



# Pharming Group NV

(NYSE Euronext: PHARM)

## Board of Management

**Sijmen de Vries, Chief Executive Officer**

**Bruno Giannetti, Chief Operating Officer**

**Robin Wright, Chief Financial Officer**

**Annual General Meeting**

**Leiden**

**25 May 2016**



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# AGM AGENDA

1. Opening and announcements
2. Presentation of the Annual Report 2015
3. Amendment of the Articles of Association
4. LTIP schemes 2016 for the Board of Supervisory Directors
5. Option scheme Mr. R.J.M. Wright
6. Appointment of the external auditor of the Company
7. Designation of the Board of Management (BOM)
8. Authorization of the BOM to repurchase shares in the Company
9. Any other business:
  - Change of Chairman of BOSD: Mr Paul Sekhri
  - New Pharming Design
10. Closing

# Presentation

# Contents

- Operational highlights
- Financial headlines
- Dutch Corporate Governance
- Corporate Social Responsibility and sustainability
- Risk Management & Controls
- Business Model
- Outlook 2016

# Operational Highlights 2015

- First patient treated in a clinical Phase II study of RUCONEST® for the prophylaxis of Hereditary Angioedema (“HAE”) in January.
- Our US partner for RUCONEST®, Salix, was acquired by Valeant Pharmaceuticals International, Inc. (“Valeant”) in April.
- Jan Egberts and Paul Sekhri appointed to the Board of Supervisory Directors in April.
- Initiation of the International HAE patient organisation’s (“HAEi”) Global Access Program for RUCONEST®, in May.
- Announced a new distribution agreement with Cytobioteck S.A.S. in May for Colombia and Venezuela.
- The planned temporary shut-down of part of our manufacturing (sterile fill & finish) partner BioConnection in October created a need to build inventory before operations resume there again in Q2 2016.

# Operational Highlights 2015

- Released positive safety and clinical efficacy data in an on-going open-label Phase II Paediatric study of RUCONEST® in June.
- Appointed Robin Wright as Chief Financial Officer and to the Board of Management at the EGM in October.
- In October, the FDA granted a five-year extension of data exclusivity as a reference product (C1 esterase inhibitor [recombinant]) (for a total of 12 years) to RUCONEST®, ensuring no further approvals of similar products (without full new biological entity development) until 2026.
- In December, the EMA renewed the RUCONEST® European marketing authorization indefinitely.
- In December, HyupJin Corporation obtained marketing authorization for RUCONEST® in South Korea.

# Operational Highlights: 2016 to date

- January: Recruitment for Phase 2 Prophylaxis of HAE completed
- February: Distribution agreement Cytobiotek extended
- February: Positive advice CHMP on EU label change for RUCONEST (IgE testing deleted and adolescents included)
- April: EU Commission adopts CHMP recommendation for RUCONEST label change

