines Agency for its biosimilar pegfilgrastim subsequent to a notification from the Committee for Medicinal Products for Human Use that the data which the Company had provided did not allow the Committee to conclude a positive benefit risk assessment.

From a geographic perspective a widened presence of Richter products in Western Europe, in China and in Latin America reduced the Group's exposure to its traditional core markets in CIS and Central and Eastern Europe.

The Board is delighted to acknowledge the consistent efforts of Mr Erik Bogsch, CEO, and his senior management team who have taken the necessary actions to deliver our investors a sustainable increase in shareholder value. I would like to take the opportunity to welcome Mr Gábor Orbán to the Executive Board and I am convinced that his fresh approach and dynamic personality will be positively received by Mr Erik Bogsch who follows me in the responsible yet challenging position of Chairman of the Board of Directors with effect from 1 January 2017.

Finally, please allow me to express my gratitude for the trust of the fellow Board members who have vested me with the title of Lifetime Honorary Chairman of the Board. I am going to support the Company and its Board of Directors as much as I did in the past. It is my strong belief that I shall witness more such tremendous achievements as I have experienced during the past eighteen years.

William de Gelsey KCSG
Chairman

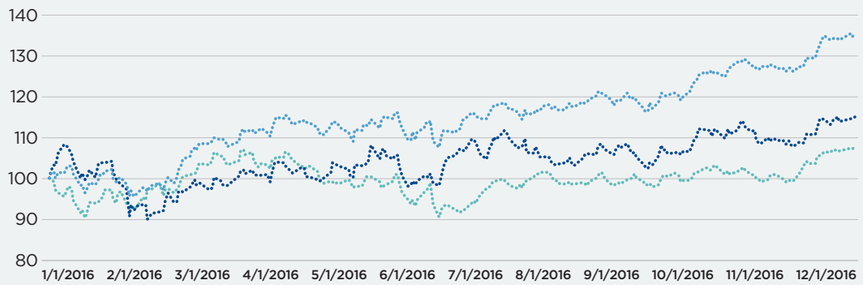
# 4 Investor Information

## a) Share Price and Market Capitalisation

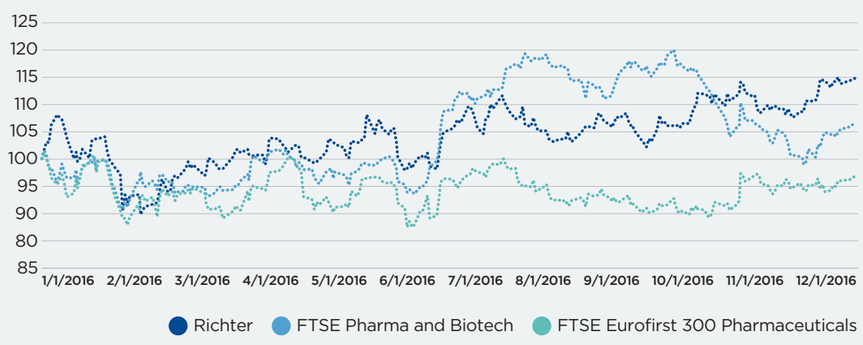
The Gedeon Richter Plc. share price on 4 January 2016 was HUF 5,400. Following a sudden increase, price bottomed at 4,850 on 17 February. From then on the share price grew interrupted by a few short and not significant declining periods, reaching by the end of the December HUF 6,210, a near 15 percent increase over the year. Its highest value was recorded on 22 December and on 30 December 2016 at HUF 6,210.

The Company's market capitalisation followed the performance of its share price on the Budapest Stock Exchange and by the end of 2016 at HUF 1,157 billion reflected a near 13 percent increase, in HUF terms when compared to its value recorded on 31 December 2015. Market capitalisation on 31 December 2016 in Euro terms was EUR 3.7 billion, about 14 percent above the EUR 3.3 billion recorded on 31 December 2015.

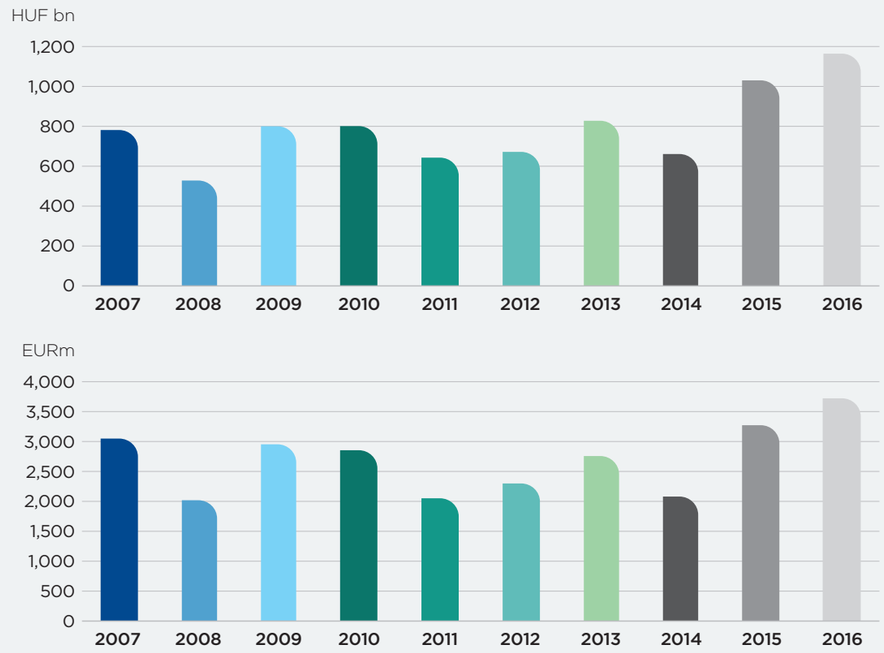
### Gedeon Richter share price on the Budapest Stock Exchange compared to BUX and CETOP indices (%)




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




### Market capitalisation*




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

## 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 26 April 2017 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 30 percent of Gedeon Richter Plc.'s net consolidated profit calculated according to International Financial Reporting Standards (IFRS) for 2016.

Dividends approved by the shareholders of Gedeon Richter Plc. at the Annual General Meeting held on 26 April 2016 totalled HUF 13.4 billion (EUR 43.3 million) in respect of 2015. The portion payable in relation to ordinary shares amounted to HUF 72 per share, 72 percent of the nominal share value. The record dates for these dividend payments were announced on 12 May 2016 with payments having commenced on 15 June 2016.

## 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 as well, 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 Managing Director and all Directors are available during the meeting to respond to questions.

Management, principally the Managing Director 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 2016. Gedeon Richter's management also held 20 meetings for approximately 39 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 18 additional conference calls were organised on request.

| Conferences in 2016 | | | |
|---|---|---|---|
| Concorde | "One on One Conference" | Budapest | 6 April 2016 |
| BAML | "Global Healthcare Conference" | London | 14-15 September 2016 |

| Investor roadshows in 2016 | |
|---|---|
| London | 11-12 February 2016 |
| London | 14 April 2016 |
| London | 4-5 October 2016 |
| London | 24 November 2016 |

The Company's website (www.richter.hu) includes an area which is intended to meet the specific stated needs of investors, analysts and media concerning information on Richter's business operations.

The Company's Investor Relations Department at its office in Budapest continues to act as a focal point for contact (Email: investor.relations@richter.hu Phone: +36 1 431 5764) with institutional shareholders.



## e) Analysts Providing Coverage

| Analysts providing regular coverage about the company during 2016 | |
|---|---|
| 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 József Puzsár |
| Raiffeisen Centrobank AG | Mr Oleg Galbur |
| Pekao Investment Banking S.A. | Ms Helena Naffa |
| 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 2016 remained unchanged from the levels reported as at 31 December 2015.

**Treasury Shares**

| Shares held by the Company in Treasury | Reason of purchase | Number | Nominal value (HUF) | % as of share capital | Book value (HUF) |
|---|---|---|---|---|---|
| **Opening balance** | | **101,371** | **10,137,100** | **0.054** | **549,819,617** |
| Purchased | Bonus, Remuneration, Programme approved by NTCA* and stock consideration in respect of business line transfer | 650,000 | 65,000,000 | 0.349 | 3,916,699,238 |
| Shares repurchased (OTC) | Bonus, Remuneration, Programme approved by NTCA* | 302,831 | 30,283,100 | 0.162 | 1,756,826,950 |
| Repurchased through Programme approved by NTCA* | Programme approved by NTCA* | 17,396 | 1,739,600 | 0.009 | 96,620,118 |
| **Total share purchased** | | **970,227** | **97,022,700** | **0.521** | **5,770,146,306** |
| Bonus, Professional Development Programme | | (217,189) | (21,718,900) | | (1,220,561,369) |
| Remuneration | | (387,600) | (38,760,000) | | (2,294,418,930) |
| Granted through Programme approved by NTCA* | | (285,459) | (28,545,900) | | (1,736,508,218) |
| **Total utilization** | | **(890,248)** | **(89,024,800)** | | **(5,251,488,517)** |
| **Closing balance** | | **181,350** | **18,135,000** | **0.097** | **1,068,477,406** |

Note: *National Tax and Customs Administration of Hungary

The number of shares held by the Parent Company in Treasury increased during 2016.

The Company purchased 650,000 shares from its subsidiaries and 302,831 shares were acquired on the OTC market.

Based on a decision of the Board of Directors of Gedeon Richter Plc., 604,789 shares held by the Company in Treasury were granted as bonuses during 2016 to qualified employees participating in the bonus share programme as well as to members of staff rendering outstanding performance.

In a programme related to employee share bonuses approved by the National Tax and Customs Administration of Hungary (NTCA), on 16 December 2016 the Company granted a total of 285,459 shares in respect of 4,342 of its employees for 2016. The above shares in the value of HUF 1,737 million will be deposited at the employees' individual securities accounts at UniCredit Bank Hungary Zrt. until 1 January 2019.

In accordance with a repurchase obligation stipulated in the programme, the Company repurchased 17,396 shares from employees who resigned from the Company during 2016.

On 2 January 2017, following the expiry of the lock-up period the Company was able to remove all restrictions on 478,725 Richter ordinary shares granted to its employees on 22 December 2014 during the third year of a three-year programme approved by National Tax and Customs Authority (NTCA) in respect of years 2012-2014, thereby enabling these shares to be traded.

The total number of Company shares at Group level held in Treasury at 31 December 2016 was 241,634.

On 31 December 2016 the Group's subsidiaries held a total of 60,284 ordinary Richter shares compared to a holding of 710,284 reported ordinary Richter shares, held on 31 December 2015.

## 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 2015. The proportion held by domestic investors increased slightly to 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 0.1 percent at the end of December 2016.

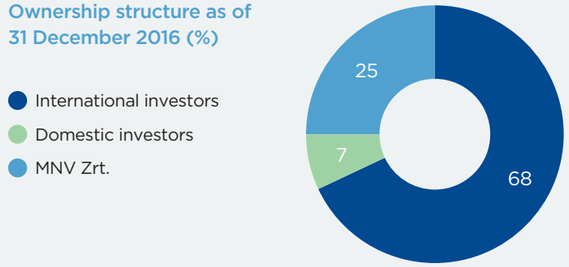
Data in the table below was compiled based on the share registry adjusted for information provided by KELER Zrt. as clearing company, global custodians and nominees.

**Ownership structure on 31 December 2016**

| Ownership | Ordinary shares Number | Voting rights % | Share capital % |
|---|---|---|---|
| Domestic ownership | 59,832,738 | 32.15 | 32.11 |
| State ownership total | 47,051,817 | 25.28 | 25.25 |
| out of which MNV Zrt. | 47,051,668 | 25.28 | 25.25 |
| out of which Municipality | 149 | 0.00 | 0.00 |
| Institutional investors | 6,070,053 | 3.26 | 3.26 |
| Retail investors | 6,710,868 | 3.61 | 3.60 |
| International ownership | 126,289,476 | 67.84 | 67.75 |
| Institutional investors | 124,591,828 | 66.93 | 66.84 |
| out of which Aberdeen Asset Mgmt. Plc. | 18,243,530 | 9.80 | 9.79 |
| out of which Harding Loevner LP | 9,367,925 | 5.03 | 5.03 |
| Retail investors | 1,697,648 | 0.91 | 0.91 |
| Treasury shares* | 241,634 | 0.00 | 0.13 |
| Undisclosed ownership | 11,012 | 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.

**Ownership structure as of 31 December 2016 (%)**




**Ordinary shareholdings by the members of the Company's Boards**

| | 31 December 2016 Number of ordinary shares | 31 December 2015 Number of ordinary shares |
|---|---|---|
| Board of Directors | 46,172 | 39,365 |
| Supervisory Committee | 4,059 | 1,506 |
| Executive Board | 19,485 | 23,176 |
| **Total** | **69,716** | **64,047** |

Membership of the Company's Boards is shown on pages 22-25 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 Managing Director and Chairman have been held separately by the end of 2016. The latter is elected amongst the non-executive 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 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 Managing Director. 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.

# 6 Company's Boards

## Board of Directors

**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. Joined the Board in 1995 Chairman between 1999 and 2016. Lifetime Honorary Chairman since 2017.

**Mr Erik Bogsch (1947)**
Appointed Managing Director. 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. Chairman of Richter's Board of Directors since 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 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. Previously General Secretary of State, Ministry of Economic Affairs. Joined the Board in 2010.

**Dr László Kovács (1944)**
Strategic adviser to Gedeon Richter Plc. Previously Deputy Managing Director with responsibility for Commerce and Marketing from 1990 to 2005. Economist, University doctorate in Economic Sciences. Formerly with Medimpex from 1966 to 1990, Secretary of the Commercial Section of the Hungarian Embassy in São Paulo Brazil, 1975 to 1978. Joined the Board in 1992.

**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 Christopher William Long (1938)**
Career diplomat. Experienced in the full range of diplomatic work including management, personnel, political and economic analysis. British Ambassador to Hungary from 1995 to 1998. Joined the Board in 1998.

**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 in 2014.

## Executive Board

**Mr Erik Bogsch (1947)**
Appointed Managing Director in 1992. 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.

**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. Previously General Secretary of State, Ministry of Economic Affairs.

**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 Gábor Orbán (1979)**
Director of Corporate Strategy since 2016, Chief Operating Officer since 2017. Began his professional career as a macro analyst, worked as an economist for the National Bank of Hungary and the European Central Bank. Later he joined Aegon Asset Management as a fund manager and head of the fixed income desk. He served as State Secretary in charge of taxation and the financial sector at the Ministry for National Economy followed by a consultant position at Banque Rothschild. He earned his MA degree at the Budapest University of Economic Sciences and has also studied in the United States.

**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.

## 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 2016

At the Annual General Meeting on 26 April 2016, the following were reappointed to the Board of Directors for a 3 year period until the 2019 AGM:

- Dr Gábor Gulácsi
- Mr Csaba Lantos
- Mr Cristopher William Long

while Dr Norbert Szivek was appointed to the Board of Directors for a 3 year period until the 2019 AGM.

