



# Q2 results 2010

Tuesday 20 July 2010

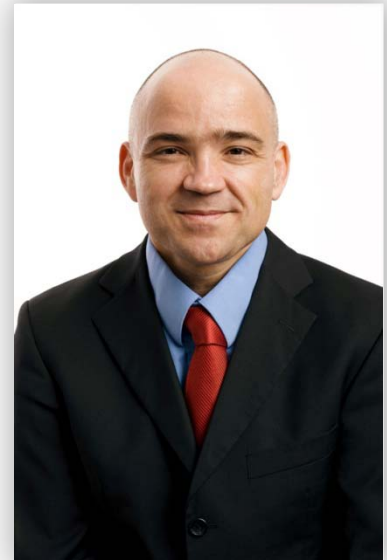
14.00 Basel / 13.00 UK / 08.00 US





# Introduction

Roland Haefeli



The following information contains certain “forward-looking statements”, relating to the company’s business, which can be identified by the use of forward-looking terminology such as “estimates”, “believes”, “expects”, “may”, “are expected to”, “will”, “will continue”, “should”, “would be”, “seeks”, “pending” or “anticipates” or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the company’s investment and research and development programs and anticipated expenditures in connection therewith, descriptions of new products expected to be introduced by the company and anticipated customer demand for such products and products in the company’s existing portfolio. Such statements reflect the current views of the company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

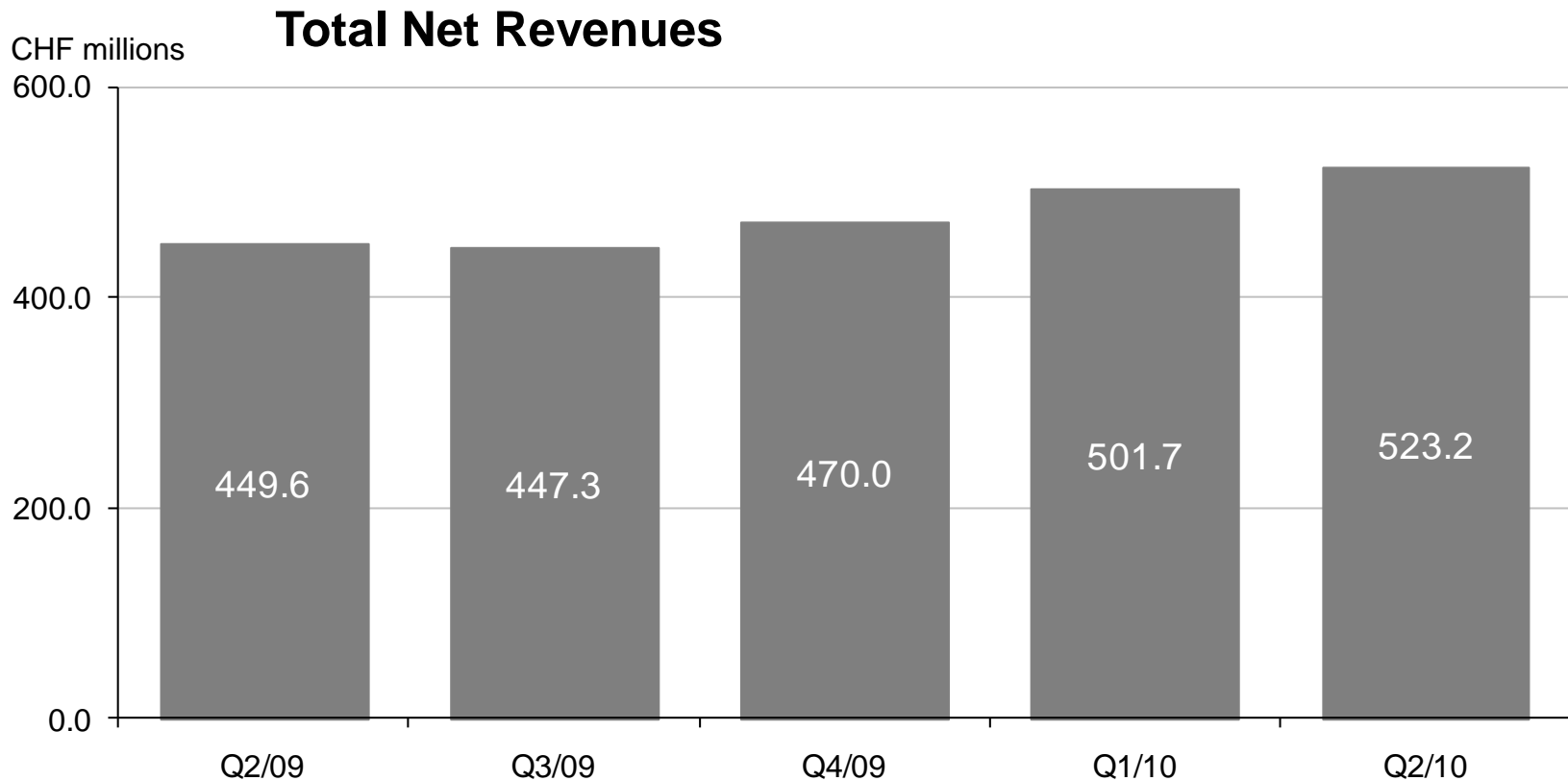


# Comments by the CEO

Jean-Paul Clozel



## Q2 2010 - Another outstanding quarter



## Strong financial performance in Q2 2010

Product Sales	CHF 483.4 million	up 13% YoY in local currencies
Tracleer Sales	CHF 430.1 million	up 12% YoY in local currencies
Non-GAAP EBIT	CHF 207.4 million	up 35% YoY in local currencies