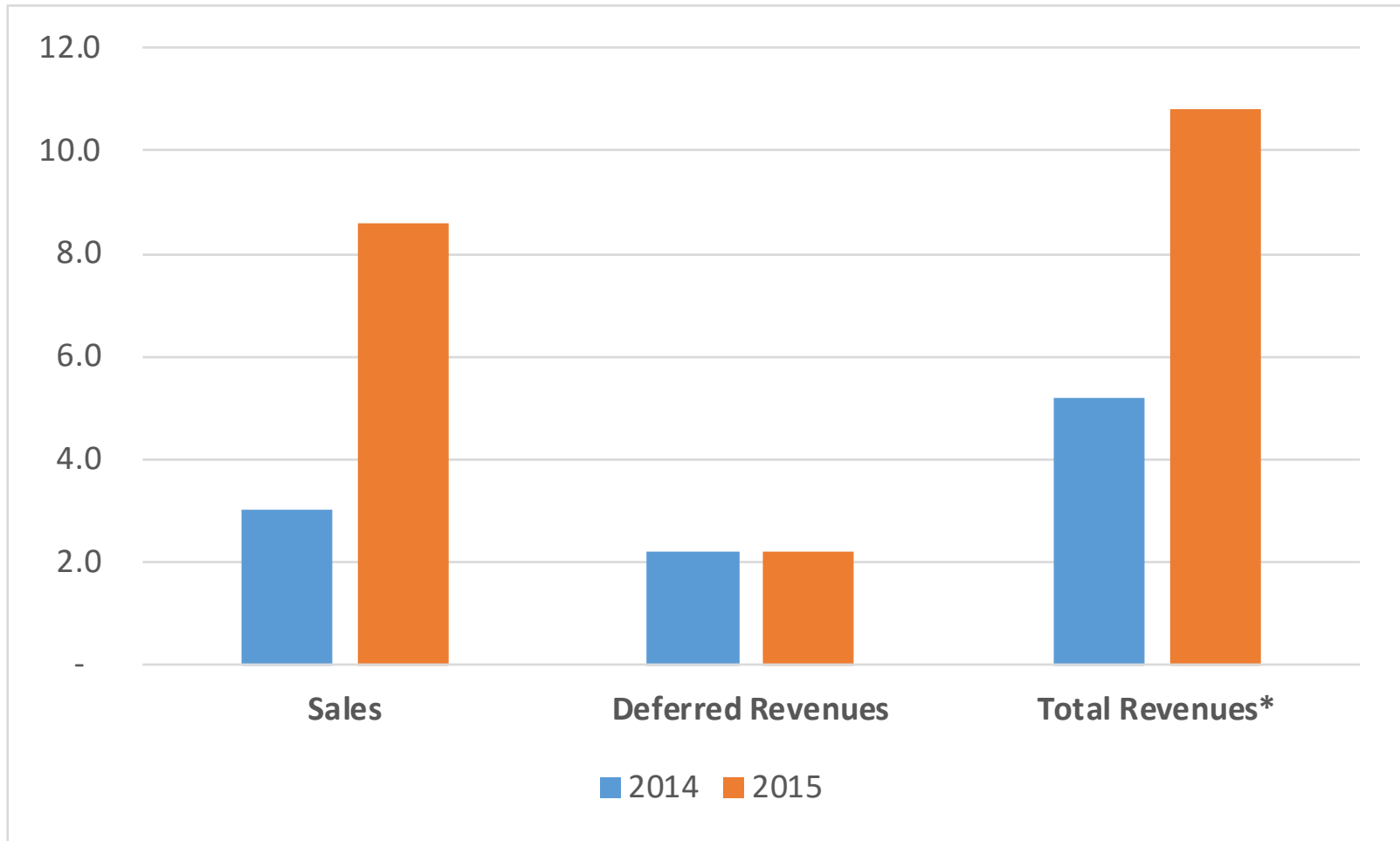


# Highlights US commercialisation

- US Partner: Salix Pharmaceuticals (A Valeant Company: NASDAQ: VRX)
  - Differentiated competitive profile in US market –
    - “First and only recombinant C1INH therapy”.
    - Efficacious: “Treats the attack in one shot”
- US launch November 2014
  - During 2015, the KAM sales force was re- aligned twice and became exclusive to RUCONEST focused on high prescribers in Q4-2015
  - Patient support through RUCONEST SOLUTIONS
  - Proceeds from supply of RUCONEST to Valeant at 30%-40% of RUCONEST Net sales by Valeant
  - Net Sales= Gross Sales minus distribution allowances and chargebacks for Government reimbursement schedules and plans
  - Government schedule rebates up to 24%
- Up to \$45M in future sales-related milestones
- Additional (agreed) development projects 50/50 funded

