Development of innovative drugs at Richter and the Richter-EIB cooperation

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Richter Group overview

- Company founded: 1901
- Nationalised: 1948
- Privatised: 1994-
- International locations: 31
- Number of employees: 11,650
- Vertically integrated pharmaceutical company
  - original research
  - process development finished form / API manufacturing
  - branded marketing and sales
  - wholesale and retail

Mr. Gedeon Richter

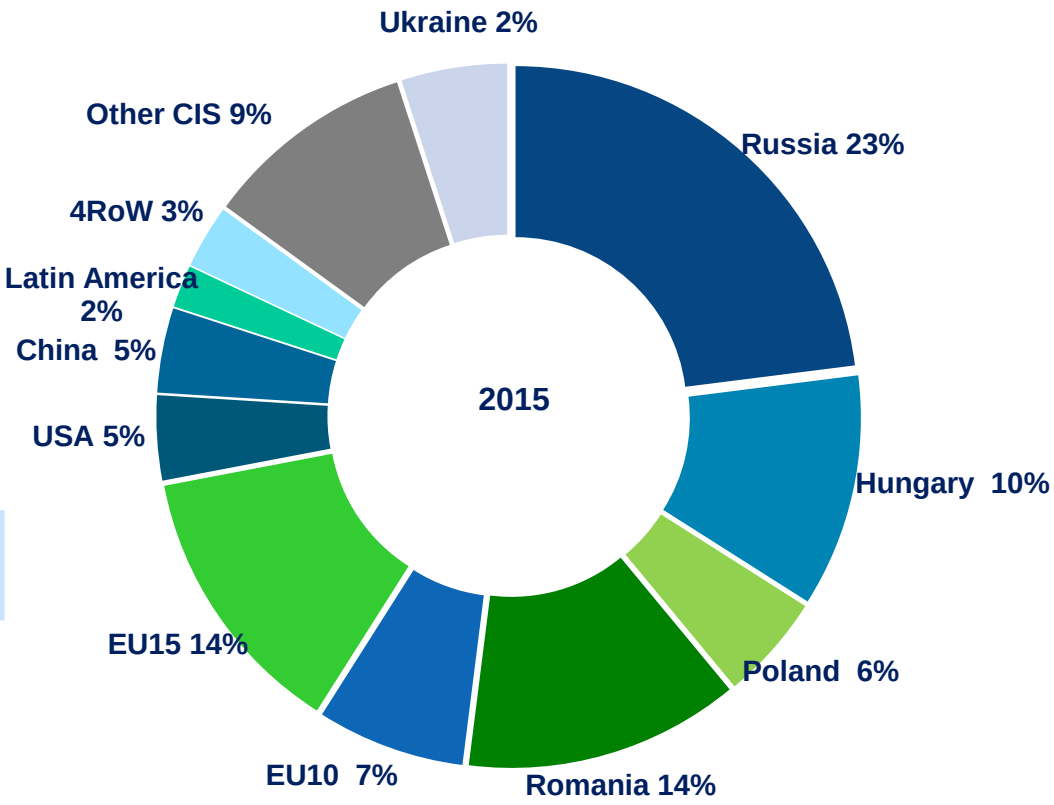
Richter's sales at a glance

Therapeutic areas (% of revenue):

- Female healthcare (38%)
- Cardiovascular (22%)
- Central nervous system (13%)
- Muscle relaxants (6%)
- Gastrointestinal (4%)
- Other (17%)

EUR 1,179 million Sales revenue and
EUR 176.1 million Net profit in 2015

Sales per geographical regions



Richter within the pharmaceutical industry

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Challenges

- Budget
- Increasing generic competition – pricing pressure

Responses

- Going global – economies of scale (Teva, Watson-Actavis-Allergan)
- Going special – high added value (Lundbeck, Almirall)

Richter's approach – specialty pharma

- New geographies
  - Western Europe, Latin America, China
- Innovative products
  - Women's healthcare
  - Central Nervous System
  - Biosimilars (oncology, immunology)

Acquisitions and development of specialty products after 2010 – need for external financing

Acquisitions in 2010

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Acquisition of Preglem (WH R&D firm in Switzerland)

- Real acquisition target: Esmya (product candidate for a treatment of uterine fibriods developed by Preglem)
- CHF150m initial purchase price
- additional CHF 295m deferred purchase price

Acquisition of Grünenthal OC portfolio (leading product: Belara)

- EUR 236m purchase price
- matured portfolio
- springboard to the WEU WH markets

Development of specialty products after 2010

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Cariprazine

- Clinical development in collaboration with Forest lab. (Allergan)
- Ongoing global F3 clinical trials in two indication and F2 trials in two additional indications

Esmya

- European F3 clinical trials in pre-operative indication
- Additional clinical trials in long term on-off indication

Biosimilars

- CAPEX projects
- Ongoing product development projects and clinical trials

Financing of the specialty strategy

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Utilization of the net cash of the Company for the initial acquisition payments

How to finance the additional acquisition liabilities (deferred payments) and the further development activities?