## A strong PAH franchise becoming stronger

- Strong demand for Tracleer®
- Strong defense for Ventavis®
- Positive initial feedback on improved epoprostenol for injection
- Macitentan – Phase III to report in H2 2011
- Selexipag – Phase III enrolling

## A clinical pipeline making progress

- Clazosentan in aSAH Phase III reporting in October
- S1P<sub>1</sub> Phase II in MS >50% enrolled
- CRTH2 Phase II to initiate
- Antibiotic Phase II to initiate
- Total of 10 compounds in development

## **Trophos – Pipeline expansion and discovery support**

- Opportunity to leverage Actelion regulatory and marketing assets
  - Phase III with Olexosime in ALS (Amyotrophic Lateral Sclerosis)
  - Fully enrolled; results by end 2011
- Terms of the agreement
  - Option for 10 million Euro to acquire privately held Trophos
  - Acquisition price between 125 – 195 million Euros
- Advance drug discovery efforts in neurological disorders
  - Access to pioneering proprietary CNS assay technology

## **Actelion – 2010 and beyond**

- Strong performance in the first 6 months of 2010
- Strong performance expected also for the rest of the year
- Successful products, broad pipeline, focused Business Development efforts - well prepared for long term growth



# Comments by the CFO

Andrew J. Oakley



## Financial highlights H1 2010

In CHF millions	H1 2009	H1 2010	% of Change CHF	% of Change LC
<b>Net Revenues</b>	855.2	<b>1,024.9</b>	20	23
<b>Operating Income</b>	242.9	<b>326.6</b>	34	42
<b>Non-GAAP EBIT</b>	304.8	<b>405.1</b>	33	39
<b>Non-GAAP diluted EPS</b>	2.31	<b>2.74</b>	19	25

USD/CHF 1.0828 average (high: 1.1721 low: 1.0131)

EUR/CHF 1.4379 average (high: 1.4889 low: 1.3164)

## Financial highlights Q2 2010

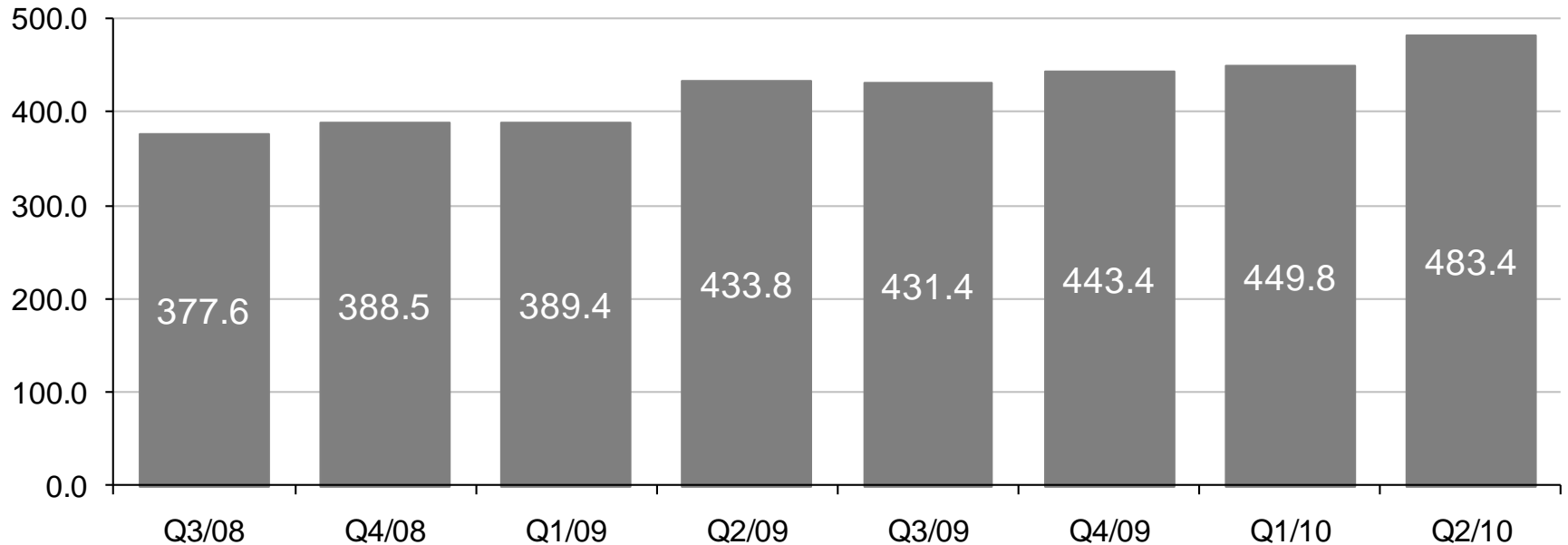
In CHF millions	Q2 2009	Q2 2010	% of Change CHF	% of Change LC
<b>Net Revenues</b>	449.6	<b>523.2</b>	16	18
<b>Operating Income</b>	121.2	<b>163.4</b>	35	40
<b>Non-GAAP EBIT</b>	158.3	<b>207.4</b>	31	35
<b>Non-GAAP diluted EPS</b>	1.26	<b>1.36</b>	8	12

USD/CHF 1.1080 average (high: 1.1721 low: 1.0436)

EUR/CHF 1.4119 average (high: 1.4589 low: 1.3164)