# 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 endeavour 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.

### 1. Strategic risks

| | Description | Key risk management methods |
|---|---|---|
| Macroeconomic Factors | Changes in macroeconomic factors affecting the Company's markets: especially the declining solvency due to the protracted economic crisis resulting from the Russian-Ukrainian conflict and the permanently low level of oil price | • Monitoring changes in major macroeconomic factors, incorporating their effects into the planning<br>• Restrictions in cost management and client relationship<br>• Flexible utilization of local manufacturing capacities |
| 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 | • Identifying competitive advantages<br>• Focusing on new original and value added products<br>• Introducing new generic products<br>• Regularly performed industry and competitor evaluation, effectiveness analysis |
| Healthcare Budget | The potential impact on the Company of changes and monetary restrictions in healthcare budgets and regulations (price reductions, increasing industry specific taxes, restrictions on reimbursement systems and delays in the acceptance of reimbursements applications) | • Regular analysis of market environment, monitoring changes in the legal and medical subsidy system<br>• Communication with authorities<br>• Adaptation in cost management |

### 2. Operational risks

| | Description | Key risk management methods |
|---|---|---|
| Original and biosimilar R&D and the establishment of manufacture | The risk relating to the success of original and biosimilar research and manufacturing activities | • To focus on CNS R&D activity and Women's Healthcare development<br>• To set up the milestones regarding the original and biosimilar R&D activity<br>• Assessment of programs and decision-making with the involvement of advisory boards and international experts according to the international standards<br>• Involving partners to minimise risk and to provide co-financing |
| The increasing complexity of Company activity, more diversified markets | The risk relating to the setup of sales forces specialised in the promotion and marketing of our Women's Healthcare products in Western Europe, China and Latin America | • Company level projects for the promotion of the new Women's Healthcare portfolio, the integration of Finox Group and the launch of ESMYA®<br>• Stregthening market presence and sales network in Western Europe<br>• Establish sales network in Latin America<br>• Increase ownership ratio in Chinese and Latin American businesses |
| Qualified Workforce | The risk relating to retention of employees in key positions and ensuring a qualified workforce | • Periodic revision of HR strategy<br>• Training plans, carrier and succession programmes<br>• Incentive and performance assessment system<br>• To determine the optimal number of staff<br>• Quality-driven replacement, retentation of employees performing high quality work |

### 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<br>More frequent inspections due to original product launches | • Implementing Quality systems and Standard Operational Processes (SOP)<br>• Monitoring the compliance with health authority regulations<br>• Separete projects to prepare for inspections |
| Intellectual Property, Patents and Litigations | The risk relating to patents and patent rights | • Continuous assessment and monitoring of intellectual property and patents<br>• Enforcement of patent rights<br>• Risk minimising agreements |
| Contracts and Liabilities | The risk relating to managing and enforcing contractual conditions and liabilities | • Centralised contracting processes<br>• Special treatment of unique contracts<br>• Introduction of global compliance programme |

### 4. Financial risks

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

## 8 Litigation Proceedings

There were no litigation proceedings that materially impacted the business of Gedeon Richter Plc. during 2016.

# Managing Director's Review

**Erik Bogsch, Managing Director**

I am very pleased to present Richter's excellent overall performance in 2016, as we made significant progress in meeting both our near and longer term strategic goals despite the economic crisis which prevailed in Ukraine and the significant currency devaluations experienced throughout the CIS region.

Our key specialty area remains Women's Healthcare, where we provide one of the broadest range of products available to women of all age groups. Women's Healthcare products represented 38 percent of our total consolidated turnover in 2016.

We made good progress in further strengthening the market position of ESMYA® in all our markets. Following its approval in 2015 for the long-term management of uterine fibroids, ESMYA® was granted reimbursed status in a number of countries in 2016 and was also launched in certain other countries.

ESMYA® reported total sales were EUR 69.0 million in 2016, compared to the EUR 49.8 million turnover recorded in the previous year.

In line with our paramount strategic initiative to enhance our existing branded Women's Healthcare product line worldwide, we progressed by making in June 2016 the acquisition of Finox Holding, a privately held Swiss biotech company focusing on development and commercialisation of innovative products addressing female fertility. Finox represents a unique opportunity for us to widen our core Women's Healthcare franchise and further emphasises our commitment to the biosimilar business. This acquisition allows us to establish our presence in the female fertility therapeutic area – a major growth market.

Finox's product, BEMFOLA® is a recombinant-human Follicle Stimulating Hormone (r-hFSH) which was developed as a biosimilar to GONAL-f®, an established reference product. BEMFOLA® was the first biosimilar r-hFSH launched in Europe. It is currently commercialised in the European Union, in Israel, in the Middle East and in Australia.

As another step on the way to further broadening our Women's Healthcare franchise, in January 2017 we signed a distribution and supply agreement with Allergan (earlier Watson / Actavis) to commercialise its levonorgestrel releasing Intrauterine System (IUS), as a contraceptive device, in Western Europe and in other European countries under the trademark of LEVOSERT®. The product is already marketed by Richter for the treatment of menorrhagia in most of the Central and Eastern European countries under an agreement established with Uteron Pharma in 2011.

It was most disappointing, that on 10 October 2016, following a notification received from Bayer HealthCare, the licensor and supplier of the transdermal patch LISVY®, according to which certain stability tests carried out under specific conditions resulted in out-of specification results, Richter initiated the voluntary withdrawal of the product. This step was taken with immediate effect on all markets involved. Consequently Bayer commenced an investigation to determine the root cause of such non-specific responses. In this endeavour Richter closely co-operates with Bayer. Richter's actions have been taken after consultation with the responsible national authorities, although, as of the date of writing this review Richter has not received reports of any adverse events associated

with this issue. The above decision to remove the product from the market reflects Richter's utmost commitment to patients' safety.

Innovation is a key element in our strategy, as it ensures our Company's future over the long-term. Therefore, I personally pay particular attention to the environment in which our R&D team operates.

I make every effort possible both to create an encouraging atmosphere and also to maintain strict scientific criteria so as to sustain projects with only the highest quality of science, which together enhances our likelihood of future success and productivity.

I am personally very proud and pleased to report that cariprazine, the first original compound discovered by Richter research team and launched on the US market, was successfully introduced by our partner, Allergan (earlier Forest / Actavis), under the trademark of VRAYLAR™ on 16 March 2016.

In August 2016 a clinical and regulatory update on cariprazine has been provided together with our partner Allergan. As a part of this update, we jointly announced the results of the MD-72 trial evaluating flexible doses of cariprazine (1.5-4.5 mg) as an adjunctive treatment to antidepressant therapy in adults with major depressive disorder who failed to adequately respond to antidepressant monotherapy. Topline results showed that cariprazine did not separate significantly from placebo as an add-on treatment.

Nevertheless the management of both companies are determined to continue the development programme of cariprazine, in the endeavour of which in 2016 we have started the patient enrollment in our Phase III clinical trial programme investigating the use of cariprazine as a treatment for bipolar depression.

Additionally, Allergan has been in active discussions with FDA regarding the submission of an efficacy supplement to provide for the treatment of predominantly negative symptoms of schizophrenia (PNS). It followed an announcement made by Richter in January 2015, about a positive Phase III study that evaluated cariprazine for the treatment of predominant negative symptoms of schizophrenia. PNS is a serious unmet need for which there are no approved treatment options available.

The European Medicines Agency (EMA) started the evaluation of Richter's marketing authorisation application for cariprazine for the treatment of schizophrenia in March 2016.

Our efforts to find a partner for the commercialisation of cariprazine in Western Europe bore fruit when in August 2016 we signed an exclusive license agreement with Recordati. I am pleased to have Recordati as our marketing partner in Western-Europe, given our long standing relationship. Their experience and well established international sales network are reflected in a proven track record of introducing successfully new products on the their markets. This partnership is aligned with our strategy to bring cariprazine to the market for the millions of people living with schizophrenia and who are seeking an effective new treatment option.



I am convinced that a pharmaceutical company, which aims to remain competitive over the long-term, should create a portfolio containing high added value products. Exploration into new innovative areas such as original research activity or biosimilar product development, carries high risks but also provide opportunities for future relatively high revenue.

The significance of biotechnology products continues unabated in the global pharmaceutical market. Approximately 30 percent of the products given marketing authorisation during 2015 in the USA and about 44 percent of all new drugs in the European Union are of biotechnological origin. Experts unanimously agree that the market share of biotechnology products will continue to grow in the future. While the small-molecule drug market is currently estimated to grow by 4 percent annually, the market for biotechnology products is expected to grow by more than 10 percent a year. This trend is further bolstered by the fact that approximately one-third of all current clinical development projects are known to be of biotechnological origin.

I am very pleased to report that in early January 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 it executes its specialty pharma strategy.

In December 2016 we announced that we have withdrawn our Marketing Authorization Application (MAA) from the European Medicines Agency (EMA) for our biosimilar pegfilgrastim. During the November 2016 Committee for Medicinal Products for Human Use (CHMP) meeting, the CHMP indicated that the data provided did not allow the Committee to conclude a positive benefit risk assessment. Nevertheless, we remain committed to continue the clinical development and regulatory process of our biosimilar pegfilgrastim in order to eliminate the uncertainties identified by CHMP during the review process.

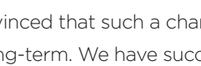
In order to provide all the necessary resources and support to the biosimilar development programme, a separate Biotechnology Business Unit was established in July 2016. The business unit includes near 200 employees and covers R&D, Clinical, Regulatory, Business Development, Project Management, Manufacturing and Marketing activities for the products under development in the biosimilar portfolio.

Our Group reported HUF 389,690 million (EUR 1,251.2 million) consolidated sales in 2016, representing a 7 percent increase in HUF terms (6 percent in EUR terms) when compared with 2015. Primarily as a consequence of a number of one-off items, which impacted the other income and other expense line, profit from operations decreased by 18 percent in HUF terms (19 percent in EUR terms) and amounted to HUF 54,616 million (EUR 175.4 million) in 2016. Profit for the year increased by 24 percent (by 24 percent in EUR terms) in 2016 to a total of HUF 67,023 million (EUR 215.2 million), which was primarily due to a substantial net financial income recorded in 2016 as a consequence of significant exchange gains realised on trade receivables as a result of the strengthening (by 23 percent) of the RUBHUF period close year-on-year exchange rate.

During the past few years we have made tremendous progress in the execution of our strategic initiative of transforming Richter to a specialty pharma company focusing on high added value products, which in turn should position Richter in a different league of companies compared to its former peers. I am strongly convinced that such a change of our business model will ensure that we remain competitive over the long-term. We have successfully managed to develop an original compound in cooperation with our long-term partner Allergan and this product is now available in the US for millions of patients suffering from either bipolar mania or schizophrenia, while under registration in Europe. We have also expanded and broadened our Women's Healthcare portfolio with either first-in-class therapies or products addressing niche therapeutic areas. This part of our business currently represents nearly 40 percent of our turnover. Additionally, in the year under review we have successfully completed the product development and registration of our first biosimilar product.

I am fully aware that we are still facing a number of challenges, but I am confident that in Richter we have the right staff which can overcome our short-term challenges and deliver longer-term sustainable growth. Strategic successes that we achieved not just in 2016, but over the last several years, are attributable first and foremost to their outstanding performance and their constant commitment. For this I would like to express my sincere appreciation to our employees. I personally also appreciate our shareholders patience and their trust which enables us to proceed steadily along our pathway to executing our strategy.

Finally, I would like to express my sincere gratitude and respect to Mr William de Gelsey, who has been Chairman of the Board of Directors since 1999. The Board of Directors accepted his intention to resign from this position with effect from 1 January 2017, whilst leaving unaffected his status as a member of the Board. Together with the Board of Directors I am delighted as an acknowledgement of his significant commitment and contribution to the Company he has accepted the title "Lifetime Honorary Chairman of Gedeon Richter Plc".



Erik Bogsch
Managing Director

Specialty Pharma

# 1 Challenging Industrial Environment

The steady growth experienced by the pharmaceutical industry over the past few decades was brought to an abrupt end when the financial crisis suddenly erupted in mid 2008. The instability of the financial institutions soon enough infected entire economies while in the pharmaceutical industry, the well known issue of increasingly limited novel development pipelines resulted in disturbing volatility for pharmaceutical corporations with a sound defensive reputation among investors.

Industry related problems that accumulated slowly over past decades suddenly broke out. Issues such as lengthy product development, increasing regulatory hurdles and exposure to constraints of national healthcare budgets underlined the vulnerability of the pharmaceutical business.

New social phenomena such as aging population and substantial changes in the lifestyle of the urbanized Western societies have also called for adequate responses from the pharmaceutical industry. Certain disease groups such as elderly dementia, Alzheimer disease or obesity gained more attention. At the same time younger generation requires new, non-oral approaches to contraception such as patches or hormone releasing devices. Generally speaking new delivery technologies (sprays, etc.) are well received by lifestyle driven patient groups.

Following the wide success of therapies across a number of cardiovascular diseases there is an increased demand to focus on oncologic and immune deficiency conditions, a demand which can be best addressed implementing high complexity novel technologies like nanotechnology or biological products.

Many of the generic companies which found themselves impacted by the double constraints of increasing peer competition and restrictive (national) budgetary environments were to select different strategies aimed at securing their future presence on the pharmaceutical market. One of the choices was to become global and retain margins through improving economies of scale. This goal could be achieved by conducting intense M&A activities which has resulted in an unprecedented concentration of the industry worldwide. The other way to secure margins and EPS growth was the implementation of a more complex, specialty driven, high added value business model.

Richter, having preserved its original research over the past century and having invested significant resources in building up one of the widest female healthcare portfolio worldwide, was a natural candidate for the latter strategy, i.e. go specialised.



# 2 Richter – Innovation and High Added Value

The previously detailed challenges encouraged Richter's Management 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 portfolio worldwide, it 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 enabled our US presence 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 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. In China our direct presence was enhanced in 2013 by acquiring a majority stakeholding in a local company involved in the distribution of prescription drugs on the local market. In 2016 following the acquisition of the outstanding 50 percent stake in our other existing JV, we achieved full control of our contraceptive and OTC business in China. We expanded our earlier established marketing agreement with HRA Pharma for ESMYA® to Latin America in 2013. Simultaneously, Richter acquired a stakeholding in a local company in Brazil with a gradual buy-out option. It also initiated in the same year a takeover of its local partner in Mexico. Together with the fully owned Columbian affiliate all these initiatives are focused on the registration of specialty products belonging to the Women's Healthcare product portfolio, targeting oral contraceptives and ESMYA® combined with establishing of a related sales network. The next step followed in 2014 with the acquisition of Mediplus, a well-established marketing company based in Curaçao, which covers through its subsidiaries a number of countries in the Latin American region, namely Ecuador, Peru, Chile and Bolivia. It also sells pharmaceutical products to Central American and Caribbean countries.

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 and with the US based Evestra Inc., to co-finance the development of its innovative advanced contraceptive devices, namely vaginal rings, through clinical development.

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 (earlier Watson / Actavis) 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 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 during 2016 in the following countries: Germany, Netherlands, Denmark, Sweden, Hungary, Estonia, Slovakia, Austria, Portugal, Slovenia, Spain, UK, Finland, Luxembourg, Ireland and Italy.

In 2016 ESMYA® was launched in Ecuador, Colombia, Iceland, Mexico and Mongolia. ESMYA® was granted marketing authorizations in the Dominican Republic, in Costa Rica and in Suriname.

ESMYA® reported total sales were EUR 69.0 million in 2016, compared to the EUR 49.8 million turnover recorded in the previous year.

During the year under review, Allergan and Richter announced positive results from both Venus I and Venus II phase III clinical trials carried out in the USA, evaluating the efficacy and safety of ulipristal acetate in women with abnormal bleeding due to uterine fibroids.

## Female Fertility

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

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

BEMFOLA®, a recombinant-human Follicle Stimulating Hormone (r hFSH) was developed by Finox as a biosimilar to GONAL-f®, an established reference product. BEMFOLA® was the first biosimilar r-hFSH launched in Europe. Subsequent to the announcement of the acquisition of Finox Holding, new marketing authorizations were granted to BEMFOLA® as follows: in October 2016 for New Zealand and for Albania, in December for Serbia and in January 2017 for Kosovo.

Sales of BEMFOLA® recorded subsequent to its acquisition, in the second half of 2016 amounted to EUR 10.6 million (US$ 11.7 million).

## 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

In January 2017 Richter signed a distribution and supply agreement with Allergan to commercialise its levonorgestrel releasing Intrauterine System (IUS), as a contraceptive device, in Western Europe and in other European countries under the trademark of LEVOSERT®. National marketing authorizations have been already granted in Western and Northern Europe and the product has been launched by Allergan in a number of these countries. The product is already marketed by Richter for the treatment of menorrhagia in most of the Central and Eastern European countries according to an agreement established with Uteron Pharma in 2011.

Following a notification received from Bayer HealthCare, the licensor and supplier of the gestodene and ethynil estradiol containing transdermal contraceptive patch, LISVY®, that certain stability tests carried out under specific conditions had resulted in out-of specification results, Richter initiated the voluntary withdrawal of the product on 10 October 2016. This step was taken with immediate effect on all markets involved. Bayer commenced an investigation to determine the root cause of such non-specific responses and in this endeavour Richter closely co-operates with Bayer.