# Financial headlines: Revenues 2015

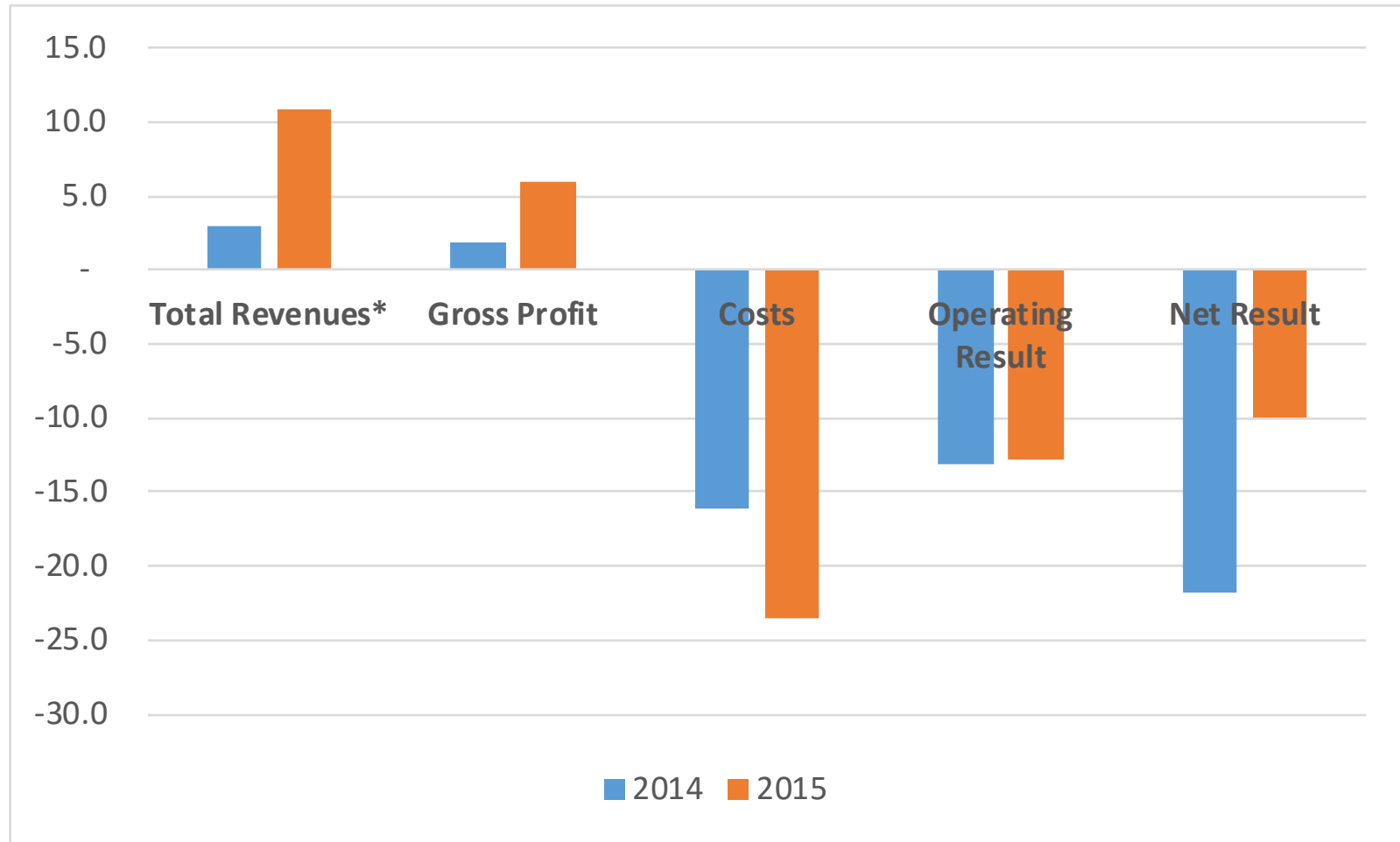
(€million)