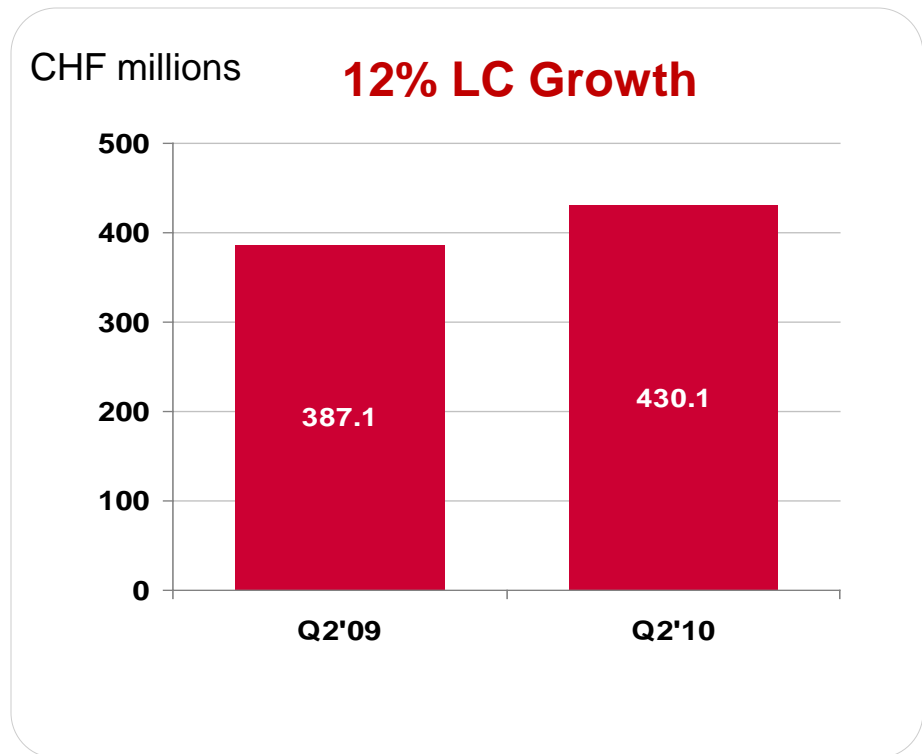
## Total product sales

CHF millions



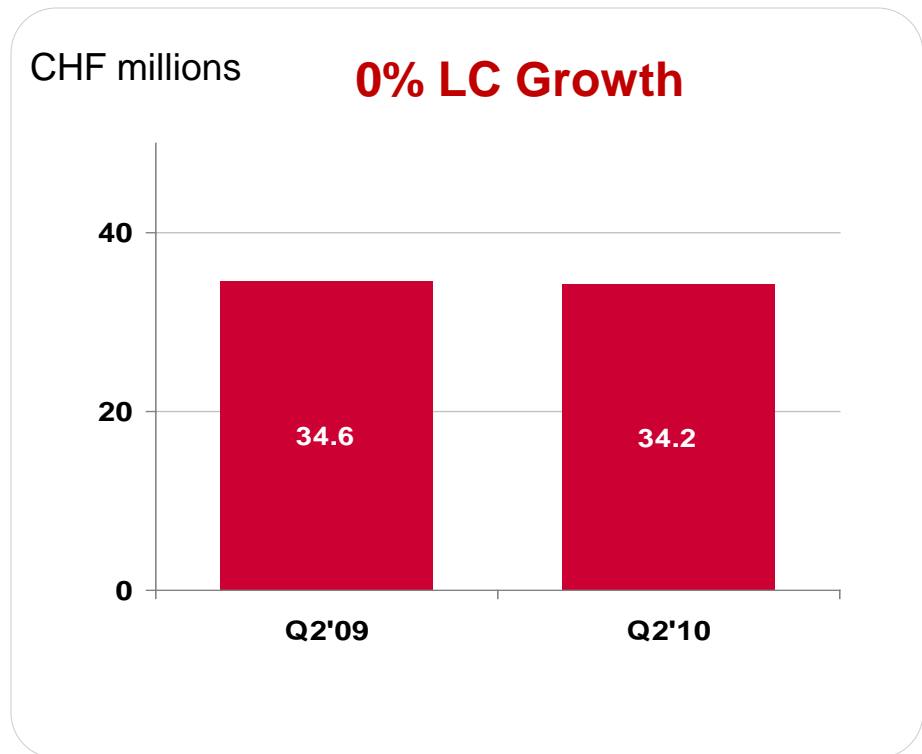
## Tracleer<sup>®</sup> - Strong volume growth globally

- Strong demand growth in all regions
- Major contributors US, Japan, emerging markets plus DU in Europe
- Pricing pressure well managed to date but expected to increase



## Ventavis<sup>®</sup> - Maintaining its position

- 70 % of patients transferred to increased strength formulation
- Limited impact of competition
- Expansion of inhaled market assumed