## 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. By the end of 2016, LENZETTO® had been launched in the following countries: Poland, Czech Republic, Hungary, Croatia, Latvia, Lithuania, Romania, Slovakia, Germany, Bulgaria and Belgium. Following the closing of the year, the product was also introduced in Estonia.

Turnover of LENZETTO® during the reported period amounted to EUR 0.7 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.

## Main Women's Healthcare products of Richter Group

| Brand name | Active ingredients | Product type | Regions where launched [1] |
|---|---|---|---|
| **Oral contraceptives (OC)** | | | |
| VOLINA / MIDIANA / ARANKA / MAITALON 30 | DRP + 30 mcg EE | Fourth generation | Hungary; EU; CIS; RoW |
| SYMICIA / DAYLETTE / VOLINA MITE / REZIA / MAITALON 20 / DARYLIA / DIMIA / LILADROS / ARANKELLE | DRP + 20 mcg EE | Fourth generation | Hungary; EU; CIS; RoW |
| REGULON / DESORELLE / DESMIN 30 | DSG + 30 mcg EE | Third generation | Hungary; EU; CIS; RoW |
| 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 |
| LINDYNETTE 20 / KARISSA | GST + 20 mcg EE | Third generation | Hungary; EU; CIS; RoW; Latin America |
| LINDYNETTE 30 | GST + 30 mcg EE | Third generation | Hungary; EU; CIS; RoW |
| MILLIGEST / TRISTIN / PERLEAN | GST + 30/40 mcg EE | Third generation | Hungary; EU |
| RIGEVIDON / MICROFEMIN | LVG + 30 mcg EE | Second generation | Hungary; EU; CIS; RoW; China; Latin America |
| TRI-REGOL | LVG + 30/40 mcg EE | Second generation | Hungary; EU; CIS; RoW; China |
| BELARA / CHARIVA / LYBELLA / BALANCA / BELARINA / EVAFEM | CLM + 30 mcg EE | | Hungary; EU; CIS; RoW; Latin America |
| NEO-EUNOMIN | BCLM + 50 mcg EE | | EU |
| EVE 20 | norethisterone + 30 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 / PLAN B ONE-STEP / EVITTA | LVG (1x) | | Hungary; EU; CIS; USA; RoW; Latin America |
| ELLAONE[2] | ulipristal acetate | | CIS; RoW |
| **Contraceptive device (CD)** | | | |
| GOLDLILY / SILVERLILY | Au + Cu, Ag + Cu | IUD | Hungary; EU; CIS; RoW |
| LEVOSERT®[2] | levonorgestrel | IUD | Hungary; EU; CIS; RoW |
| LISVY®[2] | gestodene + EE | Patch | Hungary; EU |

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

| Brand name | Active ingredients | Product type | Regions where launched [1] |
|---|---|---|---|
| **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[2] | tibolone | Hormone replacement therapy | EU |
| ESTRIMAX | estradiol | Hormone replacement therapy | Hungary; EU |
| OSSICA | ibandronate | Osteoporosis | Hungary; EU |
| SEDRON / OSTALON / BEENOS | alendronate | Osteoporosis | Hungary; EU; CIS; RoW; Latin America |
| CALCI-SEDRON-D / OSTALON CALCI D | alendronate + Ca, vitamine D | Osteoporosis | Hungary; CIS; RoW |
| LENZETTO®[2] | estradiol | Hormone replacement therapy (spray) | EU |
| **Pregnancy care and Obstetrics** | | | |
| GRAVIDA[2] | vitamins | Pregnancy care | Hungary |
| OXYTOCIN | oxytocine | Labour induction (injection) | Hungary; EU; CIS; RoW; Latin America |
| BROMOCRIPTIN | bromocriptin mesilate | Prolactin inhibitor | Hungary; EU; CIS; RoW; China |
| LORITAN[2] | | 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[2] | butoconazole nitrate | Antifungal (cream) | Hungary; EU; CIS; RoW |
| KLION D | metronidazole + miconazole | Antifungal | Hungary; EU; CIS; RoW; Latin America |
| FLUOMIZIN[2] | dequalinium chloride | Anti-infective, antiseptic | EU |
| **Other Gynaecological conditions** | | | |
| 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 America** |

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

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

### Overview

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

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

### Bipolar I Disorder

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

### Schizophrenia

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

### Cariprazine

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

While the mechanism of action of cariprazine in schizophrenia and bipolar I disorder is unknown, the efficacy of cariprazine could be mediated through a combination of partial agonist activity at central dopamine $D_2$ and serotonin 5-$HT_{1A}$ receptors and antagonist activity at serotonin 5-$HT_{2A}$ receptors.

Pharmacodynamically, cariprazine acts as a partial agonist at the dopamine $D_3$ and $D_2$ receptors with high binding affinity and at the serotonin 5-$HT_{1A}$ receptors. Cariprazine acts as an antagonist at 5-$HT_{2B}$ and 5-$HT_{2A}$ receptors with high and moderate binding affinity as well as it binds to the histamine $H_1$ receptors. Cariprazine shows lower binding affinity to the serotonin 5-$HT_{2C}$ and $\alpha_{1A}$-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

On 17 September 2015, the U.S. Food and Drug Administration (FDA) approved cariprazine capsules, an atypical antipsychotic, for the acute treatment of manic or mixed episodes associated with bipolar I disorder and for treatment of schizophrenia in adults. The product was introduced in the US market under the trademark of VRAYLAR™ on 16 March 2016.

In August 2016 a clinical and regulatory update on cariprazine has been provided by Richter and our partner Allergan. As a part of this update, we jointly announced the results of the MD-72 trial, which was a prospective, randomized, double-blind, placebo-controlled, parallel-group study evaluating flexible doses of cariprazine (1.5-4.5 mg) as an adjunctive treatment to antidepressant therapy in adults with major depressive disorder (MDD) who failed to adequately respond to antidepressant monotherapy. Topline results from this trial indicate that flexible doses of cariprazine did not separate significantly from placebo as an add-on treatment.

Nevertheless the management of both companies are determined to continue the development programme of cariprazine, in the endeavour of which in 2016 we have started patient enrolment in our Phase III clinical trial programme investigating the use of cariprazine as a treatment for bipolar

depression. Two parallel studies are conducted at approximately 85 sites across the U.S. and Europe. The companies have previously announced positive Phase IIb data for cariprazine for the treatment of bipolar depression. This data was published in the Journal of American Psychiatry in November 2015.

Additionally Allergan has been in active discussions with FDA regarding the submission of an efficacy supplement to provide for the treatment of predominantly negative symptoms of schizophrenia (PNS). It followed an announcement made by Richter in January 2015, about a positive Phase III study that evaluated cariprazine for the treatment of PNS, which is a serious unmet need for which there are no approved treatment options available.

Other positive phase III clinical studies regarding relapse prevention was completed at the end of 2014, which was required by the European Medicines Agency (EMA) for registration purposes. The unique and unprecedented outcome of the clinical study in patients with predominantly negative symptoms provides a strong argument for differentiation and for potential price negotiations. The EMA started the evaluation of Richter's marketing authorisation application for cariprazine for the treatment of schizophrenia in March 2016.

Our Japanese partner, MitsubishiTanabe Pharma, also conducts clinical development to fulfil the regulatory requirements for product introduction on the Japanese market.

In August 2016 Richter and Recordati announced the signing of an exclusive license agreement to commercialize cariprazine in Western Europe and in Algeria, in Tunisia and in Turkey. In case of an EMA approval Recordati based on their experience and well established international sales network would bring cariprazine to the market in their territories.

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

With the establishment in July 2016 of a Biotechnology Business Unit, Richter has undergone a major restructuring of resources engaged in the development or biosimilars. These steps were taken to support all the efforts related to our biosimilar programme. The business unit includes near 200 employees and currently covers R&D, Clinical, Regulatory, Business Development, Project Management, Manufacturing and Marketing activities for the products under development in the biosimilar portfolio.

In early 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, preclinical 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 EMA for its biosimilar pegfilgrastim. The MAA filing was based on comparative quality, non-clinical and clinical data from the Company's completed biosimilar development programme. During the November 2016 CHMP meeting, the CHMP indicated that the data provided did not allow the Committee to conclude a positive benefit risk assessment. The Company's management is committed to continue the clinical development and regulatory process of its biosimilar pegfilgrastim in order to eliminate the remaining uncertainties identified during the review process by the CHMP.

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

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

# Business Review

# 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.

Research and development of new chemical entities focuses on the Central Nervous System (CNS) area. In order to improve cost efficiency the CNS portfolio was reviewed in 2014 and as a result, a small number of early stage projects were terminated and related personnel and cost was reduced. For the same reason one early stage project was eliminated from the clinical portfolio.

During the year under review, we successfully managed to establish in vivo models, possessing a relatively high translational value compared to both our previous practice and industry average. This aims to minimise probability of discontinuation of development programmes in an early phase due to lack of efficacy. In execution of our R&D projects carried out jointly with our long-term partner Orion Corporation, we also made progress according to the previously established plans.

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.

Cariprazine related activities have been very much in focus for the everyday work of individual departments within the Research Directorate, notably in connection with support of the launch of VRAYLAR™ executed by our US partner Allergan (earlier Forest / Actavis) and also with the preparation of the registration dossier for cariprazine submitted to the European Medicines Agency. The criteria of the European authority differs quite substantially from that which exists in the US. Our colleagues also contributed to the design of the clinical trials in both additional indications, i.e. bipolar depression and major depression.

At the end of 2016, besides cariprazine the Company has a research portfolio of 10 ongoing projects, two of which are in their early clinical phase. The remainder are in the preclinical research phase.

It has been a pleasure to report that on 16 March 2016 cariprazine was introduced to the US market, under the trademark of VRAYLAR™, soon after its FDA approval in September 2015.

On the other hand we were disappointed with the results of clinical trials evaluating flexible doses of cariprazine (1.5-4.5 mg) as an adjunctive treatment to antidepressant therapy in adults with major depressive disorder (MDD), who failed to adequately respond to antidepressant monotherapy. However, we believe that our plan to proceed with another Phase III study in Adjunctive MDD coupled with our previous positive clinical trial would provide the two studies needed for submission. This is considered to be an important next step to further develop the cariprazine program.

The management of both companies remained determined to continue the development programme of cariprazine, in the endeavour of which in 2016 we have commenced the patient enrolment in two Phase III clinical trial programme investigating the use of cariprazine as a treatment for Bipolar Depression (BD).

Additionally, Allergan has been in active discussions with FDA regarding the submission of an efficacy supplement to provide for the treatment of predominant negative symptoms (PNS) of schizophrenia. It followed an announcement made by Richter in January 2015, about a positive Phase III study that evaluated cariprazine for the treatment of PNS of schizophrenia, which PNS is a serious unmet need for which there are no approved treatment options available.

Other positive phase III clinical studies regarding relapse prevention were completed at the end of 2014, as required by the European Medicines Agency (EMA) for registration purposes. The unique and unprecedented outcome of the clinical study in patients with predominantly negative symptoms provided a strong argument for differentiation and for potential price negotiations. The EMA started the evaluation of Richter's marketing authorisation application for cariprazine for the treatment of schizophrenia in March 2016.

In August 2016 we signed an exclusive license agreement with Recordati to commercialise cariprazine in Western Europe and in Algeria, in Tunisia and in Turkey. In case of an EMA approval Recordati, based on their experience and well established international sales network, will bring cariprazine to the market in the above mentioned regions.

Our Japanese partner, MitsubishiTanabe Pharma, is also pursuing clinical development to fulfil the regulatory requirements for a product introduction on the Japanese market.

We made also progress in the Women's Healthcare field during the year under review, as we jointly with Allergan (earlier Watson / Actavis) announced positive results from both Venus I and Venus II phase III clinical trials evaluating the efficacy and safety of ulipristal acetate in women with abnormal bleeding due to uterine fibroids. A new drug application filing for ulipristal acetate to the US FDA is planned for the second half of 2017. The product has been already marketed since 2013 in Canada under the brand name, FIBRISTAL™.

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

In early January 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 executing its specialty pharma strategy.

In December 2016 we announced that we have withdrawn our Marketing Authorization Application (MAA) from the EMA for our biosimilar pegfilgrastim. The MAA filing was based on comparative quality, non-clinical and clinical data from the Company's completed biosimilar development programme. During the November 2016 Committee for Medicinal Products for Human Use (CHMP) meeting, the CHMP indicated that the data provided did not allow the Committee to conclude a positive benefit risk assessment.

We remain committed to continue the clinical development and regulatory process of our biosimilar pegfilgrastim in order to eliminate the remaining uncertainties identified by CHMP during the review process.

The Company considers it essential to establish partnerships to facilitate the development and marketing of new molecules. We join forces with academic and university institutions in the early phase of our research activities, while we make efforts to establish cooperation with other pharmaceutical companies when it comes to the development of molecules in clinical phases. In this regard partnerships with Allergan and with the Japanese company MitsubishiTanabe Pharma have contributed substantially to the Company's research activity. In particular Richter's experience in preclinical trials is complementary with Allergan's experience in clinical trials. Richter 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 base.

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 have 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 widened 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 in charge of 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 2016. 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 medium-term. At the same time the proportion of more complex, high added value development programmes increased, while lifecycle management projects became increasingly frequent during the past few years. All these changes are linked to our strong commitment to reshape our business substantially 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. 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 2016:

| Brand name | Active ingredient | Therapeutic area | Country |
|---|---|---|---|
| **Own-Developed products / Acquired** | | | |
| BELARA | chlormadinone + 30 mcg EE* | Women's Healthcare, oral contraceptive | Moldova, Kyrgyzstan, Uzbekistan |
| ESMYA® | ulipristal acetate | Women's Healthcare, uterine myoma | Mongolia, Ecuador |
| SILUETTE | dienogest + 30 mcg EE* | Women's Healthcare, oral contraceptive | Kazakhstan |
| AMLODIPINE-PERINDOPRIL-RICHTER | amlodipine + perindopril | Cardiovascular, antihypertensive | Azerbaijan |
| BEATIL | amlodipine + perindopril | Cardiovascular, antihypertensive | Romania |
| EKVAMER | amlodipine + lisinopril + rosuvastatin | Cardiovascular, cardiac therapy | Russia |
| RAENOM | ivabradin | Cardiovascular, cardiac therapy | Russia |
| MEMANTIN-RICHTER | memantine | Central Nervous System, Alzheimer's disease | Russia |
| MIRVEDOL | memantine | Central Nervous System, Alzheimer's disease | Ukraine |
| RABAKIR | pregabalin | Central Nervous System, antiepileptic | Slovakia |
| RESTIGULIN | aripiprazole | Central Nervous System, antipsychotic | Bulgaria, Romania, Slovakia |
| OMSAL | tamsulosine | Benign Prostatic Hyperplasia | Serbia |

| Brand name | Active ingredient | Therapeutic area | Country |
|---|---|---|---|
| **Licensed-in products** | | | |
| LENZETTO® | estradiol | Women's Healthcare, hormone replacement therapy (spray) | Hungary, Baltic States, Belgium, Bulgaria, Czech Republic, Croatia, Slovakia, Germany |
| LISVY® | gestodene + EE* | Women's Healthcare, contraceptive (patch) | Baltic States, Belgium, Luxemburg, Finland, France, Netherlands, Romania, Spain, Switzerland, Bulgaria |
| FLUOMIZIN | dequalinium-chloride | Women's Healthcare, anti-infective, antiseptic | Austria, Spain |
| FLAMBORIN | metamizole sodium | Central Nervous System, analgetic | Hungary |
| ANTACLAST | cilostazol | Antithrombotic | Hungary |
| XILOMARE | xylometazoline | Respiratory | Hungary |
| AERTAL creme | aceclofenac | Non-steroid anti-inflammatory | Azerbaijan |
| NIBIX | imatinib | Oncology, anticancer | Hungary |
| POLITRATE DEPOT | leuproreline | Urology, Oncology, anticancer | Hungary |

Note: * Ethynil estradiol

The Group reported in 2016 a 1.0 percent in HUF terms (0.4 percent in EUR terms) increase in its spending on research and development which totalled to HUF 35,153 million (EUR 112.9 million), representing 9.0 percent of consolidated sales. Lower than expected expenses were primarily due to delays in the timing of some of the clinical trials.