\* Excludes €18.2m milestones received in 2014, to show like-for-like basis

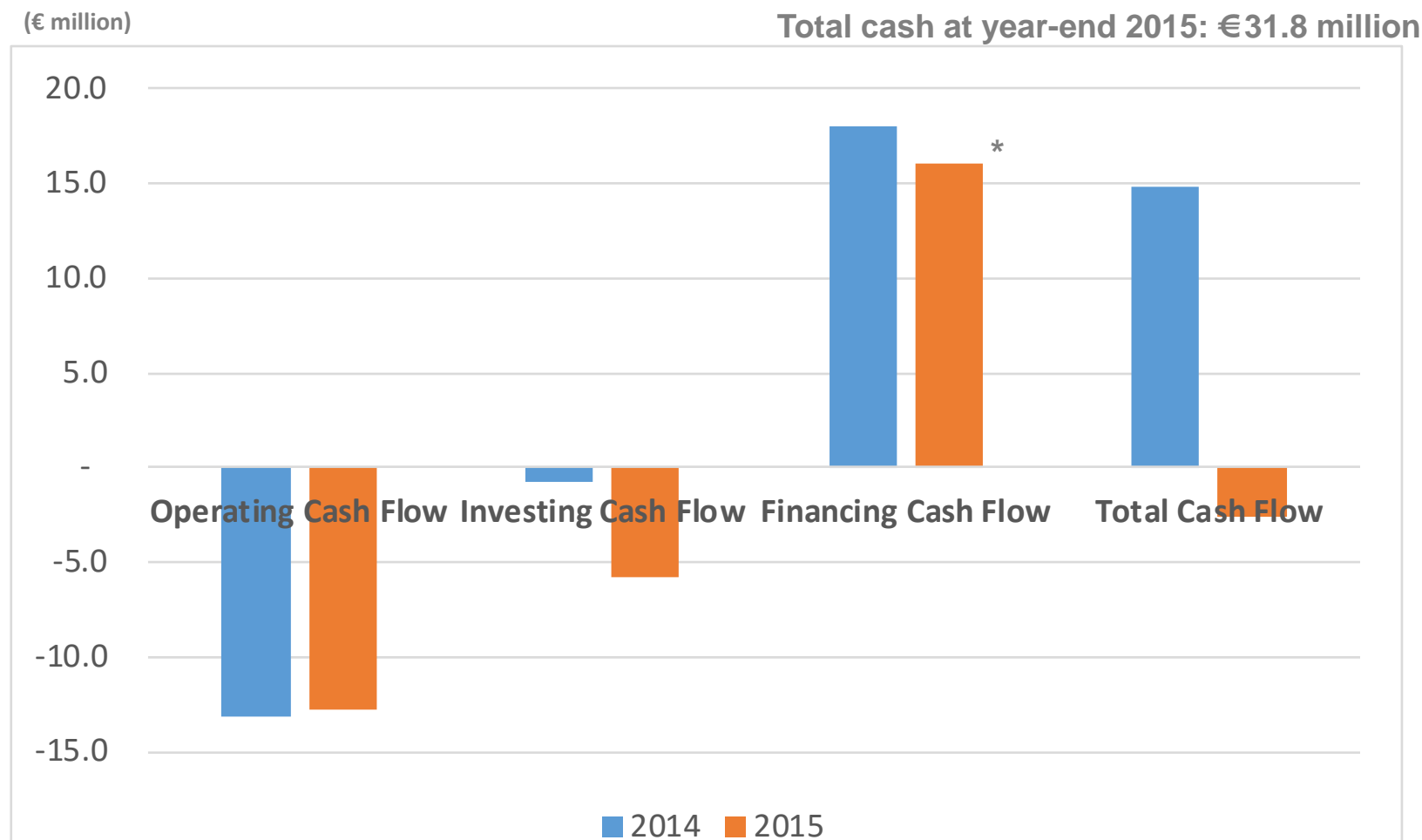
# Financial headlines: Income statement 2015

(€ million)