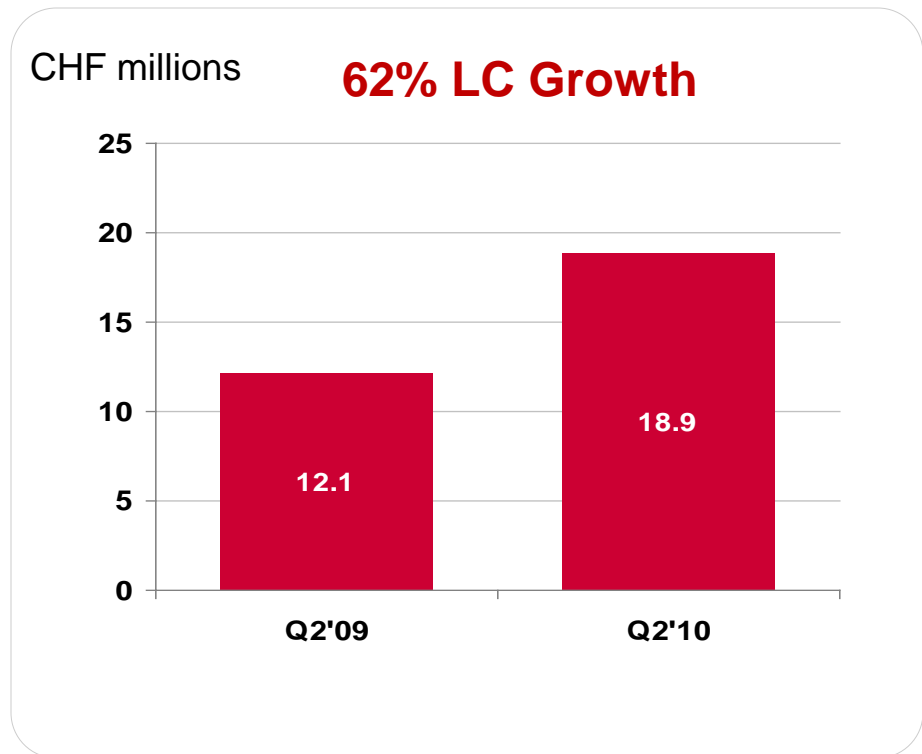


## **Epoprostenol for Injection: Further strengthens Actelion's PAH franchise**

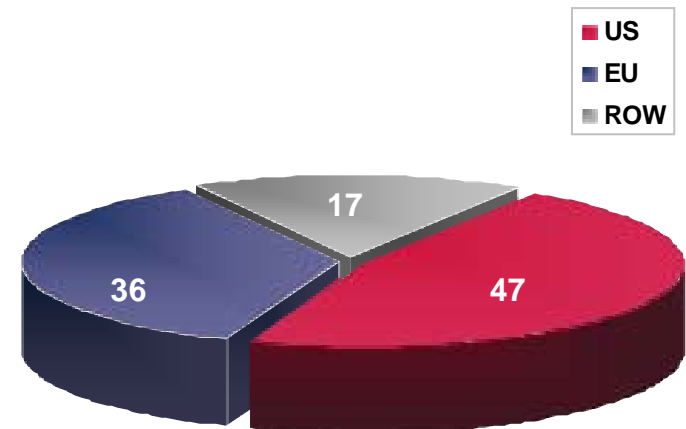
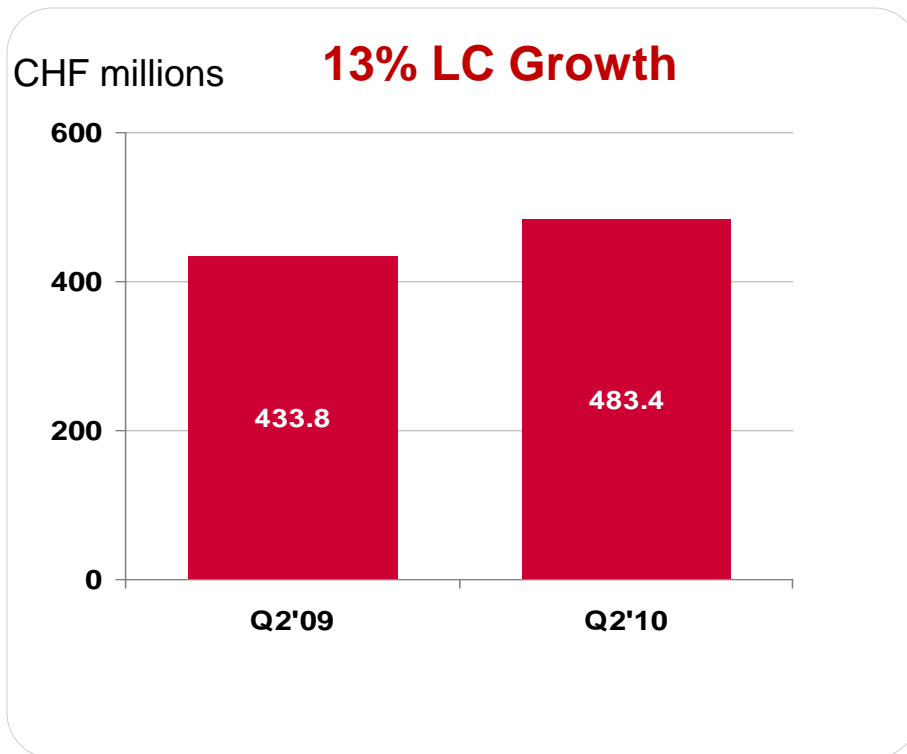
- Improved formulation of epoprostenol
  - Room temperature stable for up to 24 hours for patient convenience
- Launched in US April 2010
  - Q2 sales of 0.2 m USD
  - Demand to increase with experience
- Global availability
  - Filed in France in Q1 2010
  - Preparing filings in other territories

## Zavesca<sup>®</sup> - Strong growth in NP-C and GD1

- Strong growth in GD1 in Europe/US
- US strategy re NP-C under review
- ERT shortage to support demand



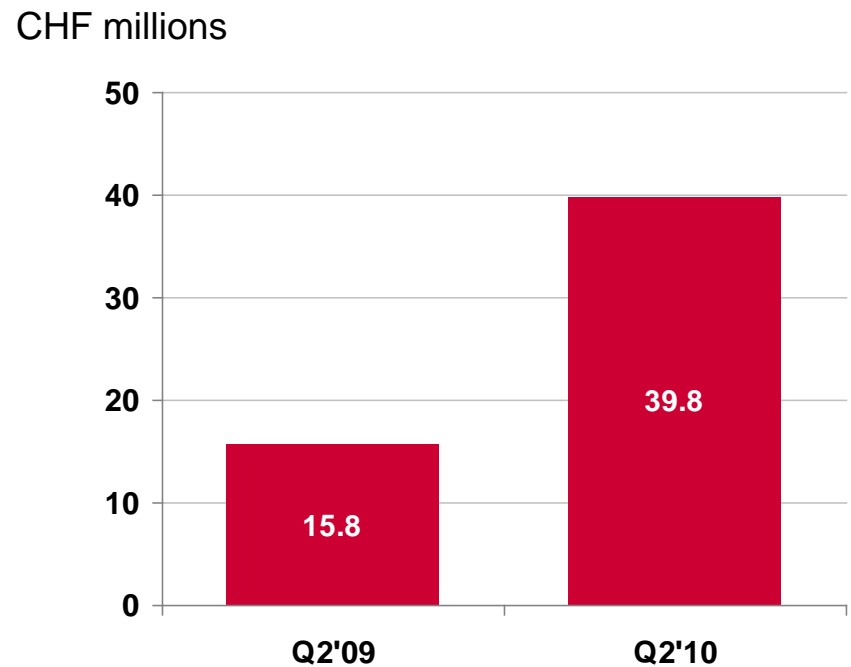
## Strong product sales growth in all markets