## b) Manufacturing and Supply

### Our focus

Richter has always paid special attention to being in a position to offer reliable and modern products at affordable prices. Our key objective is to satisfy market demand by providing sufficient quantities of quality products in a timely and a cost efficient manner. We manage that by continually optimizing cost efficiency of products and technologies and by operating an integrated supply process system including all subsidiaries.

In 2016 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 wide ranging cost and efficiency programme.

### Production

Manufactured volumes of finished products increased slightly by 1.7 percent in 2016, compared to the levels reported in 2015, which was accompanied by higher level (3.2 percent) growth in bulk production. At the parent company the manufactured volumes of finished products decreased by 3.3 percent, attributable to the transfer of certain packaging activities to Russia and the impact of lower maintained stock levels. In respect of our manufacturing subsidiaries shipped volumes of finished products increased by 27.2 percent in Russia, by 12.1 percent in Poland and by 5.1 percent in Romania.

The volumes of API manufacturing in Hungary decreased by 2.0 percent when compared to the levels recorded in the previous year. Steroid API volumes also declined slightly (1.8 percent) due to different manufacturing schedules across the years. As far as the share of production is concerned the Dorog site provides two thirds of API manufacturing.

### Investments

In order to support the long-term strategic targets of the Group a number of investments were initiated as part of larger projects in 2016, which, including payments for intangible assets, amounted to HUF 36,453 million.

In Hungary the new sterile vial injection manufacturing and packaging plants and a high-bay warehouse were completed, but they did not become operational during the year under review. In order to modernise manufacturing conditions of ampoule products we commenced another greenfield investment. This project remains in the detailed construction design phase. At our Dorog site we continued a programme aiming towards the manufacturing and preparative chromatographic purification of steroid intermediates and active ingredients. This programme is expected to be completed in stages over the next several years. In addition, a number of small-scale projects were completed during 2016, including the purchase of certain equipment, auxiliary and infrastructure investments as well as improvements to environmental protection and to workplace safety.

During 2016 at our Russian plant we have put in operation a vial packing line for tablets. At our Romanian subsidiary we commenced the preparation of a partial reconstruction of the production site. For our Polish subsidiary we completed the purchase of several items of equipment linked to manufacturing – tablet coating, sachet packaging, liquid filling and capsule sorting machines. We have started the implementation of a serialization project ensuring individual codes for each product for all production sites.

## 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 Department.

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 proper control at all times. It covers all the critical system-elements, so that they are integrated with each other and it involves the active participation of both 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.

The maintenance of good relationships with our partners and retaining the confidence of patients and doctors in Richter products is of foremost importance to the Company. Therefore, we place great emphasis on investigating every comment and complaint received and preventing 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 2016 we successfully passed customer audits conducted by 18 partners and completed 5 inspections at our Budapest, Dorog and Debrecen sites. Audits confirmed our high-level GMP compliance and reliability. As a result of the successfully completed Russian inspection conducted by the State Institute of Medicine and Good Practices, we received the Russian GMP certificate which is crucial for marketing authorizations and renewals. Additionally, the Agency for Management System Certification, Moscow, extended our ISO9001 certificate following their inspection. At our Budapest and Dorog sites the National Institute of Pharmacy and Nutrition carried out a comprehensive inspection including our API and finished products manufacturing, which resulted in the extension of our GMP/GDP certificates and API manufacturing license. At our Dorog site we passed the FDA inspection without notice which also contributed to the Company's positive status.



## 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.

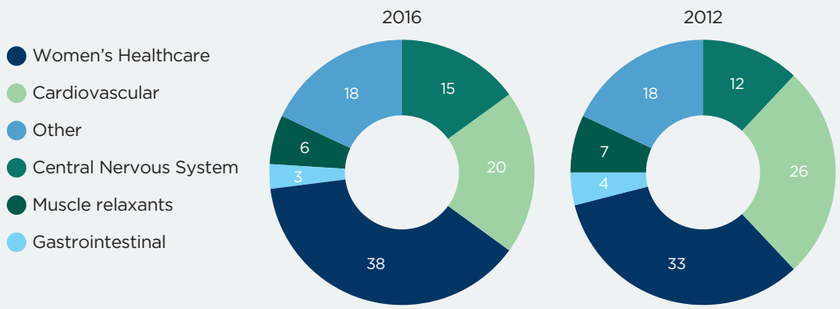
**Main licencing-in partners of Richter**

| Company | Country | Product | Therapeutic area |
|---|---|---|---|
| Acrux | Australia | LENZETTO® | Women's Healthcare |
| Allergan (earlier Forest / Actavis) | Ireland | Several products | Gastrointestinal, Urology, Women's Healthcare |
| Almirall Prodesfarma | Spain | AFLAMIN | Non-steroid antiinflammatory |
| Astellas | Japan | SUPRAX | Antibiotic |
| Bayer | Germany | LISVY® | Women's Healthcare, oral contraceptives |
| Biogen Idec | USA | AVONEX, TYSABRI | Central Nervous System, sclerosis multiplex |
| Helm | Germany | FENTANYL patch, ANASTAZOL, LETROZOL | Oncology |
| Janssen | Belgium | Several products | Central Nervous System, Antifungal, Antibacterial |
| Medinova | Switzerland | FLUOMIZIN | Women's Healthcare, anti-infective, antiseptic |
| ProStrakan | United Kingdom | LUNALDIN | Oncology |
| Sanofi-Aventis | France | TARIVID | Antibiotic |

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 2016 originated from the three largest therapeutic categories. Products belonging to the therapeutic areas of Gynaecological, Cardiovascular and Central Nervous System together generated 73 percent of total pharmaceutical sales.

Cardiovascular drugs showed a sales decline in 2016, although still accounting for 20 percent of total pharmaceutical sales. The cardiac therapy PANANGIN (asparaginates) the leading product in this therapeutic area, decreased by 12.8 percent in 2016 as sales declined in Russia, the main market for this product. Although sales of VEROSPIRON (spironolactone) increased slightly during the reported year, the turnover of ACE inhibitors (DIROTON / LISOPRESS / EDNYT) declined due to stagnating RUB sales recorded in Russia. The turnover of antihypertensive EKVATOR / LISONORM / DIRONORM decreased substantially compared to 2015 as a result of a decline in Ukraine. However the cholesterol lowering XETER / MERTENIL / ZARANTA (rosuvastatin) sales increased by 8.9 percent in 2016 thanks to sales growth primarily in the CIS region.

### Products by therapeutic groups (%)




Central Nervous System related drugs contributed altogether 15 percent of total pharmaceutical sales and showed an increase of 16.6 percent compared to 2015. Royalty income of 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 8.3 percent compared with the previous year primarily due to higher sales levels in China. LUNALDIN / DOLFORIN (fentanyl), an opioid analgesic drug recorded 12.1 percent sales growth due to the good sales performance primarily in Romania. Furthermore a number of products also showed sales growth during the reported period, notably the gabapentin containing GORDIUS, the analgesic FASCONAL and the antiepileptic LAMOLEP.

Muscle relaxant drugs amounted to 6 percent of total pharmaceutical revenue of the Group in 2016. Sales of the original product MYDETON / MYDOCALM (tolperisone) increased by 3.3 percent in the reported period primarily due to higher sales in Russia.

Gastrointestinal products represented 3 percent of total pharmaceutical sales led by the $H_2$-blocker QUAMATEL (famotidine) in 2016.

**TOP 10 products**

| | | | 2016 | 2015 | Change | |
|---|---|---|---|---|---|---|
| **Brand name** | **Active ingredient** | **Therapeutic area** | **HUFm** | **HUFm** | **HUFm** | **%** |
| Oral contraceptives | hormones | Women's Healthcare, oral contraceptives | 87,002 | 90,680 | (3,678) | (4.1) |
| CAVINTON | vinpocetine | Central Nervous System, nootropic | 28,760 | 26,567 | 2,193 | 8.3 |
| ESMYA® | ulipristal acetate | Women's Healthcare, uterine myoma | 21,504 | 15,406 | 6,098 | 39.6 |
| MYDETON | tolperisone | Muscle relaxant | 17,647 | 17,086 | 561 | 3.3 |
| PANANGIN | asparaginates | Cardiovascular, cardiac therapy | 13,150 | 15,084 | (1,934) | (12.8) |
| VEROSPIRON | spironolactone | Cardiovascular, diuretic | 12,239 | 12,012 | 227 | 1.9 |
| GROPRINOSIN | inosine pranobex | Antiviral | 9,108 | 6,286 | 2,822 | 44.9 |
| LISOPRESS | lisinopril | Cardiovascular, antihypertensive | 8,978 | 9,624 | (646) | (6.7) |
| AFLAMIN* | aceclofenac | Non-steroid antiinflammatory | 7,562 | 7,042 | 520 | 7.4 |
| LISONORM | lisinopril + amlodipine | Cardiovascular, antihypertensive | 7,175 | 8,556 | (1,381) | (16.1) |
| **Subtotal** | | | **213,125** | **208,343** | **4,782** | **2.3** |
| Other | | | 110,714 | 100,567 | 10,147 | 10.1 |
| **Total** | | | **323,839** | **308,910** | **14,929** | **4.8** |
| **Share of the TOP 10 products** | | | **65.8%** | **67.4%** | | |

Note: *Licenced-in product.

In line with Group strategy the product portfolio has been successfully enhanced and it is under continuous renewal. This focus continues through withdrawing low volume and low margin products and introducing new products with improved profitability. Progress by the Group in launching new products continued in 2016.

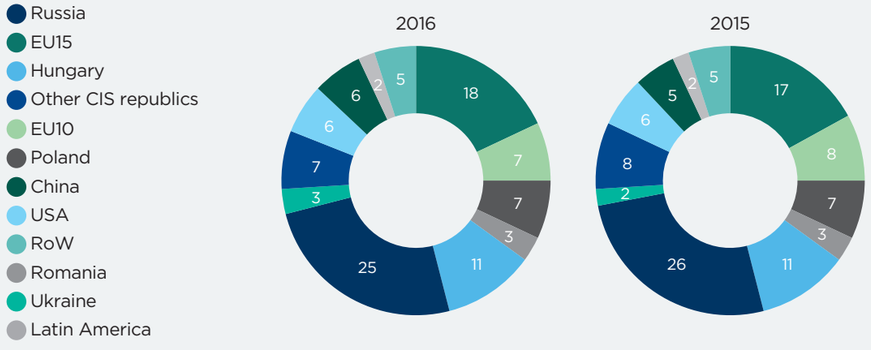
## e) Sales by Markets

Sales in the pharmaceutical segment in 2016 totalled HUF 323,839 million (EUR 1,039.7 million), representing an increase of 4.8 percent in HUF terms (4.2 percent in Euro terms) when compared to 2015.

| Sales by region | 2016 | 2015 | Change | | 2016 | 2015 | Change | |
|---|---|---|---|---|---|---|---|---|
| | HUFm | HUFm | HUFm | % | EURm | EURm | EURm | % |
| **Hungary** | **34,979** | **34,038** | **941** | **2.8** | **112.3** | **109.9** | **2.4** | **2.2** |
| **EU*** | **114,631** | **107,378** | **7,253** | **6.8** | **368.0** | **346.7** | **21.3** | **6.1** |
| Poland | 22,220 | 21,577 | 643 | 3.0 | 71.3 | 69.7 | 1.6 | 2.3 |
| Romania | 9,606 | 8,898 | 708 | 8.0 | 30.8 | 28.7 | 2.1 | 7.3 |
| EU 10 | 23,825 | 24,150 | (325) | (1.3) | 76.5 | 78.0 | (1.5) | (1.9) |
| EU 15 | 58,980 | 52,753 | 6,227 | 11.8 | 189.4 | 170.3 | 19.1 | 11.2 |
| **CIS** | **111,598** | **111,964** | **(366)** | **(0.3)** | **358.3** | **361.6** | **(3.3)** | **(0.9)** |
| Russia | 80,240 | 79,781 | 459 | 0.6 | 257.6 | 257.7 | (0.1) | 0.0 |
| Ukraine | 9,216 | 8,235 | 981 | 11.9 | 29.6 | 26.6 | 3.0 | 11.3 |
| Other CIS republics | 22,142 | 23,948 | (1,806) | (7.5) | 71.1 | 77.3 | (6.2) | (8.0) |
| **USA** | **18,813** | **18,103** | **710** | **3.9** | **60.4** | **58.5** | **1.9** | **3.2** |
| **China** | **21,616** | **16,849** | **4,767** | **28.3** | **69.4** | **54.4** | **15.0** | **27.6** |
| **Latin America** | **5,819** | **5,997** | **(178)** | **(3.0)** | **18.7** | **19.3** | **(0.6)** | **(3.1)** |
| **Rest of the World** | **16,383** | **14,581** | **1,802** | **12.4** | **52.6** | **47.1** | **5.5** | **11.7** |
| **Total** | **323,839** | **308,910** | **14,929** | **4.8** | **1,039.7** | **997.5** | **42.2** | **4.2** |

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

### Sales analysis by region (%)




## Hungary

Hungary's economy recorded a moderate 2.0 percent GDP growth in 2016. Strong domestic demand, record-low interest rates and a solid labour market contributed the most to the performance achieved. Consumer prices rose by 0.4 percent on average while the unemployment rate decreased by 1.7 percentage points to 5.1 percent, a multi-year low compared to previous years. The pharmaceutical market followed the positive trend and, according to market research data, increased by 3.3 percent.

In Hungary sales totalled HUF 34,979 million (EUR 112.3 million) in 2016, a slight increase of 2.8 percent in HUF terms (2.2 percent in Euro terms) when compared to 2015. A number of products showed significant sales growth during the reported period, notably SUPRAX, ESMYA®, VIDOTIN KOMB and DUAMILD.

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 in Hungary. Price cuts applied with effect from 1 October 2016 are expected to amount to an annual revenue loss of approximately HUF 35 million.

Retail sales of Richter products increased by 5.4 percent compared to 2015. Richter is now the third player on the Hungarian pharmaceutical market with a 5.4 percent share, based on the latest available market audit (IMS) data for the twelve months to December 2016. When considering only the market for retail prescription drugs, Richter qualified 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. Extraordinary taxes levied on the industry are reclaimable at a maximum rate of 90 percent subject to adequate R&D expenditures and employment levels being maintained. Given its high level of such expenses Richter qualifies for this maximum allowance. Furthermore by virtue of the law, the R&D linked allowances may be carried over across calendar years.

The methodology for the tax calculations in respect of healthcare budget overspending was amended with effect from 1 January 2016, which did not result in any additional tax paying obligation in Richter's case.

| New products launched in Hungary during 2016 | | | |
|---|---|---|---|
| **Brand name** | **Active ingredient** | **Therapeutic area** | **Launch date** |
| FLAMBORIN* | metamizole sodium | Central Nervous System, analgetic | Q1 2016 |
| LENZETTO®** | estradiol | Women's Healthcare, hormone replacement therapy (spary) | Q1 2016 |
| XILOMARE* | xylometazoline | Respiratory | Q1 2016 |
| ANTACLAST* | cilostazol | Antithrombotic | Q2 2016 |
| NIBIX* | imatinib | Oncology, anticancer | Q4 2016 |
| POLITRATE DEPOT* | leuproreline | Urology, Oncology, anticancer | Q4 2016 |

Note: *Licenced-in products.