\* Excludes €18.2m milestones received in 2014, to show like-for-like basis

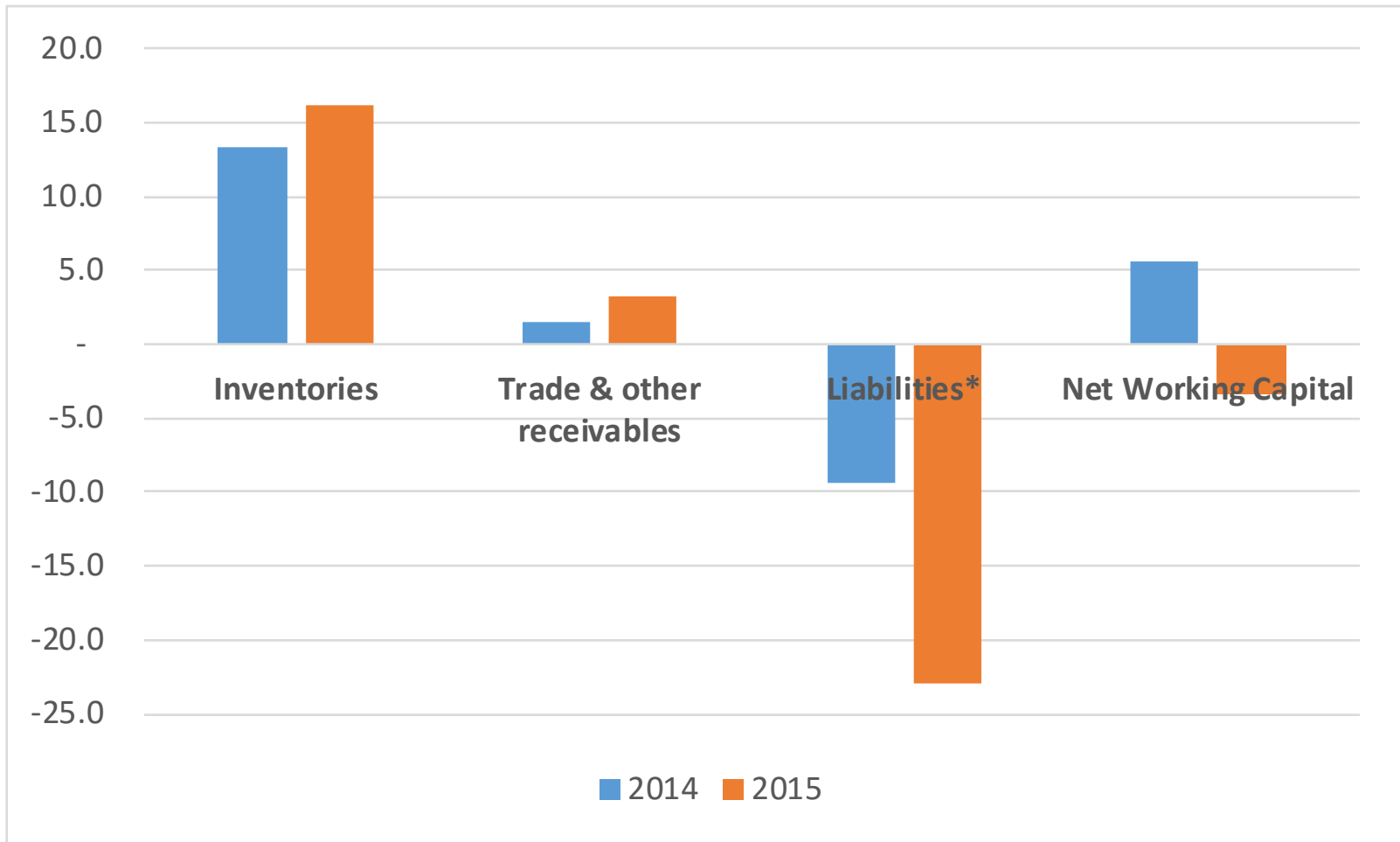
# Financial headlines: Cash flows 2015



\* 2015 financing was entirely non-dilutive, through a \$17m loan from Oxford Finance and Silicon Valley Bank

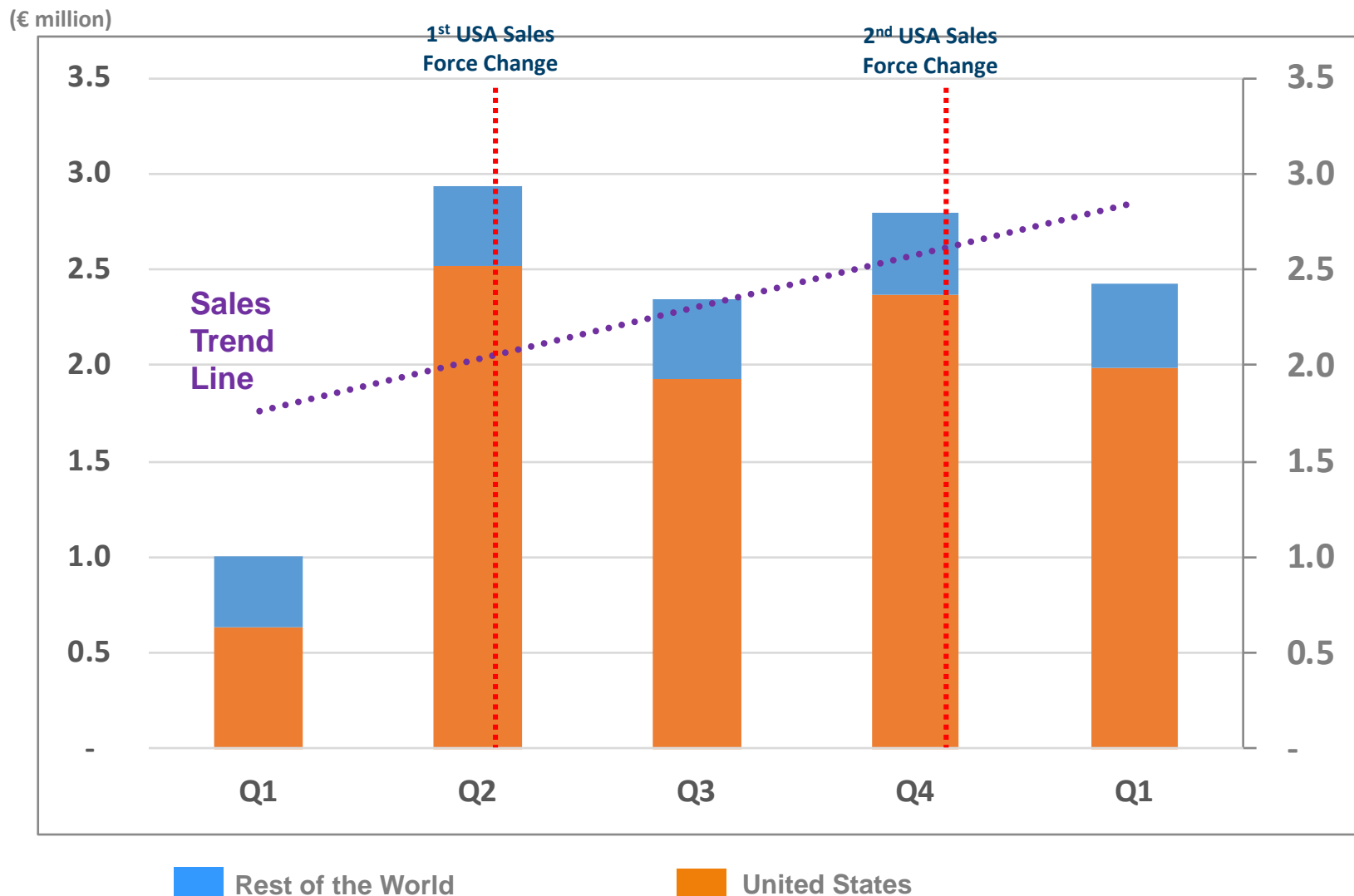
# Financial headlines: Working capital 2015