**Q2 2010 product sales by region in %**

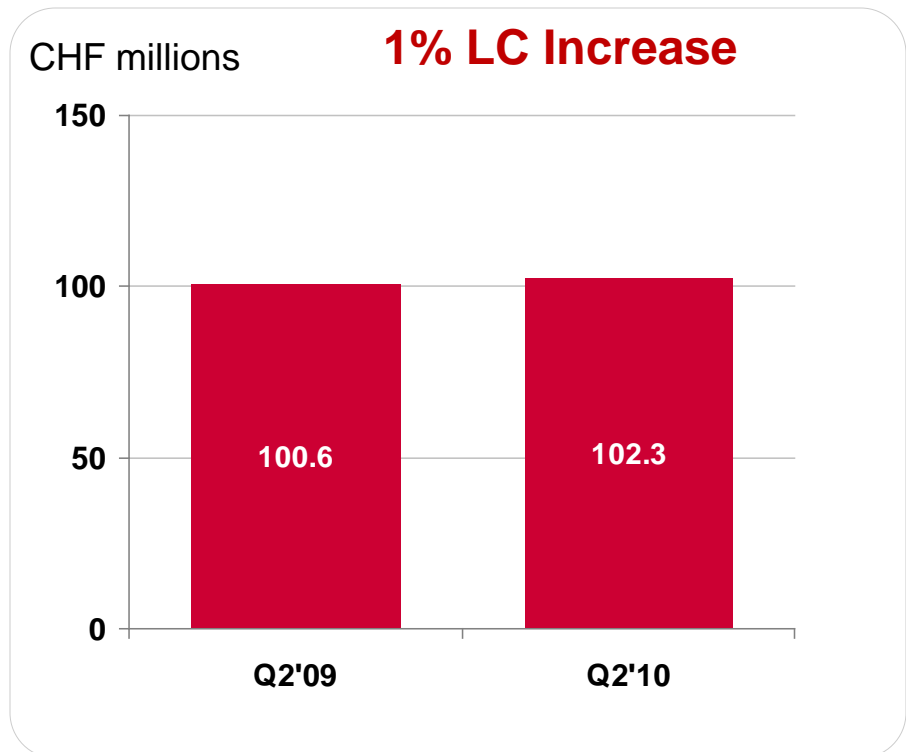
## Contract revenues – S1P<sub>1</sub> milestone effect

- GSK - CHF 5.2 m
- Roche - CHF 32.9 m
- Other - CHF 1.7 m



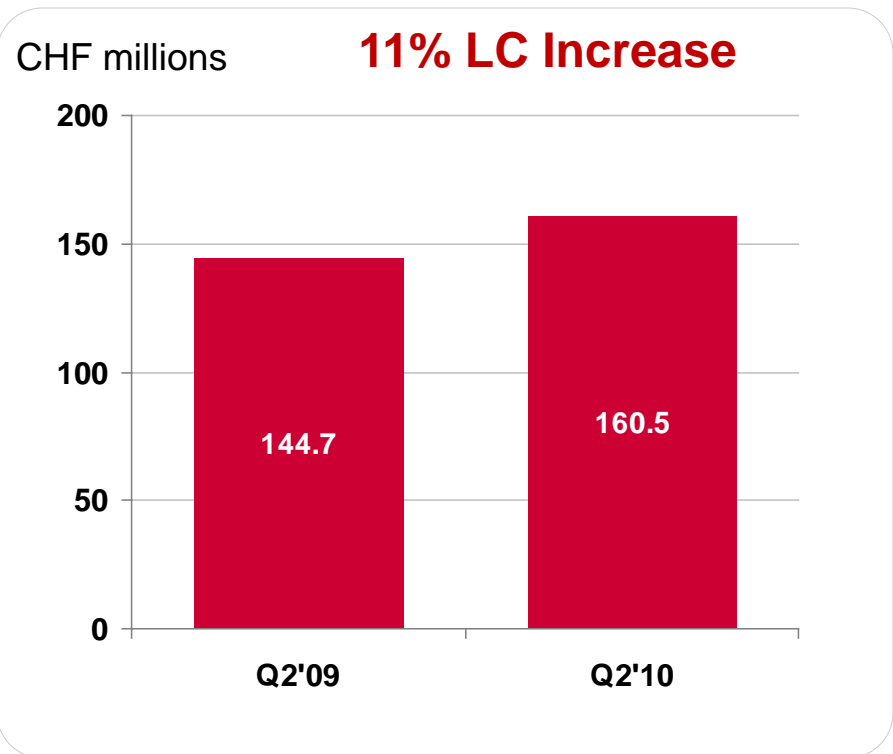
## Non-GAAP R&D OPEX

- Increases in S1P1, selexipag and room-stable epoprostenol
- Decreases from Restora I and BUILD III
- Acceleration of toxicology studies