## TOP 10 products in Hungary

| | | | 2016 | 2015 | Change | |
|---|---|---|---|---|---|---|
| **Brand name** | **Active ingredient** | **Therapeutic area** | **HUFm** | **HUFm** | **HUFm** | **%** |
| Oral contraceptives | hormones | Women's Healthcare, oral contraceptive | 3,076 | 3,168 | (92) | (2.9) |
| CAVINTON | vinpocetine | Central Nervous System, nootropic | 2,046 | 1,983 | 63 | 3.2 |
| QUAMATEL | famotidine | Gastrointestinal, antiulcer | 1,661 | 1,594 | 67 | 4.2 |
| XETER | rosuvastatin | Cardiovascular, cholesterol-lowering | 1,568 | 1,567 | 1 | 0.1 |
| PANANGIN | asparaginates | Cardiovascular, cardiac therapy | 1,085 | 1,065 | 20 | 1.9 |
| LAMOLEP | lamotrigine | Central Nervous System, antiepileptic | 1,040 | 971 | 69 | 7.1 |
| AKTIL* | amoxicillin + clavulanic acid | Antibiotic | 1,006 | 994 | 12 | 1.2 |
| TANYDON | telmisartan + hydrochlorothiazide | Cardiovascular, antihypertensive | 1,001 | 946 | 55 | 5.8 |
| LISONORM | lisinopril + amlodipine | Cardiovascular, antihypertensive | 956 | 1,055 | (99) | (9.4) |
| ESMYA® | ulipristal acetate | Women's Healthcare, uterine myoma | 906 | 710 | 196 | 27.6 |
| **Subtotal** | | | **14,345** | **14,053** | **292** | **2.1** |
| Other | | | 20,634 | 19,985 | 649 | 3.2 |
| **Total** | | | **34,979** | **34,038** | **941** | **2.8** |
| **Share of the TOP 10 products in Hungary** | | | **41.0%** | **41.3%** | | |

Note: *Licenced-in product.

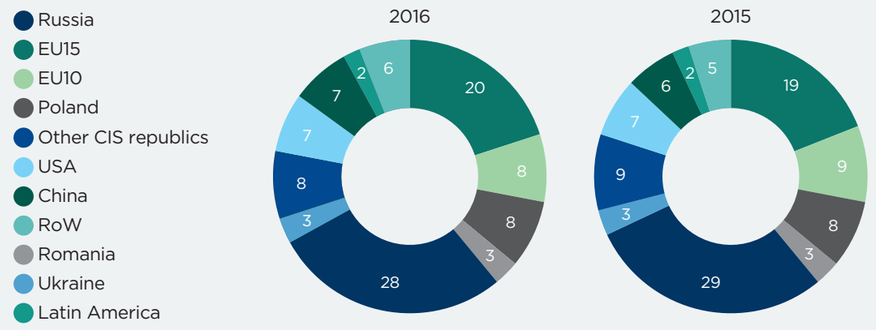
## International Sales

International sales amounted to EUR 927.4 million in 2016, an increase of EUR 39.8 million or 4.5 percent compared to 2015. Sales to the CIS totalled EUR 358.3 million (US$ 396.8 million), a decline of 0.9 percent (1.1 percent in US$ terms) compared to the sales levels achieved in 2015. As a result of the adverse FX environment which prevailed across the CIS region lower sales levels were recorded in Other CIS republics while stagnating EUR denominated sales incurred in Russia. An increase of 11.2 percent in US$ terms was reported in Ukraine compared to 2015, although from a very low base. The increase in turnover reported for the EU region (6.1 percent in Euro terms) was primarily driven by higher sales levels recorded in EU15 countries and in Romania. Sales recorded in the USA increased by 3.2 percent both in US$ terms and in EUR terms. Sales to China amounted to EUR 69.4 million in 2016, 27.6 percent higher than in 2015. Turnover reported in the Rest of the World region increased by 11.7 percent in EUR terms in 2016 when compared to the base year.

## Sales to TOP 10 international markets

| | 2016 | 2015 | Change | |
|---|---|---|---|---|
| | **EURm** | **EURm** | **EURm** | **%** |
| Russia | 257.6 | 257.7 | (0.1) | 0.0 |
| Poland | 71.3 | 69.7 | 1.6 | 2.3 |
| China | 69.2 | 54.1 | 15.1 | 27.9 |
| Germany | 63.7 | 64.0 | (0.3) | (0.5) |
| USA | 60.4 | 58.5 | 1.9 | 3.2 |
| Romania | 30.8 | 28.7 | 2.1 | 7.3 |
| Ukraine | 29.6 | 26.6 | 3.0 | 11.3 |
| Spain | 23.3 | 16.4 | 6.9 | 42.1 |
| Czech Republic | 22.8 | 23.9 | (1.1) | (4.7) |
| France | 22.7 | 21.0 | 1.7 | 8.4 |
| **Subtotal** | **651.4** | **620.6** | **30.8** | **5.0** |
| **Total international sales** | **927.4** | **887.6** | **39.8** | **4.5** |
| **Share of the TOP 10 international markets** | **70.2%** | **69.9%** | | |

### International sales analysis by region (%)

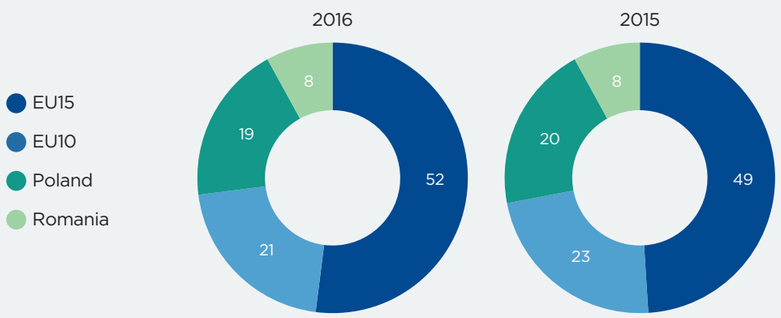


## European Union

Sales in the European Union, excluding Hungary, amounted to EUR 368.0 million in 2016, representing an increase of 6.1 percent when compared to 2015.

The reported sales growth for the EU was mostly due to good growth recorded in the EU15 region, despite the fact that the Group continued to face strong competition and sustained pressure from governments which together resulted in year-on-year both lower prices and reimbursement levels. Higher sales levels of ESMYA® in the EU15 region contributed strongly to the turnover growth.

### Sales to the EU (%)




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

Following the strong GDP growth rate acceleration over recent years, Poland's economy lost momentum during 2016 and recorded a growth rate of 2.8 percent according to the preliminary estimate by Central Statistical Office of Poland. However the Group sales increased by 6.9 percent in PLN terms (2.3 percent in EUR terms) and reached PLN 311.4 million (EUR 71.3 million) in 2016. The main contributor to the sales increase was the strong flu season that impacted positively the sales of our leading product, GROPRINOSIN. Furthermore a number of products showed sales growth during the reported period, notably GROFIBRAT (GROFIBRAT S), LISIPROL and CAVINTON.

Romania's GDP continued to grow by 4.8 percent in 2016, driven by strong domestic consumption, low interest rates and labour market improvements. Nevertheless the government is facing a crucial challenge keeping the budget deficit under control. In line with the positive macro environment, sales to this country amounted to RON 138.6 million (EUR 30.8 million) in 2016, an increase of 8.8 percent in RON terms (7.3 percent in EUR terms) compared with the turnover reported for 2015. Sales of LUNALDIN, CAVINTON, FASCONAL and OSSICA contributed the most to the sales growth achieved during 2016.

**New products launched in Central and Eastern Europe during 2016**

| Brand name | Active ingredient | Therapeutic area | Launch date |
|---|---|---|---|
| RABAKIR | pregabalin | Central Nervous System, antiepileptic | Q1 2016 |
| LENZETTO®[1] | estradiol | Women's Healthcare, hormone replacement therapy (spray) | Q1 2016 |
| LISVY®[1] | gestodene + EE[2] | Women's Healthcare, contraceptive (patch) | Q1 2016 |
| RESTIGULIN | aripiprazole | Central Nervous System, antipsychotic | Q1 2016 |
| BEATIL | amlodipine + perindopril | Cardiovascular, antihypertensive | Q3 2016 |
| BEMFOLA® | follitropin alfa | Women's Healthcare, female fertility | Q4 2016 |
| DAYLETTE | drospirenone + 20 mcg EE[2] | Women's Healthcare, oral contraceptive | Q4 2016 |
| VIOLETTA | gestodene + EE[2] | Women's Healthcare, oral contraceptive | Q4 2016 |

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

Strong competition and various austerity measures introduced by local governments characterised continuously the EU10 region in 2016. Group sales totalled EUR 76.5 million in the reported year, 1.9 percent lower when compared to the previous year. This region represented 21 percent of total EU region sales of the Group's pharmaceutical segment.

Following an outstanding expansion in 2015, the Czech economy recorded a slowdown with a 2.3 percent growth rate mainly due to a decline in EU investment funds. Turnover on this market amounted to CZK 616.1 million (EUR 22.8 million) in 2016, representing a 5.4 percent decline in CZK terms (4.7 percent in EUR terms) compared to the sales level achieved in 2015. Turnover of the range of oral contraceptives, VEROSPIRON, LUNALDIN and MERTENIL contributed the most to the turnover achieved. According to the latest flash estimates Slovakia's GDP growth continued in 2016 at a rate of 3.3 percent, driven by strong domestic demand and growing automotive industry, whilst the employment rate increased by more than 2.0 percent year-on-year over the past quarters. In spite of this positive macro environment, our turnover amounted to EUR 18.4 million in 2016, 1.5 percent lower when compared to 2015. Sales of oral contraceptives, CAVINTON, SUPRAX and ESMYA® contributed the most to the turnover achieved during the reported period. In the Baltic States sales amounted to EUR 14.1 million in 2016, EUR 1.4 million lower when compared to 2015. The primary reason for the substantial year-on-year decline was the termination in March 2015 of the licensing agreement for AVONEX and a change implemented in our distribution channel in these countries with effect from 1 January 2016. In Bulgaria sales totalled EUR 16.8 million in the reported period, representing a slightly (1.2 percent) higher performance when compared with turnover achieved in 2015.

In the EU15 region sales amounted to EUR 189.4 million in 2016, 11.2 percent higher than in the previous year. This region contributed 51 percent of total EU pharmaceutical sales.

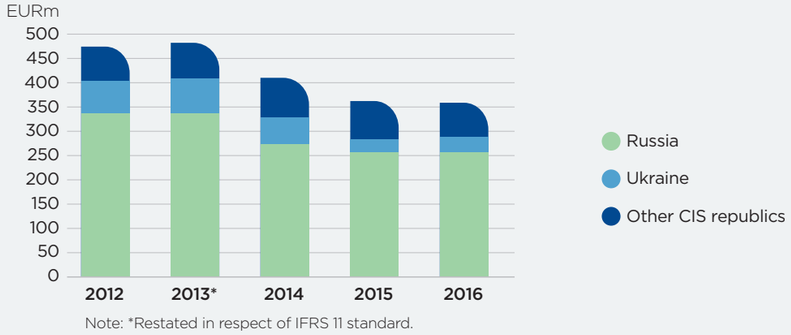
In Germany, the largest market for the Group in the region, the reported sales of EUR 63.7 million in 2016 was 0.5 percent lower than in the base period. Robust growth of ESMYA® was more than offset by declining sales of OCs as a consequence to negative media campaigns linked to potential side effects of OCs in general, drospirenones in particular. According to IMS market intelligence the overall OC market also declined in Germany. Turnover in Spain totalled EUR 23.3 million in 2016, exceeding the base period by EUR 6.9 million, mainly due to higher ESMYA® sales. BEMFOLA® also contributed to achieved turnover levels. In France the Group's turnover amounted to EUR 22.7 million, 8.4 percent higher than in the base period primarily due to higher sales levels of ESMYA®. Sales in Italy amounted to EUR 21.1 million in 2016, representing a 14.6 percent increase compared with 2015. Sales in the UK were GBP 17.7 million (EUR 21.1 million), an increase of 16.1 percent in GBP terms (decline of 0.1 percent in EUR terms) when compared to the previous year. Turnover in the Benelux countries were EUR 14.7 million, while sales in Portugal amounted to EUR 10.1 million, EUR 2.7 million higher than in the base period, mainly due to the good sales performance of the range of oral contraceptives and ESMYA®.

## CIS

Sales to the CIS in 2016 totalled EUR 358.3 million, representing a decline of EUR 3.3 million (0.9 percent) compared to the sales levels achieved in the previous year.

According to a flash estimate published by the Federal State Statistics Service (Rosstat), the economy contracted by 0.2 percent in 2016. Following a depreciation of the Rouble against the Euro prevailing until mid February and peaking at EURRUB 90, the Russian currency strengthened to just below EURRUB 64 by the end of December 2016. In spite of a weak performance compared to the previous year, 2016 has seen generally increasing oil prices which closed the year as high as just above 55 US$/barrel. The improving economic environment together with a tight monetary policy successfully brought down inflation to 5.4 percent by the end of December according to the Russian Statistical Office. Sales totalled RUB 19.2 billion (EUR 257.6 million) in 2016, 12.8 percent higher in RUB terms (unchanged in EUR terms). The higher sales achieved resulted from a price increase which was applied during the first quarter 2016 to certain products of our portfolio (which, when projected across the entire range of products, resulted in an average 4 percent price increase) and higher sales volumes reported. In addition, an improving product mix and a higher share of the Women's Healthcare franchise also contributed to the higher turnover achieved. During 2016 the year-on-year devaluation (12.8 percent) of the average exchange rate of the Rouble against the Euro impacted adversely our sales performance in Russia. Good sales performances of the range of oral contraceptives, MYDOCALM, VEROSPIRON, AIRTAL and GROPRINOSIN contributed the most to the higher RUB turnover achieved.

### Sales to the CIS




Note: *Restated in respect of IFRS 11 standard.

Sales to Ukraine amounted to US$ 32.8 million (EUR 29.6 million) in 2016, an increase of US$ 3.3 million (EUR 3.0 million) compared to the turnover reported in 2015, although from a very low base. A more strict receivables control and voluntary shipment restrictions were implemented by the Company as a reaction to the recent political turmoil and the deep economic recession which have characterised the country since the beginning of 2014. By the end of 2016, the local currency, UAH, had devalued against the US$ by 17.3 percent year-on-year.

Sales in Other CIS republics totalled EUR 71.1 million (US$ 78.7 million) in 2016, representing a decrease of EUR 6.2 million (US$ 7.1 million) compared to 2015. Oil and natural gas prices remained below their levels recorded two years ago which combined with currency devaluations in most of the countries have negatively impacted the overall performance of this region. Notwithstanding this economic background, sales growth was achieved when reported in Euro terms in Moldavia and in Kyrgyzstan, although from a low base. In mid August 2015 the Kazakh Tenge (KZT) was floated which resulted in a more volatile FOREX environment. Sales declines, resulting from deteriorating exchange rates and weaker market performance, prevailed in most of the countries of the region, primarily in Belarus and in Kazakhstan with the latter experiencing a sharply declining (by 73.3 percent) EURKZT average exchange rate by the end of December 2016 when compared with the base year.

**New products launched in the CIS republics during 2016**

| Brand name | Active ingredient | Therapeutic area | Launch date |
|---|---|---|---|
| BELARA | chlormadinone + 30 mcg EE[2] | Women's Healthcare, oral contraceptive | Q1 2016 |
| BIDOP | bisoprolol | Cardiovascular, antihypertensive | Q1 2016 |
| EKVAMER | amlodipine + lisinopril + rosuvastatin | Cardiovascular, cardiac therapy | Q1 2016 |
| RAENOM | ivabradine | Cardiovascular, cardiac therapy | Q1 2016 |
| AMLODIPINE-PERINDOPRIL-RICHTER | amlodipine + perindopril | Cardiovascular, antihypertensive | Q2 2016 |
| AERTAL creme[1] | aceclofenac | Non-steroid anti-inflammatory | Q2 2016 |
| PREGABALIN-RICHTER | pregabalin | Central Nervous System, antiepileptic | Q2 2016 |
| MEMANTIN-RICHTER | memantine | Central Nervous System, Alzheimer's disease | Q3 2016 |
| MIRVEDOL | memantine | Central Nervous System, Alzheimer's disease | Q4 2016 |

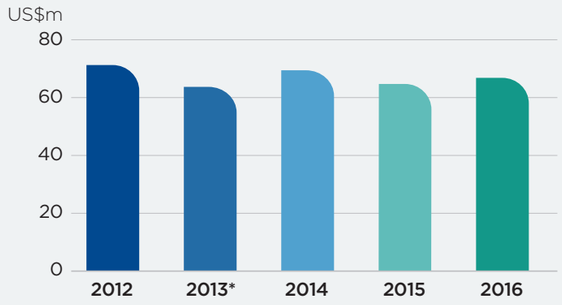
Notes:
[1] Licenced-in product.
[2] Ethynil estradiol

## USA

Sales in the USA totalled US$ 66.9 million (EUR 60.4 million) in 2016, an increase of 3.2 percent both in US$ terms and in EUR terms. Proceeds from our emergency contraceptives contributed substantially to the sales levels achieved in 2016. Revenues resulting from oral contraceptive related profit sharing agreements, nevertheless, declined substantially due to increased generic competition.