(€ million)



\* Includes new \$17m (€15.6m) loan, but excludes (non-cash) deferred license fees and derivatives

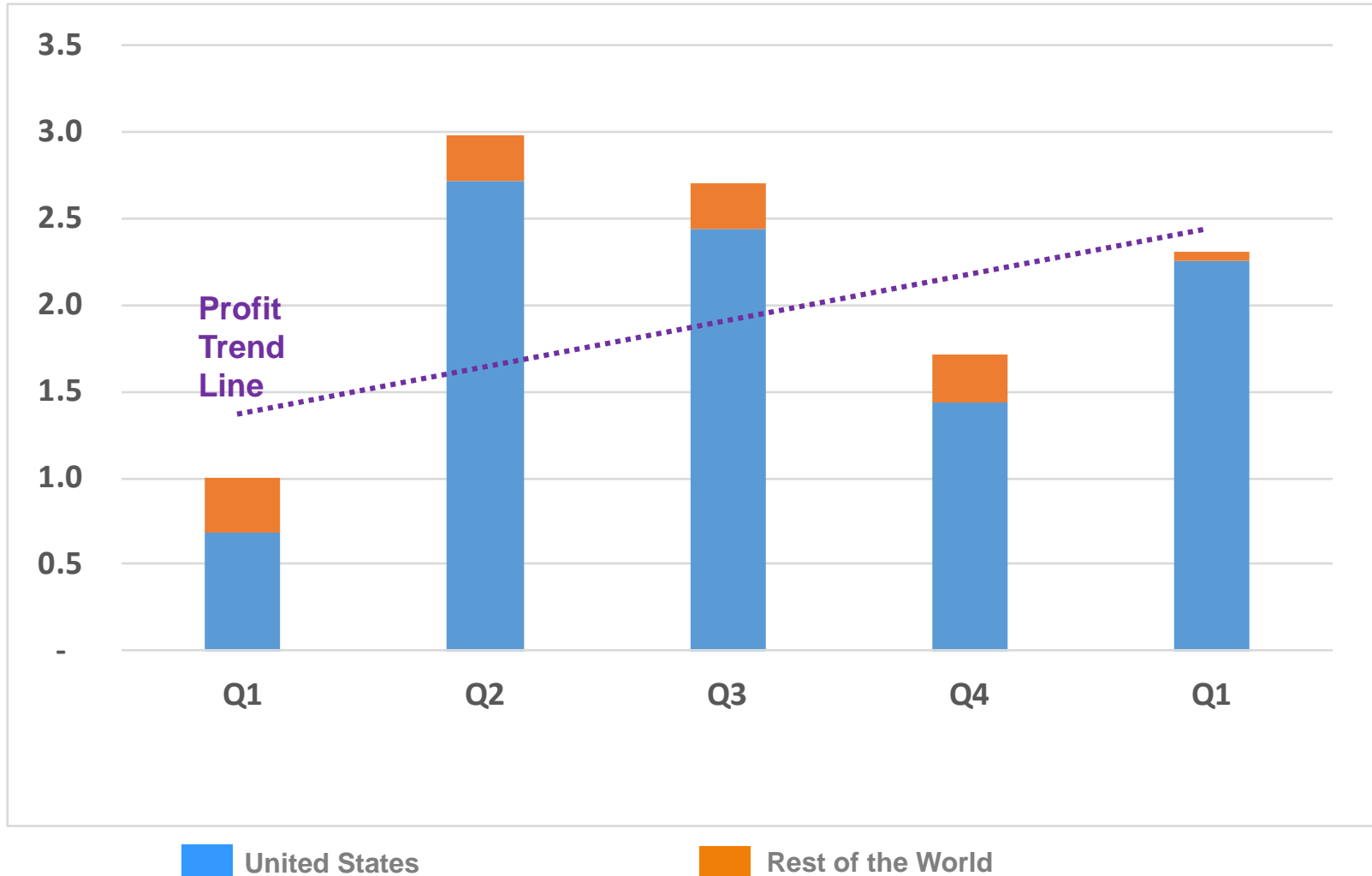
# Sales Indication: Indexed Sales Change 2015 - Current