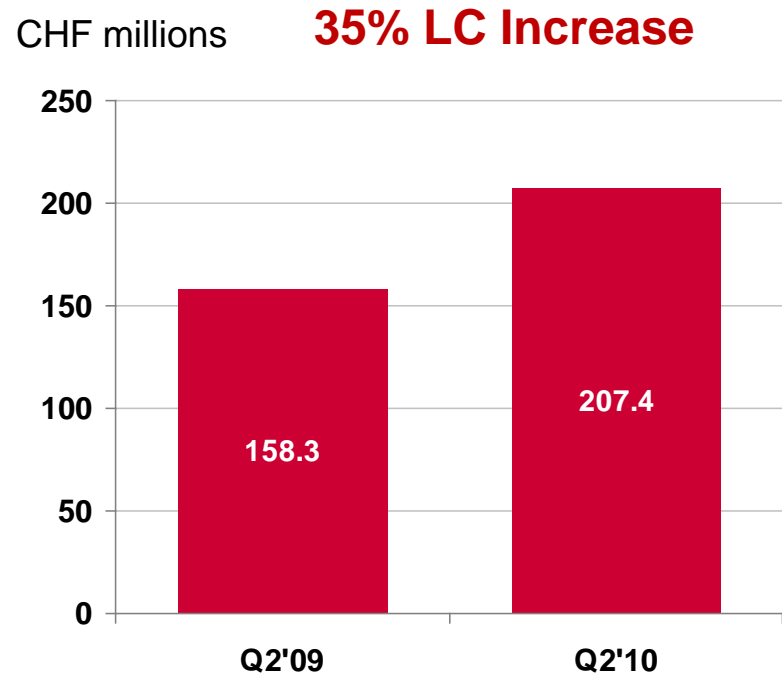
## Non-GAAP SG&A OPEX

- Ongoing geographic expansion
- Launch of room-stable epoprostenol
- IT standardization project



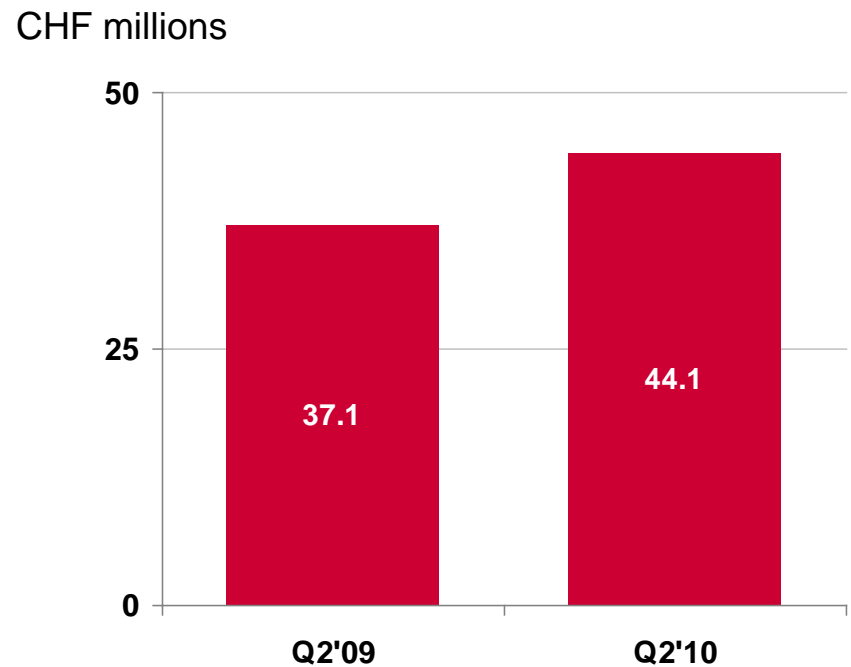
## Non-GAAP EBIT

- Negative currency headwind of CHF 7.2 million
- Positive impact from contract revenue increase
- Ongoing operational leverage



## Other GAAP OPEX

- Stock comp: CHF 24.9 m
- Depreciation: CHF 8.1 m
- Amortization: CHF 11.0 m

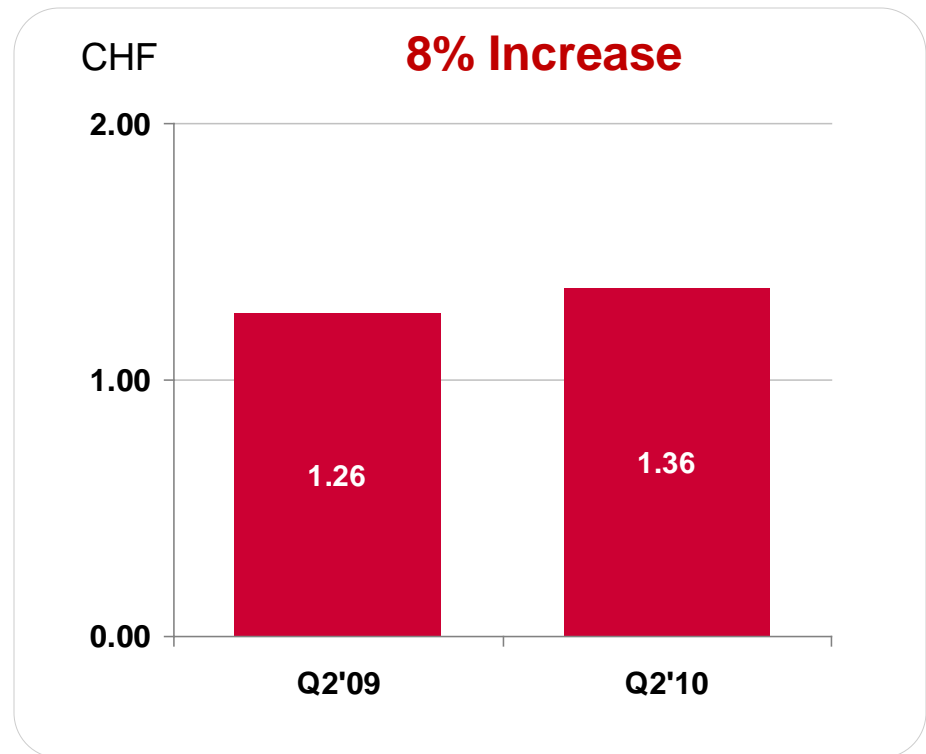


## **Below the operating line**

- Interest income of CHF 0.8 m
- Interest expense of CHF 2.0 m
- Non-cash charge of CHF 4.6 m for convertible bond
- Foreign exchange related valuation losses of CHF 20.7 m
- Income tax expense of CHF 15.4 m (11 percent)