Royalty income of US$ 17.3 million (EUR 15.6 million) related to the full year 2016 sales performance of cariprazine (VRAYLAR™) contributed materially to the sales levels achieved during the reported period.

### Sales to the USA




Note: *Restated in respect of IFRS 11 standard.

## China

Sales to China amounted to EUR 69.4 million in 2016, 27.6 percent higher than in 2015, Turnover of CAVINTON and ESCAPELLE contributed the most to the sales growth recorded. The sales figure reported for our emergency contraceptive reflects the impact of the full inclusion as of January 2016 into the Group consolidation of the joint venture which distributes this product.

## Latin America

Sales in Latin American countries amounted to US$ 20.7 million in 2016, a decrease of 3.7 percent when compared to 2015. Devaluation of local currencies and a more competitive pricing environment had a negative effect on market developments.

## Rest of the World

Sales in these countries totalled EUR 52.6 million (US$ 58.3 million) in 2016, an increase of 11.7 percent both in EUR terms and in US$ terms when compared to 2015. This significant growth was the combined result of higher ESMYA® sales primarily to Canada, BEMFOLA® sales first included into the consolidation during the reported year and higher turnover achieved by range of oral contraceptives mostly in Vietnam.



## Women's Healthcare

In recognition of the strategic importance of this therapeutic area to the Company a brief presentation of the Women's Healthcare (WH) franchise is provided below. This therapeutic area includes the following product groups and therapeutic indications: oral contraceptives and contraceptive patch, emergency contraceptives, contraceptive devices; menopausal care, pregnancy care and obstetrics, gynaecological infections and other gynaecological conditions, including the treatment of uterine myomas.

Women's Healthcare sales totalled EUR 400.1 million in 2016, an increase of 4.7 percent compared to the levels reported in 2015 Total turnover generated from Richter's range of own developed oral contraceptive portfolio amounted to EUR 229.2 million, EUR 13.0 million lower when compared to 2015, primarily due to increasing generic competition experienced in the USA and across Central and Eastern Europe. Turnover arising from the OC portfolio acquired in 2010 amounted to EUR 46.7 million, EUR 3.1 million below the base period figure. ESMYA® sales amounted to EUR 69.0 million in 2016, compared to the EUR 49.8 million turnover recorded in 2015.

**Women's Healthcare sales by region**

| | 2016 | 2015 | Change | | 2016 | 2015 | Change | |
|---|---|---|---|---|---|---|---|---|
| | HUFm | HUFm | HUFm | % | EURm | EURm | EURm | % |
| **Hungary** | **5,064** | **5,023** | **41** | **0.8** | **16.3** | **16.2** | **0.1** | **0.6** |
| **EU*** | **60,428** | **56,547** | **3,881** | **6.9** | **194.0** | **182.6** | **11.4** | **6.2** |
| Poland | 2,931 | 3,620 | (689) | (19.0) | 9.4 | 11.7 | (2.3) | (19.7) |
| Romania | 2,220 | 2,051 | 169 | 8.2 | 7.1 | 6.6 | 0.5 | 7.6 |
| EU 10 | 7,251 | 7,499 | (248) | (3.3) | 23.3 | 24.2 | (0.9) | (3.7) |
| EU 15 | 48,026 | 43,377 | 4,649 | 10.7 | 154.2 | 140.1 | 14.1 | 10.1 |
| **CIS** | **27,751** | **27,236** | **515** | **1.9** | **89.1** | **88.0** | **1.1** | **1.3** |
| Russia | 22,326 | 21,292 | 1,034 | 4.9 | 71.7 | 68.8 | 2.9 | 4.2 |
| Ukraine | 1,824 | 1,876 | (52) | (2.8) | 5.9 | 6.1 | (0.2) | (3.3) |
| Other CIS republics | 3,601 | 4,068 | (467) | (11.5) | 11.5 | 13.1 | (1.6) | (12.2) |
| **USA** | **11,997** | **14,779** | **(2,782)** | **(18.8)** | **38.5** | **47.7** | **(9.2)** | **(19.3)** |
| **China** | **6,569** | **4,029** | **2,540** | **63.0** | **21.1** | **13.0** | **8.1** | **62.3** |
| **Latin America** | **4,772** | **4,718** | **54** | **1.1** | **15.3** | **15.3** | **0.0** | **0.0** |
| **Rest of the World** | **8,018** | **6,047** | **1,971** | **32.6** | **25.8** | **19.5** | **6.3** | **32.3** |
| **Total** | **124,599** | **118,379** | **6,220** | **5.3** | **400.1** | **382.3** | **17.8** | **4.7** |

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

## Hungary

In Hungary WH sales totalled HUF 5,064 million (EUR 16.3 million) in 2016, representing a slight increase of 0.8 percent in HUF terms (0.6 percent in EUR terms) compared to the levels reported in the previous year. Sales of ESMYA® were initiated in Hungary in May 2012 and the product was granted 90 percent reimbursed status in February 2013. Reimbursed status for the intermittent use in the long-term management of uterine fibroids of ESMYA® was granted in September 2015. Its turnover during the reported period amounted to HUF 906 million (EUR 2.9 million).

## European Union

WH sales in the European Union, excluding Hungary, amounted to EUR 194.0 million in 2016, representing an increase of EUR 11.4 million (6.2 percent) when compared to 2015.

Sales of ESMYA®, our original product, were EUR 56.0 million during the reported year, EUR 14.4 million (34.5 percent) higher than in the base period.

Sales of WH products represented 53 percent of the turnover in this region in 2016.

WH sales in Poland decreased by 15.9 percent in PLN terms (19.7 percent in EUR terms) to PLN 41.4 million (EUR 9.4 million) in 2016, as a consequence of high levels of parallel import and an environment of sustained price erosion. Turnover in Romania increased by RON 2.7 million (EUR 0.5 million) and amounted to RON 32.0 million (EUR 7.1 million) during the reported year.

In the EU10 region WH sales totalled EUR 23.3 million in 2016, EUR 0.9 million (3.7 percent) below the levels recorded in the previous year. With respect to WH sales the EU10 countries altogether represented 12 percent of the Group's WH sales to the whole EU region.

In the EU15 Member States WH sales amounted to EUR 154.2 million in 2016, showing a EUR 14.1 million (10.1 percent) growth over the levels recorded in the previous year. This region contributed 79 percent of total EU WH sales.

In Germany Richter Group reported Women's Healthcare sales of EUR 46.5 million, 7.5 percent below the levels reported in 2015. Due to a negative media campaign related to hormonal contraceptives in general by the end of 2016 the overall market of contraceptives contracted by 6 percent (measured in cycles) year-on-year. Notwithstanding the above, sales of ESMYA® had grown by EUR 3.4 million by the end of 2016 year-on-year.

In Spain the Group's turnover arising from WH products amounted to EUR 22.1 million, EUR 7.5 million higher than in the base period. The year-on-year increase was primarily due to higher sales levels of ESMYA® and the good performance of BEMFOLA®.

In Italy the Group realised a WH turnover of EUR 19.6 million, EUR 3.0 million above the levels recorded in 2015.

In France Richter Group achieved Women's Healthcare sales of EUR 19.4 million in the reported period, EUR 1.9 million above the levels reported in 2015.

WH sales in the UK totalled GBP 16.2 million (EUR 19.3 million), an increase of 19.5 percent (2.4 percent in EUR terms) compared to the base period primarily due to higher ESMYA® sales.

In Portugal the Group achieved EUR 9.6 million sales of WH products, EUR 3.5 million above the turnover recorded in 2015.

Sales of WH products represented 81 percent of the turnover in the EU15 region during 2016, a creditable performance by the recently established sales force teams.



## CIS

WH sales to the CIS in 2016 totalled EUR 89.1 million representing an increase of 1.3 percent from the sales levels achieved in 2015. In RUB terms sales to Russia, within the region, reached RUB 5,328.3 million, showing an increase of RUB 798.2 million or 17.6 percent due to the positive impact of a price increase and the higher sales level of a range of oral contraceptives. ESMYA® also contributed to the turnover reported.

Turnover of WH products represented 25 percent of total CIS sales in the reported period.

## USA

WH sales in the USA totalled US$ 42.6 million (EUR 38.5 million) in 2016, a US$ 10.3 million (EUR 9.2 million) decline when compared to the previous year. Proceeds from our emergency contraceptives contributed substantially to the sales levels achieved in 2016. Revenues resulting from oral contraceptive related profit sharing agreements, nevertheless, declined substantially due to increased generic competition.

Sales of WH products, including the profit sharing related to drospirenone, represented 64 percent of US sales.

## China

Sales of WH totalled EUR 21.1 million in the reported year, EUR 8.1 million higher than in 2015. The substantial increase was primarily due to the impact of the full inclusion as of January 2016 into the Group consolidation of the joint venture which distributes our emergency contraceptive, ESCAPELLE.

## Latin America

Sales of WH totalled US$ 17.0 million in 2016, showing a virtually flat performance (increase of US$ 0.1 million) when compared to the previous year. Devaluation of local currencies and a more competitive pricing environment had a negative effect on market developments.

## Rest of the World

WH sales in these countries amounted to EUR 25.8 million (US$ 28.5 million) in 2016, an increase of EUR 6.3 million (US$ 6.8 million) when compared to the previous year. The significant growth was the combined result of higher ESMYA® sales primarily to Canada, BEMFOLA® sales first included into the consolidation during the reported year and higher turnover achieved by range of oral contraceptives mostly in Vietnam.


## 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, this 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 11,000 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-quality, rewarding employment;
- valuing our employees and protecting their safety;
- ensuring access to our products for those who need them;
- minimising the environmental impact of our products and operations;
- supporting community-based projects and encouraging innovation in science.

### Environmental Protection

Our role as a healthcare provider is not limited to providing medications to patients. We recognise that the environment that people live in is as much 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. The IPPC permit for our Dorog facility is has been granted by the relevant authority in 2016.

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. 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, which was 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 2016. The elimination of ground water contamination required by the relevant authorities continued in 2016 at our Vecsés warehouse site. Following the evaluation of the necessary documents, an intervention plan aimed at the elimination of ground water contamination at our Budapest site is expected to be prepared in 2017. The hazardous waste treatment facility at our Debrecen site was completed during the year under review, which meets the needs of a future plant expansion. The continuous upgrade of our facilities treating waste water disposal at the Dorog site was ongoing in 2016.

## Health and Safety at Work

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

## Occupational Health and Safety Management System

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

Our Occupational Health and Safety Management System (OHSMS) in compliance with OHSAS 18001:1999 standard, was officially certified at the beginning of 2006, making Richter the first Hungarian pharmaceutical company to obtain this type of certification. Following a recent 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.

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). Following a reorganization project, the two laboratories were merged in one single organization during 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. According to this we submitted 40 REACH registration dossiers for own-developed API intermediates during the reported year out of which we assumed in 33 cases 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 2017.

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

No fatal accidents or other serious work related injuries occurred at any of our facilities during 2016.

## 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 number of these students further increased during 2016. The scope of the Foundation has been widened in order to include secondary school students, thereby providing them with future career opportunities.

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: 54 towns have benefited and 133,800 people have participated, with their presence increasing by an extra HUF 156 million Richter's initial donation. Over the seven years some 51 hospitals have received a total of HUF 250 million financial assistance from Richter. During this period specialists have carried out 114,279 screenings, out of which 26,128 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 2016 for the third consecutive year since the award was initiated.

## 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 11,000 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.

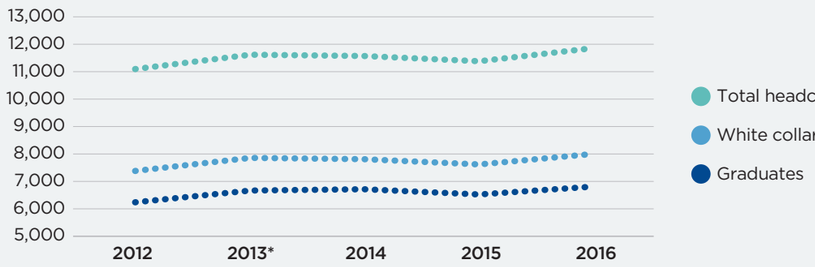
Successful and great companies are defined by people who embrace a shared sense of purpose, put extra energy and passion into their jobs and identify with common goals. That is the kind of engagement we aim for at Richter. We start from a foundation of respect; we passionately believe that a company 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 11,892 at the end of 2016, a 4.0 percent (461) increase when compared to 2015. The year on year increase was a result of integration of the joint venture Gedeon Richter Rxmidas JV Co. Ltd. and Finox Holding into Richter Group together with an increased level of personnel in manufacturing and in sales and marketing.

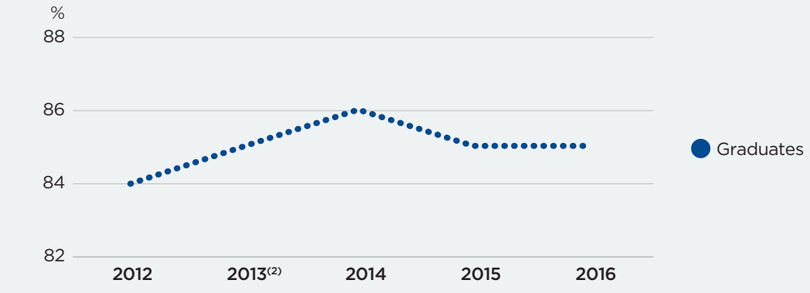
The number of skilled employees at the Group increased to 6,806 at the end of 2016, from 6,503 reported in 2015. Graduate educated personnel represented 85 percent of white collar staff and 57 percent of the total number of employees at the Group.

**Number of staff**




Note: *Restated in respect of IFRS 11 standard.

**Proportion of graduates[1]**




Notes:
[1]Within the white collar staff at the Group.
[2]Restated in respect of IFRS 11 standard.

## 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 2016 to support employees to participate in university education, including PhD courses. During 2016 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 2016 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 2016. 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 2016. 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.

- For recently appointed managers a special manager training programme was implemented 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 further expanded and thereby completed across the whole Company during 2016.

## 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 can 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, similar to that in 2014 and in 2015, Richter was again selected in 2016 as the most desired workplace in the pharmaceutical and chemical industry sector winning the "Randstad Award". Such recognition confirms that Richter's values are very much appreciated by employees in Hungary.

# 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 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 88 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 239.1 million in 2016, a 16.2 percent increase compared to the previous year.

Our Romanian subsidiaries realised 76 percent of the turnover in the Wholesale and Retail segment (RON 818.9 million), with the remainder primarily being invoiced by our subsidiaries in the CIS region. The sales increase in Romania was 23.4 percent in RON terms (21.8 percent in EUR terms) in 2016. A slow reduction in payment delays continued on the Romanian pharma market during the reported period, yet excessive delays continue to prevail in the pharma sector.

| Wholesale and retail sales | | | | | | |
|---|---|---|---|---|---|---|
| | 2016 | 2015 | Change | 2016 | 2015 | Change |
| | HUFm | HUFm | % | EURm | EURm | % |
| Hungary | 121 | 133 | (9.0) | 0.4 | 0.4 | 0.0 |
| Romania | 56,758 | 46,353 | 22.4 | 182.3 | 149.7 | 21.8 |
| Other CIS republics | 13,523 | 13,143 | 2.9 | 43.4 | 42.5 | 2.1 |
| Latin America | 4,062 | 4,062 | 0.0 | 13.0 | 13.1 | (0.8) |
| **Total** | **74,464** | **63,691** | **16.9** | **239.1** | **205.7** | **16.2** |

# 3 Group Figures

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

## a) Business Segment Information

**Business Segment Information**

| | Pharmaceuticals | | Wholesale and retail | | Other | | Eliminations | | Group total | |
|---|---|---|---|---|---|---|---|---|---|---|
| | HUFm | | HUFm | | HUFm | | HUFm | | HUFm | |
| | 2016 Audited | 2015* Restated | 2016 Audited | 2015 Audited | 2016 Audited | 2015 Audited | 2016 Audited | 2015 Audited | 2016 Audited | 2015* Restated |
| **Revenues** | **323,839** | **308,910** | **74,464** | **63,691** | **4,603** | **4,602** | **(13,216)** | **(11,983)** | **389,690** | **365,220** |
| Gross profit | 217,283 | 212,170 | 7,629 | 7,776 | 571 | 911 | 205 | (248) | 225,688 | 220,609 |
| Profit from operations | 55,204 | 66,148 | 1,158 | 893 | 151 | (98) | (1,897) | (261) | 54,616 | 66,682 |
| Share of profit of associates and joint ventures | (835) | 228 | 2,566 | 1,308 | 41 | 4 | 26 | (38) | 1,798 | 1,502 |
| Number of employees at period end | 10,073 | 9,649 | 1,475 | 1,443 | 344 | 339 | - | - | 11,892 | 11,431 |

Note: *Restated. For details see Explanatory note on page 104.