\* Indexed Sales, based on sales into the market by Valeant, SOBI and other partners (Pharming does not own the actual sales data)

# Gross Profit Development: Indexed Change 2015 - Current

(€ million)



\* Indexed Gross Profit based on sales into the market by Valeant, SOBI and other partners

# Dutch Corporate Governance Code

Corporate Governance Statement 2016 on website

<http://www.pharming.com/aboutus/corporate-governance>

The best practices where the Company deviates from the Dutch Corporate Governance Code are as follows:

II.2.4. (Options for the Management board)

II.2.6. (Option exercise price)

III.6.5 (Ownership and transactions in securities other than issued by the Company)

III.7.1. (Shares for the Supervisory Board of Directors)

IV.3.1 (Follow in real-time all the meetings)

IV.3.12 (Independent third party to hold proxies)

IV.3.13 (Outline policy in bilateral contact with shareholders)

III.5.4c-III.5.4d and V.3.1.-V3.3. (Internal auditor)



# Corporate Social responsibility/ sustainability

- Medical need and patient safety
- Code of Conduct
- Animal care code of conduct and animal welfare
- Environmental impact of operations and trace- ability of supply chain
- Diversity and equal opportunities

# Risk management and controls

- **Periodic risk assessments and reviews**
  - Types of risk assessed (in no particular order)
  - Macro-economic, Clinical and Regulatory, Research & Development, Manufacturing, Commercial, Financial, IT, Human Resources and Legal
  
- **Financial control systems**
  - All revenues are generated and controlled by mother company
  - Expenses and capital expenditures are regulated by the Company's internal chart of authority

# Business Model

## Future profitability initially driven by:

- Proceeds from RUCONEST US sales
  - Tiered supply price to Valeant: 30-40% of net sales
- Proceeds from RUCONEST ROW sales
  - Direct commercialisation by Pharming in Austria, Germany and Netherlands
  - Fixed supply price per vial to SOBI, Megapharm, Cytobioteck and Hyupjin
  - Expansion of territories for successful partners e.g. Cytobioteck
- Future additional Proceeds from RUCONEST ROW sales
  - HAEi Global Access Plan (supplied via Clinigen PLC)
  - Partnerships: Turkey, SE Asia
  - Business development ROW
- Potential for increases of profitability (per vial) as results of
  - Economies of scale in current manufacturing process (Sanofi)
  - Future supplies from 2<sup>nd</sup> manufacturing site at SIPI

# Business Model

- Potential for increasing profitability from development of RUCONEST in additional delivery forms (eg. sub-cutaneous) and for additional indications (eg. Prophylaxis of HAE, Delayed Graft Function, Acute Pancreatitis)
- Potential for increasing profitability through balanced investment in development of pipeline of new products
  - De-risks company through diversification of revenue streams
  - Through internal Pharming R&D as well as potential acquisition of opportunities
  - SIPI development collaboration
- Competition
  - Intense, embedded and new competitors, continuous innovation
  - Long development cycles and high hurdles for entry (no “surprise entries”)
  - Risk of rapid erosion of profitability as result of new entries