## Non-GAAP EPS – Fully diluted

- Adverse foreign exchange impact
- Reduced share count



## Guidance for FY 2010 – earnings upgrade

In Local Currencies	Guidance 2010
Total Net Revenues	Low double digit growth
Non-GAAP (cash) EBIT	<b>21 to 24 percent</b> (previously < 20 percent)
Tax rate	10 to 12 percent

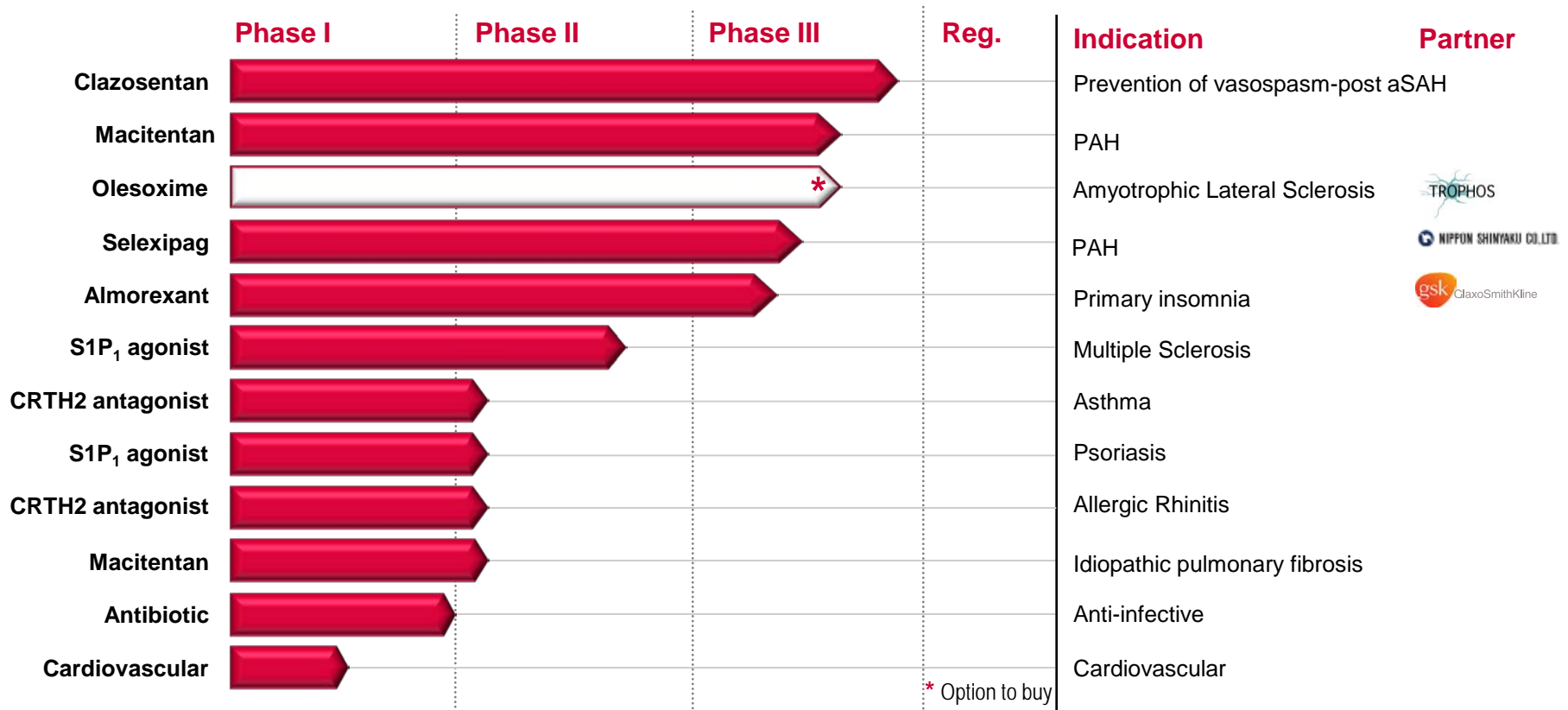


# Comments by the Head of Clinical Development

Guy Braunstein



# Actelion's pipeline overview



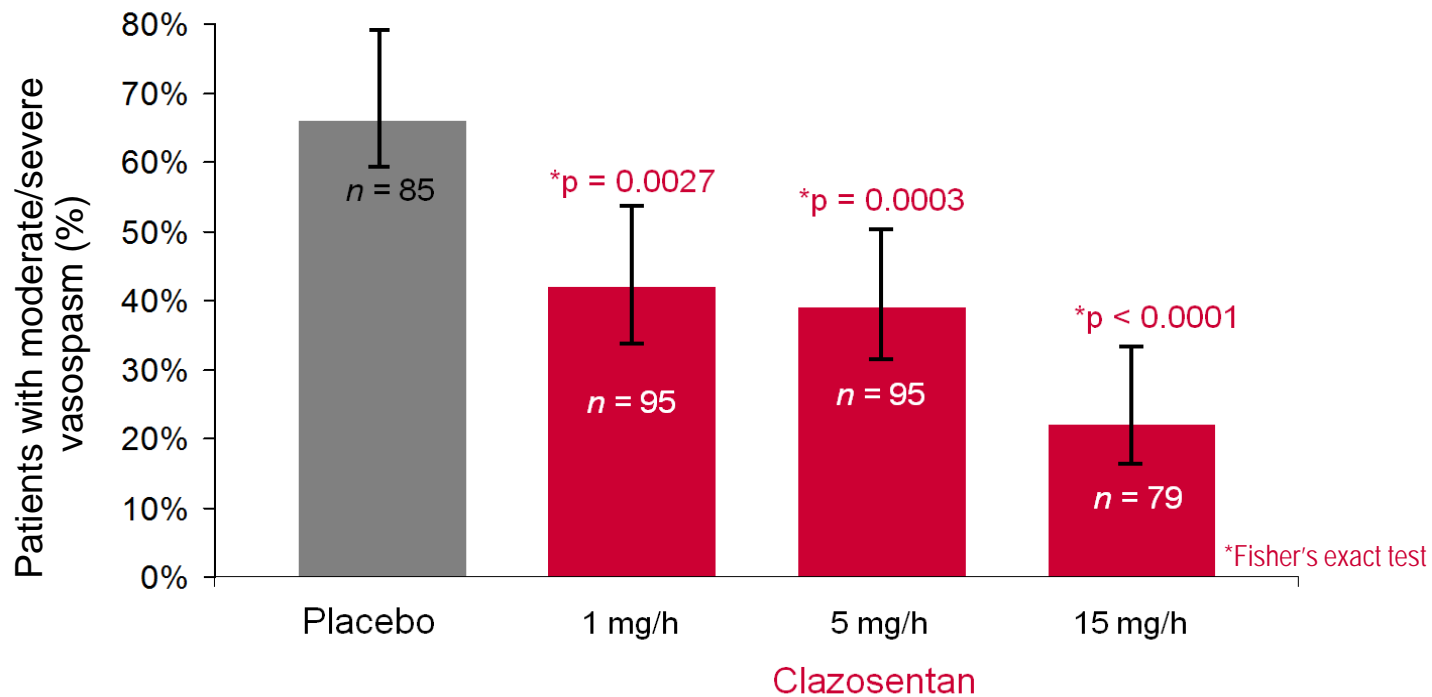
## **Clazosentan in aSAH: Significant untapped market opportunity**

- aSAH is a life threatening condition effecting more than 85,000 people in EU, US, Japan per year
- Major unmet medical need and limited treatment
  - Potential to establish new standard of care in these patients to prevent vasospasm related morbidity and improve long-term patient outcomes



# CONSCIOUS-1: Primary end-point results

Clazosentan reduces incidence of cerebral vasospasm



## **Clazosentan: Pivotal CONSCIOUS-2 data expected in October 2010**

- Intravenous endothelin receptor antagonist
- Pivotal Phase III CONSCIOUS-2 trial fully enrolled
  - >1,150 patients
  - 2:1 randomization, clazosentan : placebo
  - Infusion given for up to 14 days
  - Primary endpoint: Reduction in vasospasm-related morbidity and all-cause mortality in patients with aSAH post surgical clipping
- Potential for NDA filing based on CONSCIOUS-2 results



## Macitentan: The future of PAH treatment

- Internally-discovered next generation ERA
  - Once-daily dosing
  - Potential for improved safety and tolerability profile
  - Patent life through mid-2020s
- Pivotal Phase III SERAPHIN results before end 2011
  - Event driven morbidity/mortality study with > 700 patients
  - Long-term exposure
  - Conducted under SPA with FDA

## Selexipag: The future of PAH treatment

- A first-in-class, orally available, selective IP receptor agonist