## b) Consolidated Turnover

| Sales by region | 2016 | 2015 | | Change | 2016 | 2015 | | Change |
|---|---|---|---|---|---|---|---|---|
| | HUFm | HUFm | HUFm | % | EURm | EURm | EURm | % |
| **Hungary** | **35,776** | **34,976** | **800** | **2.3** | **114.9** | **112.9** | **2.0** | **1.8** |
| **EU*** | **166,167** | **149,596** | **16,571** | **11.1** | **533.5** | **483.1** | **50.4** | **10.4** |
| Poland | 22,220 | 21,577 | 643 | 3.0 | 71.3 | 69.7 | 1.6 | 2.3 |
| Romania | 61,114 | 51,096 | 10,018 | 19.6 | 196.2 | 165.0 | 31.2 | 18.9 |
| EU 10 | 23,825 | 24,150 | (325) | (1.3) | 76.5 | 78.0 | (1.5) | (1.9) |
| EU 15 | 59,008 | 52,773 | 6,235 | 11.8 | 189.5 | 170.4 | 19.1 | 11.2 |
| **CIS** | **121,736** | **122,058** | **(322)** | **(0.3)** | **390.9** | **394.2** | **(3.3)** | **(0.8)** |
| Russia | 80,243 | 79,786 | 457 | 0.6 | 257.6 | 257.7 | (0.1) | 0.0 |
| Ukraine | 9,269 | 8,293 | 976 | 11.8 | 29.8 | 26.8 | 3.0 | 11.2 |
| Other CIS republics | 32,224 | 33,979 | (1,755) | (5.2) | 103.5 | 109.7 | (6.2) | (5.7) |
| **USA** | **18,813** | **18,103** | **710** | **3.9** | **60.4** | **58.5** | **1.9** | **3.2** |
| **China** | **21,616** | **16,849** | **4,767** | **28.3** | **69.4** | **54.4** | **15.0** | **27.6** |
| **Latin America** | **9,187** | **9,057** | **130** | **1.4** | **29.5** | **29.2** | **0.3** | **1.0** |
| **Rest of the World** | **16,395** | **14,581** | **1,814** | **12.4** | **52.6** | **47.1** | **5.5** | **11.7** |
| **Total** | **389,690** | **365,220** | **24,470** | **6.7** | **1,251.2** | **1,179.4** | **71.8** | **6.1** |

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

## c) Key Financial Data

| Key Financial Data | 2016 | 2015[3] | Change | 2016 | 2015[3] | Change |
|---|---|---|---|---|---|---|
| | HUFm | HUFm | % | EURm | EURm | % |
| Revenues | 389,690 | 365,220 | 6.7 | 1,251.2 | 1,179.4 | 6.1 |
| Gross profit | 225,688 | 220,609 | 2.3 | 724.6 | 712.4 | 1.7 |
| **Gross margin %** | **57.9** | **60.4** | | **57.9** | **60.4** | |
| Profit from operations | 54,616 | 66,682 | (18.1) | 175.4 | 215.4 | (18.6) |
| **Operating margin %** | **14.0** | **18.3** | | **14.0** | **18.3** | |
| Profit before income tax | 68,226 | 59,877 | 13.9 | 219.1 | 193.4 | 13.3 |
| Profit for the year | 67,023 | 53,863 | 24.4 | 215.2 | 173.9 | 23.7 |
| **Net margin %** | **17.2** | **14.7** | | **17.2** | **14.7** | |
| EPS (HUF, EUR)[1] | 356 | 291 | 22.3 | 1.14 | 0.94 | 21.3 |
| | | | | | | |
| Total assets and total equity and liabilities | 813,877 | 746,994 | 9.0 | 2,616.8 | 2,385.6 | 9.7 |
| Capital and reserves[2] | 681,873 | 618,389 | 10.3 | 2,192.4 | 1,974.9 | 11.0 |
| Capital expenditure | 36,453 | 33,302 | 9.5 | 117.0 | 107.5 | 8.8 |
| | | | | | | |
| Number of employees at year-end | 11,892 | 11,431 | 4.0 | | | |

Notes: [1] EPS calculations were based on the total number of shares issued.
[2] Includes non-controlling interest.
[3] Restated. For details see Explanatory note on page 104.



## d) Profit and Loss Items

Sales amounted to HUF 389,690 million (EUR 1,251.2 million) in 2016, representing a 6.7 percent increase in HUF and 6.1 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 164,002 million (EUR 526.6 million) in 2016, an increase of HUF 19,391 million (EUR 59.6 million) when compared to 2015. Amortization in 2016 of the acquired intangible asset Esmya amounted to HUF 2,887 million while amortization of another intangible asset Bemfola, acquired mid year and thus impacting only the last two quarters of the year was HUF 1,010 million.

Gross margin in 2016 at 57.9 percent declined from the 60.4 percent level reported for the previous year. The year-on-year declining Rouble exchange rate against both the Euro and HUF and lower sales levels recorded in Other CIS region, together with the amortization of intangible assets 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 and it also negatively impacted gross margin during the reported period. All the above were only partly offset by royalty income received from Allergan (earlier Forest / Actavis) in respect of VRAYLAR™ sales and the increasing turnover recorded in higher than average margin geographies of the Group, namely EU15 and China.

Sales and marketing expenses amounted to HUF 107,564 million (EUR 345.3 million) in 2016, an increase of 9.4 percent in HUF terms (8.8 percent in EUR terms) when compared with 2015. 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 were only partly offset by a decrease of such expenses in Russia, in Ukraine and in Other CIS region (notably sales force reductions in the latter two countries) together with a further devaluation 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 27.6 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 4,427 million represented 1.1 percent of sales achieved in the reported period. After adjustment for this amortization, S&M expenses represented 26.5 percent of turnover.

The annual registration fee payable in respect of medical representatives in Hungary amounted to HUF 253 million (EUR 0.8 million) in 2016. In accordance with the regulations we expect to offset the tax payable in 2016 on this ground by 90 percent of the tax liability of the same kind incurred during 2015.

Administration and general expenses totalled HUF 20,339 million (EUR 65.3 million) in 2016, representing a 4.9 percent increase in HUF terms (4.3 percent in EUR terms) when compared with the level recorded in the previous year. These expenses grew due to higher legal assistance and other advisory fees.

Research and development expenses represented 9.0 percent of sales and after an increase of 1.0 percent in HUF terms and 0.4 percent in EUR terms they amounted to HUF 35,153 million or EUR 112.9 million during the reported year. Lower than expected expenses were primarily due to delays experienced on some of the clinical trials. These expenses include the ongoing clinical trials being carried out in the field of biotechnology together with those managed in co-operation with Allergan. R&D expenses of the Group also include such costs at the operations of GR Polska and GR Romania.

Other income and other expenses (net) increased to an expense of HUF 8,016 million (EUR 25.7 million) in 2016 when compared to an expense of HUF 1,398 million (EUR 4.5 million) recorded in the previous year. This base period figure included an outstanding amount of milestones received from our partners, mainly related to the USA marketing authorization of cariprazine granted by FDA. 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 million) as stipulated in the concluded agreement relating to future European sales and marketing of cariprazine.

In addition, further one-off income and expense items also impacted results in the reported period. A one-off income amounting to HUF 3,453 million (EUR 11.1 million) was recorded in connection with the 100 percent acquisition of Gedeon Richter Rxmidas JV Co. Ltd. engaged in the trading of OTC products on the Chinese market. Having applied the accounting standards for business combinations as established by IFRS 3 the 50 percent stake held prior to the transaction was reassessed at fair value at the time of the acquisition (22 January 2016) including the gains proceeding thereof in the Income Statement.

The product withdrawal of LISVY® resulted in a write-off amounting to HUF 2,405 million (EUR 7.7 million) accounted for in respect of intangible assets. An additional HUF 849 million (EUR 2.7 million) impairment loss was accounted for in the third quarter 2016 in respect of inventories, an amount which Richter expects to receive as compensation as notified by Bayer. Further compensation claims remain under negotiation between the Parties.

In the twelve months to December 2016 an expense of HUF 379 million (EUR 1.2 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 we expect to offset the tax payable in 2016 on this ground by 90 percent of the tax liability of the same kind incurred during 2015.

During the reported period other income and expenses include liabilities amounting to HUF 5,432 million (EUR 17.5 million) in respect of the claw-back regimes effective in Romania, Germany, France, Spain, Portugal, Belgium, Italy, Bulgaria and Latvia.

An impairment loss amounting to HUF 1,720 million (EUR 5.5 million) was recorded in respect of the Goodwill accounted for on the acquisition of Mediplus.

Taking into account that Richter withdrew its application for the marketing authorization in respect of PEG-GCSF an impairment loss totalling HUF 660 million (EUR 2.1 million) was also recorded in respect of these inventories.

Profit from operations decreased by 18.1 percent in HUF terms (18.6 percent in EUR terms) and amounted to HUF 54,616 million (EUR 175.4 million) in 2016. The decrease resulted primarily from the year-on-year 12.8 percent EURRUB devaluation and the inclusion of amortization costs of BEMFOLA®, higher sales and marketing expenses, write-offs accounted for in respect of LISVY® product withdrawal and an impairment loss accounted for in respect of Mediplus goodwill and costs related to Finox Holding integration. The above were only partly offset by royalty income received from Allergan in respect of VRAYLAR™ sales and a one-off reassessment-related income accounted for among Other expenses together with milestone income received from Recordati and a slowdown in the increase of R&D expenses. The consolidated operating margin decreased to 14.0 percent during the reported period from the 18.3 percent reported in 2015.



Net financial income for the Group is analysed in detail in the following table:

**Net financial income**

| | 2016 | 2015 | Change | 2016 | 2015 | Change |
|---|---|---|---|---|---|---|
| | HUFm | HUFm | HUFm | EURm | EURm | EURm |
| **Unrealised financial items** | **4,679** | **(6,568)** | **11,247** | **15.0** | **(21.2)** | **36.2** |
| Exchange gain/(loss) on trade receivables and trade payables | 3,658 | (5,984) | 9,642 | 11.7 | (19.3) | 31.0 |
| (Loss)/gain on foreign currency loans receivable | (148) | 1,360 | (1,508) | (0.5) | 4.4 | (4.9) |
| Year-end foreign exchange translation difference of borrowing | 245 | 243 | 2 | 0.8 | 0.8 | 0.0 |
| Exchange gain/(loss) on other currency related items | 1,939 | (1,625) | 3,564 | 6.3 | (5.3) | 11.6 |
| Unwinding of discounted value related to contingent-deferred purchase price liabilities | (948) | (573) | (375) | (3.0) | (1.9) | (1.1) |
| Result of unrealised forward exchange contracts | (4) | 11 | (15) | (0.1) | 0.1 | (0.2) |
| Impairment loss on investments | (63) | - | (63) | (0.2) | - | (0.2) |
| **Realised financial items** | **7,133** | **(1,739)** | **8,872** | **22.9** | **(5.6)** | **28.5** |
| Gain on forward exchange contracts* | - | 621 | (621) | - | 2.0 | (2.0) |
| Exchange gain/(loss) realised on trade receivables and trade payables | 2,670 | (2,867) | 5,537 | 8.6 | (9.3) | 17.9 |
| Foreign exchange difference on conversion of cash | 218 | (1,062) | 1,280 | 0.7 | (3.4) | 4.1 |
| Dividend income | 2,792 | 1 | 2,791 | 9.0 | 0.0 | 9.0 |
| Interest income | 2,566 | 2,641 | (75) | 8.2 | 8.5 | (0.3) |
| Interest expense | (827) | (1,160) | 333 | (2.7) | (3.7) | 1.0 |
| Other financial items | (286) | 87 | (373) | (0.9) | 0.3 | (1.2) |
| **Total** | **11,812** | **(8,307)** | **20,119** | **37.9** | **(26.8)** | **64.7** |

Note: *Contains only the result of the net settled (settling through mark to market procedures) forward exchange contracts. Gain and loss of delivery fx deal is presented as "Foreign exchange difference on conversion of cash".

The net financial gain in 2016 totalled HUF 11,812 million (EUR 37.9 million), reflecting an increase of HUF 20,119 million (EUR 64.7 million) when compared to a net financial loss of HUF 8,307 million (EUR 26.8 million) recorded in the base period.

At the end of each reporting period foreign currency related assets and liabilities are routinely reassessed with the change in value being reflected as unrealised financial items. The total impact of such reassessments amounted to a HUF 5,694 million (EUR 18.3 million) gain at 31 December 2016, HUF 11,700 million (EUR 37.7 million) higher when compared with the HUF 6,006 million (EUR 19.4 million) loss reported in the same period of 2015.

A substantial loss accounted for in the base period resulted from exchange translation differences incurred on trade receivables subsequent to the devaluations of the Rouble and Kazakh Tenge. Contrary to the above, significant exchange gains have been realised on trade receivables during 2016 as a result of the strengthening (by 23.2 percent) of the RUBHUF period close year-on-year exchange rate.

The net financial gain reported on the realised financial items in 2016, reflected the impact of exchange gains realised on trade receivables and trade payables amounting to HUF 2,670 million (EUR 8.6 million). This gain was incurred primarily as a consequence of the RUBHUF exchange rate which improved in the second part of the reported period when compared to the beginning of 2016. The impact of other key currency exchange rate movements was insignificant. Dividend income contributed HUF 2,792 million (EUR 9.0 million) while net interest income of HUF 1,739 million (EUR 5.5 million) added to the results achieved. The change of the fair value of the „exchangeable bond" option connected to MNV bond was HUF 1,016 million.

Share of profit of associates and joint ventures amounted to HUF 1,798 million (EUR 5.8 million) in 2016.

Profit before income tax amounted to HUF 68,226 million (EUR 219.1 million) in 2016, an increase of HUF 8,349 million (EUR 25.7 million) compared with 2015.

By virtue of Hungarian Tax Regulations, the base of the corporate tax applied at the Parent Company of the Group (incorporated in Hungary) can 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 2016 the Group accounted for HUF 2,014 million (EUR 6.5 million) in respect of corporate tax and HUF 5,019 million (EUR 16.1 million) deferred tax income resulting in HUF 3,005 million income taxes (EUR 9.6 million). An additional amount of HUF 4,208 million (EUR 13.5 million) was accounted for in respect of local business tax and innovation fee.

On 12 December 2016 the Hungarian Parliament enacted a decrease of the corporate income tax rate from the previous 19 percent to 9 percent with effect from 1 January 2017 which consequently reduced significantly the deferred tax amounts which had already been included in our accounts.

Profit for the year was HUF 67,023 million (EUR 215.2 million), HUF 13,160 million (EUR 41.3 million) higher than the profit for the period realised in 2015.

Profit attributable to owners of the parent increased by HUF 12,337 million (EUR 38.7 million) during the reported period to HUF 66,200 million (EUR 212.6 million). It increased to 17.0 percent of sales compared with the 14.7 percent reported in the previous year.

## e) Balance Sheet Items

Total assets and total shareholders' equity and liabilities of the Group amounted to HUF 813,877 million on 31 December 2016, HUF 66,883 million, or 9.0 percent higher than that reported at 31 December 2015.