Need for external financing

Responses:

- EUR 150m loan in 2010 from Hungarian Banks to finance additional acquisition liabilities

- **EUR 150m loan in 2011 from EIB to finance the further innovative development activities**

Gedeon Richter innovative drugs Risk Sharing Finance Facility provided by EIB

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The project:

- Development of New Chemical entities (mainly in CNS area) and development of biosimilar products in Budapest between 2011-2014

-Total cost of the project EUR 360m

The financing:

- Amount of the loan provided by EIB: EUR 150m

- Disbursement currency: selectable (EUR, HUF or any „widely traded currency”)

- Disbursements: in three EUR 50 m tranches (2011-2013)

- Repayment: in semiannual installments, 3 years grace period, final maturity 9 years from the disbursement of each tranche

-Interest: fixed or floating (determined at the drawdown of each disbursement)

Advantages for Richter:

- Favorable maturity, flexibility in disbursements, competitive pricing

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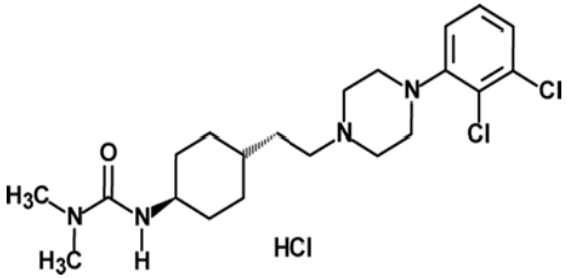
Results of the innovative drug development during Richter-EIB cooperation

Cariprazine at a glance

- NCE (new chemical entity), atypical antipsychotics, invented by Richter's chemists
- In 2004 License and collaboration agreement with Forest Labs (currently Allergan) and Mitsubishi-Tanabe
- Potential indications
  - Schizophrenia
  - Bipolar mania
  - Major depressive disorder
  - Bipolar depression
  - Schizophrenia with predominantly negative symptoms
- Patent protection

  Global expiry – 2027



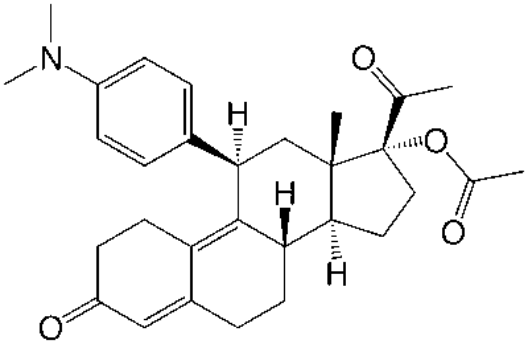
Chemical structure of cariprazine HCl (Vraylar)

Cariprazine: results and expectations

- Ph3 clinical trials started in 2008, successfully completed between 2010-2013
- FDA approval received in Sept. 2015 (brandname: Vraylar) in two indications (Schizophrenia, Bipolar mania) - first FDA approved NCE invented in Hungary!
- US market launch in March 2016, high peak sales expectations disclosed by Allergan
- EU registration started in March 2016 in two indications (Schizophrenia and in Schizophrenia with predominantly negative symptoms), approval expected in 2017H1

Esmya® at a glance

- Ulipristal acetate (UPA): NCE, patented by HRA as emergency contraceptives
- UPA rights licensed in and a new product (Esmya) developed by Preglem (subsidiary of Richter) in a new indication (treatment of uterine fibroids) in two different dosage forms
- Selective progesterone receptor modulator blocking the action of progesterone
- Once-a-day oral therapy
  - Rapid control of fibroid symptoms; stops uterine bleeding,
  - Corrects anaemia and reduces fibroid volume
  - Reduces pain and improves quality of life
  - No castration side effects compared to GnRH agonists
  - Opportunity to perform less invasive surgeries or avoid surgery



ulipristal acetate

- License and collaboration agreement with Watson (currently Allergan) for US and Canada
- Data exclusivity protection in EU expires in May 2020, claim for indication patent still pending

Esmya: results and expectations

- EU approval for pre-operative treatment of uterine fibroids in February 2012
- EU approval for long term on off treatment in May 2015 - therapeutic breakthrough in the treatment of uterine fibroids!
- EUR 50 million sales revenue performed in 2015 in Europe, EUR 65 million expected in 2016 and EUR 80-100 million expected in two years time
- Successful Ph3 clinical trial in US, expected date of US approval 2018H1, high peak sales expectations disclosed by Allergan

Biosimilar products under development

- Pegfilgrastim: development and clinical trials completed in Q2 2015
  - pegylated recombinant, human granulocyte-colony stimulating factor used in adult patients for treatment of neutropenia
  - started in Q1 2014 → completed in Q2 2015 → filed in Q4 2015
  - non-exclusive distribution agreement with STADA in Europe

- Teriparatide development and clinical trials completed in Q2 2015

  (co-developed with Richter-Helm BioLogics)
  - for treatment of postmenopausal osteoporosis
  - started in Q3 2014 → completed in Q2 2015 → filed in Q4 2015
  - non-exclusive distribution agreement with STADA in Europe

Biosimilars: results and expectations

- 214 jobs created in the development and manufacturing facilities in Debrecen
- First two (bacterial) biosimilar products under registration
- A mammalian biosimilar product in Ph3 clinical trial
- Collaboration agreements with Stada and Mochida
- Great saving potential for the national reimbursement authorities

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Thank you for your attention!