# Business Model: Pharming pipeline development

- New Product Leads in development
  - Enzyme replacement treatments (Pompe's disease and Fabry's disease)
  - Factor VIII (at Sinopharm/ SIPI)
- French research group
  - Lead development and optimisation
  - Enhancement of the rabbit founder technology
- Netherlands
  - Up-scaling from founder to (pre-)production
  - GMP purification and Fill& Finish (out-sourced to CMO)
  - Analytics development, IND enabling studies, IND submissions
- Boston R&D office project management
  - ERT development networks and expertise
- We expect to present updates mid-year on our plans for new IND submissions

# Business Model: Product Development Collaboration

## Shanghai Institute for Pharmaceutical Industry: A Sinopharm company

- Product development at SIPI
  - Under Pharming's fully ICH compliant QA systems
  - Fully compliant with CFDA, FDA and EMA standards
  - Funded by SIPI up to IND
  - Aligned clinical development (SIPI funds China/ Pharming funds ROW)
- Technology transfer of Pharming platform to SIPI facilities in Shanghai
  - C1-inhibitor Technology Transfer progress according to plan
  - Factor VIII lead evaluation initiated
  - Includes manufacturing and supply of (future) finished products
- SIPI's product development resources and favorable cost structures for development and manufacturing combined with the competitive features of the Pharming platform

# Business model summary

Revenues from US net sales: 30% of up to US\$100M annual sales, increasing stepwise to 40%

Profitable Ruconest® sales increasing in Europe and RoW

Increasing sales volumes will drive significant economies of scale

Development of additional indications for Ruconest® with 50/50 cost sharing with partner

New Pipeline developments from Pharming R&D, business development and SIPI collaboration

# Outlook 2016 and beyond

- Achieved a stable base from which to grow pipeline and achieve positive cash flow and profitability
- Solid balance sheet, lean cost structure and growing sales
  - Year end 2015 cash balance €31.8m/ Q1 2016 €27.7m
  - Increasing revenues and gross profits from RUCONEST sales
- Balanced investment in clinical development
  - Continued investment in clinical trials for additional indications and methods of administration for Ruconest®
  - Continuing to build new pipeline programs: Pompe, Fabry, Factor VIII
- Investigating additional opportunities to accelerate growth and/or expedite reaching profitability
- No financial guidance for 2016



# AGM AGENDA - continued

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# Mr. P. Sekhri



## Lycera Corporation

President and Chief Executive Officer (February 2015 – Present)

## Sanofi S.A.

Senior Vice President, Integrated Care, Global Center of Excellence (April 2014 – January 2015)

## Teva Pharmaceutical Industries, Ltd.

Group Executive Vice President, Global BD and Chief Strategy Officer (June 2013 – March 2014)

## TPG Biotech (wholly-owned venture affiliate of TPG Capital)

Operating Partner (2009 – 2013)

## Cerimon Pharmaceuticals, Inc.

Founder, President, and Chief Executive Officer (2005 - 2008)

## ARIAD Pharmaceuticals, Inc.

President and Chief Business Officer (2003 – 2004)



# Pharming



## Pharming

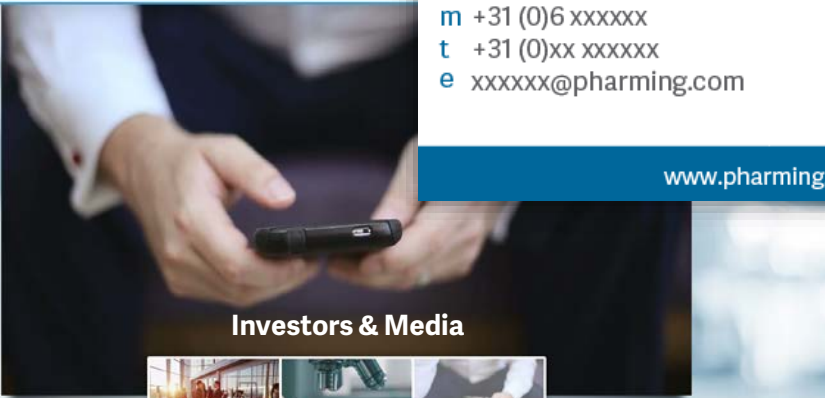
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