

# Q3 2015 results

## Progressing our transformation to a leading global biotech

October 23, 2015



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*CEO*

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*CFO*

# “SAFE HARBOR” statement under the Private Securities Litigation Reform Act of 1995

Statements included herein that are not historical facts, including without limitation statements concerning our 10x20 ambitions and target financial performance, are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. If any of the risks or uncertainties materialize, Shire's results could be materially adversely affected. The risks and uncertainties include, but are not limited to:

- Shire's products may not be a commercial success;
- product sales from ADDERALL XR and INTUNIV are subject to generic competition;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payers in a timely manner may affect future revenues, financial condition and results of operations;
- Shire conducts its own manufacturing operations for certain of its products and is reliant on third party contract manufacturers to manufacture certain products and to provide goods and services. Some of Shire's products or ingredients are only available from a single approved source. Any disruption to the supply chain for any of Shire's products may result in Shire being unable to continue marketing or developing such products or result in Shire being unable to do so on a commercially viable basis for some period of time;
- the manufacture of Shire's products is subject to extensive oversight by various regulatory agencies. Regulatory approvals or interactions with changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, an increase in operating costs, reduced product sales, an interruption of research activities or the delay of new product launches;
- Shire has a portfolio of products in various stages of research and development. The successful development of these products is a long and costly process that requires significant expenditures and time, and there is no guarantee that these products will receive regulatory approval;
- the actions of certain customers could affect Shire's ability to sell or market products profitably. Fluctuations in buying or distribution patterns of customers can adversely affect Shire's revenues, financial condition or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to Shire's activities in the highly competitive pharmaceutical industry in which it operates may result in significant legal costs and the payment of substantial compensation or fines;
- adverse outcomes in legal matters and other disputes, including Shire's ability to enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on Shire's revenues, financial condition or results of operations;
- Shire faces intense competition for highly qualified personnel from other companies and organizations. Shire is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect Shire's ability to retain the highly skilled personnel needed for Shire to meet its strategic objectives;
- failure to achieve Shire's strategic objectives with respect to the acquisition of NPS Pharmaceuticals Inc. may adversely affect Shire's revenues, financial condition and results of operations;
- Shire's strategy to acquire Baxalta may not be successful: Baxalta may refuse to cooperate with Shire; if the proposed combination of the businesses may not be integrated successfully, including that expected synergies and other benefits of the combination may not be realized; unforeseen costs may arise; and disruption caused by the proposed transaction may adversely affect Shire; and

# Agenda

**Our progression towards becoming a leading global biotech**



Flemming Ornskov,

**Financial review**



Poul

**Summary**



Flemming Ornskov,

**Q & A**

All

# Our continuous transformation

2013

2014

2015

2016

2017

2018

2019

2020

Investing to create  
further long-term value

## 2013-2015 Becoming OneShire

- Step-change in performance
- Effective and efficient organization
- Set basis for long-term growth

## Building a leading global biotech company

- Creating scale and momentum
- Culture of bold innovation, internal and external
- Patient-centric Rare Disease mindset to all business

On track to meet 10x20

# Q3 2015: Progress towards becoming a leading global biotechnology company

## GROWTH

- ✔ Double digit CER<sup>(1)</sup> product sales growth excluding INTUNIV
- ✔ Non GAAP diluted earnings per ADS growth guidance reiterated at mid-to-high single digit percent range for the full year
- ✔ Continued investment and progress in expected future growth drivers, including VYVANSE BED, GATTEX/REVESTIVE, NATPARA and lifitegrast
- ✔ Strong performance driven by VYVANSE, CINRYZE, and FIRAZYR
- ✔ GATTEX and NATPARA continue to benefit from Shire's Rare Disease expertise

## INNOVATION

- ✔ European approval for IN
- ✔ Phase 3 OPUS3 study for in symptoms of dry eye d completed: topline result Q4 2015 and, if positive, t basis of Shire's response
- ✔ Phase 3 pediatrics study enrolling ahead of sched
- ✔ Multiple Phase 3 trials ex start in late Q4 2015/early 2016, including SHP620 f cytomegalovirus ("CMV" in transplant patients, SH Eosinophilic Esophagitis and CINRYZE in AMR
- ✔ Acquired Foresight Bioth bringing global rights to l (now referred to as SHP6 stage asset for the treatm infectious conjunctivitis

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