Non-current assets amounted to HUF 503,931 million on 31 December 2016, 14.8 percent higher than the levels reported for 31 December 2015. The level of Other intangible assets increased primarily as a result of the acquisition of property rights for BEMFOLA partly offset by impairment losses accounted for in respect of the product withdrawal of LISVY® together with the amortization and the foreign exchange difference at period-end related to the Esmya intangible asset. Property, plant and equipment increased due to the inauguration of a new bottle filling and lyophilisation unit. The amount of Goodwill accounted for increased as a result of the reassessment made in respect of the Chinese acquisition together with the revaluation of the Goodwill accounted for in respect of the acquisitions realised in preceding years and the impairment loss incurred with regard to goodwill at Mediplus. The level of Other financial assets increased as a result of a change in the fair value of Richter's investment in the Russian wholesaler and retail Group, Protek.

Current assets amounted to HUF 309,946 million and remained virtually flat (increased by HUF 1,917 million or 0.6 percent) when compared to the level reported on 31 December 2015. A decrease in the amount of Cash and cash equivalents resulted from the acquisition of Finox Group and a loan repayment to EIB which amounted to EUR 21 million. Current assets on the contrary increased mainly related to the acquisition of Finox Group which resulted in higher levels of Inventories and Trade receivables. The latter figure also includes an exchange rate impact of Russian trade receivables.

Capital and reserves of the Group increased by 10.3 percent and amounted to HUF 681,873 million when compared to the balance as at 31 December 2015. Retained earnings increased by HUF 53,327 million and amounted to HUF 614,657 million.

Non-current liabilities of the Group on 31 December 2016 at HUF 42,792 million were HUF 14,080 million lower than the levels as at the end of the previous year. The decline is a result of reclassification as current liabilities, i.e. with payments due within a year, of an EUR 25 million loan together with deferred purchase price payments related to our acquisitions in China and in Mexico. The above decrease was partly offset by the advance amount of subvention granted by the Ministry for National Economy to support innovative pharmaceutical research and development activity.

Current liabilities of the Group at HUF 89,212 million on 31 December 2016 were HUF 17,479 million higher than their level reported on 31 December 2015. The increase was a result of higher levels of Other payables and accruals together with increased Trade payables.

## f) Cash Flow

As indicated by the cash flow statement, the Group generated net cash from operating activities of HUF 77,419 million during 2016. Cash from operating activities remained below the levels reported for the previous year mainly as a result of an increase in trade and other receivables and a substantial increase in inventories, the latter being mostly connected to acquisition of Finox Holding. Not insignificant amounts of cash were directed towards capital expenditure and payment of dividends. Overall, during 2016 cash decreased by HUF 35,716 million primarily as a result of higher net cash outflow on acquisition of subsidiaries.

| Cash flow | | |
|---|---|---|
| | 2016 | 2015 |
| | HUFm | HUFm |
| **Net cash flow** | | |
| From operating activities | 77,419 | 95,047 |
| To investing activities | (91,001) | (39,100) |
| To financing activities | (22,134) | (23,413) |
| Effect of foreign exchange rate changes | (605) | 1,900 |
| **Net (decrease)/increase in cash and cash equivalents** | **(35,716)** | **32,534** |

## 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 2016 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 2016.

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 36,453 million in the twelve months to December 2016 when compared to HUF 33,302 million reported for 2015.

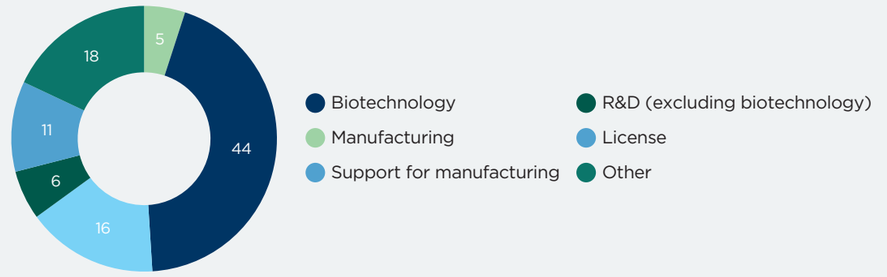
In order to further expand the manufacturing capacities of our finished form products we continued to progress a greenfield investment targeting the establishment of a new, state-of-the-art sterile bottle filling and lyophilisation unit. Construction works were completed together with the technical supply systems. The production line to execute lyophilisation and filling is currently in a testing phase. The plant dedicated to packaging of injectables together with other units (a warehouse and certain R&D-linked facilities) were completed. Planning activities were completed for another greenfield investment project which aims towards the establishment of clearly defined and integrated sterile production capacity.

The manufacturing capacities of steroid intermediates and preparative chromatographic units are also undergoing over several years various phases of expansion and improvement at our Dorog site. The Modernisation of the potassium-aspartate manufacturing unit has been completed during the reported year. Concept design was completed to expand our biosimilar production line in Debrecen.

A number of small scale investments have been carried out to ensure or maintain the quality of the production, environmental protection and improve certain controlling and monitoring activities both at our Hungarian sites as well as at our subsidiaries abroad.

Modernisation of the production site at the Group's Romanian subsidiary in Marosvásárhely continues while at our Russian plant we have installed a vial packing line for tablets. A preparation area was reconstructed at our Polish subsidiary, while new coating equipment, a sachet packaging unit, equipment for preparation of solutions and a capsule weight checker were also put into operation during the year.

### Capital expenditure analysed by function in 2016 (%)




## Disclosures

I, the undersigned declare, that Gedeon Richter Plc. takes full responsibility that the management report, which contains the Group's 2016 results is prepared in accordance with the applicable accounting standards and according to the best of our knowledge. The report above provides a true and fair view of the financial position of Gedeon Richter Plc., comprises the subsidiaries included in the consolidation, 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.

Erik Bogsch
Managing Director

# Appendices

## Consolidated Financial Record

| Consolidated Balance Sheet | | |
|---|---|---|
| at 31 December | 2016 | 2015* |
| | HUFm | HUFm |
| **ASSETS** | **813,877** | **746,994** |
| **Non-current assets** | **503,931** | **438,965** |
| Property, plant and equipment | 191,002 | 177,950 |
| Goodwill | 68,632 | 64,888 |
| Other intangible assets | 192,677 | 150,827 |
| Investments in associates and joint ventures | 8,541 | 7,140 |
| Other financial assets | 32,864 | 26,414 |
| Deferred tax assets | 5,416 | 8,063 |
| Loans receivable | 4,799 | 3,683 |
| **Current assets** | **309,946** | **308,029** |
| Inventories | 81,246 | 64,680 |
| Trade receivables | 116,223 | 92,539 |
| Other current assets | 14,991 | 13,927 |
| Investments in securities | 751 | 3,970 |
| Current tax assets | 682 | 539 |
| Cash and cash equivalents | 96,053 | 132,374 |
| **EQUITY AND LIABILITIES** | **813,877** | **746,994** |
| **Capital and reserves** | **681,873** | **618,389** |
| Share capital | 18,638 | 18,638 |
| Treasury shares | (1,285) | (3,206) |
| Share premium | 15,214 | 15,214 |
| Capital reserves | 3,475 | 3,475 |
| Foreign currency translation reserves | 18,478 | 16,478 |
| Revaluation reserve for available for sale investments | 8,825 | 3,323 |
| Retained earnings | 614,657 | 561,330 |
| Non-controlling interest | 3,871 | 3,137 |
| **Non-current liabilities** | **42,792** | **56,872** |
| Borrowings | 28,874 | 37,188 |
| Deferred tax liability | 5,962 | 8,939 |
| Other non-current liabilities and accruals | 4,448 | 7,817 |
| Provisions | 3,508 | 2,928 |
| **Current liabilities** | **89,212** | **71,733** |
| Borrowings | 7,776 | 6,523 |
| Trade payables | 45,926 | 38,209 |
| Current tax liabilities | 655 | 425 |
| Other payables and accruals | 32,929 | 24,669 |
| Provisions | 1,926 | 1,907 |

Note: * Restated. For details see Explanatory note on page 104.

| Consolidated Income Statement | | |
|---|---|---|
| for the year ended 31 December | 2016 | 2015* |
| | HUFm | HUFm |
| **Revenues** | **389,690** | **365,220** |
| Cost of sales | (164,002) | (144,611) |
| **Gross profit** | **225,688** | **220,609** |
| Sales and marketing expenses | (107,564) | (98,310) |
| Administration and general expenses | (20,339) | (19,397) |
| Research and development expenses | (35,153) | (34,822) |
| Other income and other expenses (net) | (8,016) | (1,398) |
| **Profit from operations** | **54,616** | **66,682** |
| Finance income | 26,600 | 24,230 |
| Finance costs | (14,788) | (32,537) |
| **Net financial income/(loss)** | **11,812** | **(8,307)** |
| Share of profit of associates and joint ventures | 1,798 | 1,502 |
| **Profit before income tax** | **68,226** | **59,877** |
| Income tax | (1,203) | (6,014) |
| **Profit for the year** | **67,023** | **53,863** |
| Profit attributable to | | |
| Owners of the parent | 66,200 | 53,863 |
| Non-controlling interest | 823 | 0 |
| **Consolidated Statement of Comprehensive Income** | | |
| **Profit for the year** | **67,023** | **53,863** |
| **Items that will not be reclassified to profit or loss** | **(44)** | **(22)** |
| Actuarial loss on retirement defined benefit plans | (44) | (22) |
| **Items that may be subsequently reclassified to profit or loss** | **7,082** | **8,677** |
| Exchange differences arising on translation of foreign operations | 1,546 | 7,179 |
| Exchange differences arising on translation of associates and joint ventures | 34 | 51 |
| Revaluation of available for sale investments | 5,502 | 1,447 |
| **Other comprehensive income for the year** | **7,038** | **8,655** |
| **Total comprehensive income for the year** | **74,061** | **62,518** |
| Attributable to | | |
| Owners of the parent | 73,203 | 62,404 |
| Non-controlling interest | 858 | 114 |
| **Earnings per share (EPS)** | **HUF** | **HUF** |
| Basic | 356 | 291 |
| Diluted | 356 | 291 |

Note: * Restated. For details see Explanatory note on page 104.

## Consolidated Income Statement

| for the year ended 31 December | 2016 | 2015* |
|---|---|---|
| | EURm | EURm |
| **Revenues** | **1,251.2** | **1,179.4** |
| Cost of sales | (526.6) | (467.0) |
| **Gross profit** | **724.6** | **712.4** |
| Sales and marketing expenses | (345.3) | (317.5) |
| Administration and general expenses | (65.3) | (62.6) |
| Research and development expenses | (112.9) | (112.4) |
| Other income and other expenses (net) | (25.7) | (4.5) |
| **Profit from operations** | **175.4** | **215.4** |
| Finance income | 85.4 | 78.3 |
| Finance costs | (47.5) | (105.1) |
| **Net financial income/(loss)** | **37.9** | **(26.8)** |
| Share of profit of associates and joint ventures | 5.8 | 4.8 |
| **Profit before income tax** | **219.1** | **193.4** |
| Income tax | (3.9) | (19.5) |
| **Profit for the year** | **215.2** | **173.9** |
| Profit attributable to | | |
| Owners of the parent | 212.6 | 173.9 |
| Non-controlling interest | 2.6 | 0.0 |
| **Average exchange rate (EURHUF)** | **311.46** | **309.67** |
| **Consolidated Statement of Comprehensive Income** | | |
| **Profit for the year** | **215.2** | **173.9** |
| **Items that will not be reclassified to profit or loss** | **(0.1)** | **(0.1)** |
| Actuarial loss on retirement defined benefit plans | (0.1) | (0.1) |
| **Items that may be subsequently reclassified to profit or loss** | **22.7** | **28.1** |
| Exchange differences arising on translation of foreign operations | 5.0 | 23.2 |
| Exchange differences arising on translation of associates and joint ventures | 0.1 | 0.2 |
| Revaluation of available for sale investments | 17.6 | 4.7 |
| **Other comprehensive income for the year** | **22.6** | **28.0** |
| **Total comprehensive income for the year** | **237.8** | **201.9** |
| Attributable to | | |
| Owners of the parent | 235.0 | 201.5 |
| Non-controlling interest | 2.8 | 0.4 |
| **Earnings per share (EPS)** | **EUR** | **EUR** |
| Basic | 1.14 | 0.94 |
| Diluted | 1.14 | 0.94 |

Note: * Restated. For details see Explanatory note on page 104.



## Consolidated Cash Flow Statement

| for the year ended 31 December | 2016 | 2015* |
|---|---|---|
| | HUFm | HUFm |
| **Operating activities** | | |
| Profit before income tax | 68,226 | 59,877 |
| Depreciation and amortisation | 32,895 | 31,248 |
| Non-cash items accounted through Total Comprehensive Income | (6,725) | (1,850) |
| Year-end foreign exchange translation difference of borrowings | (245) | (243) |
| Net interest and dividend income | (4,531) | (1,482) |
| Changes in provision for defined benefit plans | (15) | 158 |
| Increase on changes of property, plant and equipment and intangible assets | (461) | (830) |
| Impairment recognised on intangible assets | 3,873 | 3,484 |
| Impairment on investments | 63 | - |
| Expense recognised in respect of equity-settled share based payments | 4,724 | 4,260 |
| Movements in working capital | | |
| (Increase)/decrease in trade and other receivables | (18,095) | 2,773 |
| Increase in inventories | (11,446) | (2,770) |
| Increase in payables and other liabilities | 16,358 | 7,231 |
| Interest expense | (827) | (1,160) |
| Income tax paid | (6,375) | (5,649) |
| **Net cash flow from operating activities** | **77,419** | **95,047** |
| **Cash flow from investing activities** | | |
| Payments for property, plant and equipment | (30,551) | (27,708) |
| Payments for intangible assets | (5,902) | (5,594) |
| Proceeds from disposal of property, plant and equipment | 401 | 1,332 |
| Payments to acquire financial assets | (88) | (2,043) |
| Proceeds on sale or redemption on maturity of financial assets | 3,950 | 18,429 |
| Disbursement of loans net | (614) | (836) |
| Interest income | 2,566 | 2,641 |
| Dividend income | 2,792 | 1 |
| Net cash outflow on acquisition of subsidiaries | (63,555) | (25,322) |
| **Net cash flow to investing activities** | **(91,001)** | **(39,100)** |
| **Cahs flow from financing activities** | | |
| Purchase of treasury shares | (1,758) | (2,542) |
| Dividend paid | (13,563) | (6,245) |
| Repayment of borrowings | (6,813) | (14,628) |
| Proceeds from borrowings | - | 2 |
| **Net cash flow to financing activities** | **(22,134)** | **(23,413)** |
| **Net (decrease)/increase in cash and cash equivalents** | **(35,716)** | **32,534** |
| **Cash and cash equivalents at beginning of year** | **132,374** | **97,940** |
| Effect of foreign exchange rate changes on the balances held in foreign currencies | (605) | 1,900 |
| **Cash and cash equivalents at end of year** | **96,053** | **132,374** |

Note: * Restated. For details see Explanatory note on page 104.

## Explanatory Note

### Changes impacting Consolidated Financial Statements in respect of 2015

With effect from 1 January 2017 stand-alone IFRS reporting also became compulsory for Gedeon Richter Plc. The Company implemented changes to the IT system supporting the transition. As part of this development the Company reviewed its methodology to eliminate intra-group profit on sale of inventories. This review discovered that previously applied average margin for elimination was not precise on purchased inventories and that intra-group profit on own manufactured inventories was not fully eliminated. As a consequence, the inventory had been incorrectly overstated and cost of sales understated. The above described IT development enabled the Group to fully eliminate intra-group profit on sale of inventory.

Additionally, the preparation of stand-alone IFRS report of Gedeon Richter Plc. has revealed that the book value of previously identified difference between the IFRS and statutory value of property, plant and equipment and its depreciation have not been reviewed annually. As a consequence, the balance of property, plant and equipment was understated and previous years' depreciation was overstated. The review resulted in correction of the value of property, plant and equipment and retained earnings.

In accordance with IAS 8 standard the corresponding figures for previous periods have been restated accordingly.



## Notes

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