  - In-licensed in March 2008 from Nippon Shinyaku
  - Patent life through mid-2020s
- Promising Phase II data - highly significant reduction in pulmonary vascular resistance when added to existing oral therapy
- Pivotal Phase III GRIPHON enrolling
  - 670 patients,
  - Event driven morbidity/mortality study with background oral therapy
  - Conducted under SPA with FDA

## **Almorexant: Primary insomnia**

- First-in-class, dual orexin receptor antagonist
  - Actelion/GSK to jointly develop and commercialize
- RESTORA-1 met its primary endpoint
  - Highly statistically significant improvement in subjective wake after sleep onset ( $p < 0.001$ )
  - Certain safety observations were made
- Non-pivotal program expanded to better understand tolerability/safety
- Decision to initiate additional Phase III studies expected in Q1 2011

## Macitentan: Additional opportunity in IPF

- Significant unmet need in IPF market
  - 200,000 patients in the U.S. and EU with IPF
  - 30,000 new diagnoses per year
- Phase II Study of Macitentan in IPF (MUSIC) fully enrolled
  - 156 patients targeted, 178 enrolled
  - Double-blind, randomized, placebo-controlled, multicenter study
  - Evaluating the safety and efficacy of macitentan
- Data from MUSIC expected in H2 2011

## **S1P<sub>1</sub> agonist: Therapeutic potential in multiple indications**

- Orally active, selective, S1P<sub>1</sub> receptor agonist
  - Blocks lymphocyte migration out of lymphoid tissue into the lymphatic and blood circulation
  - Short half life
  - Rapid restoration of immune system post discontinuation
- 400 patient Phase II trial in multiple sclerosis
  - > 50% enrolled at the end of Q2 2010
  - Multicenter, randomized, double-blind, placebo-controlled, parallel-group, dose-finding
  - Data expected in H2 2011
- Phase II trial in Psoriasis to start later this year

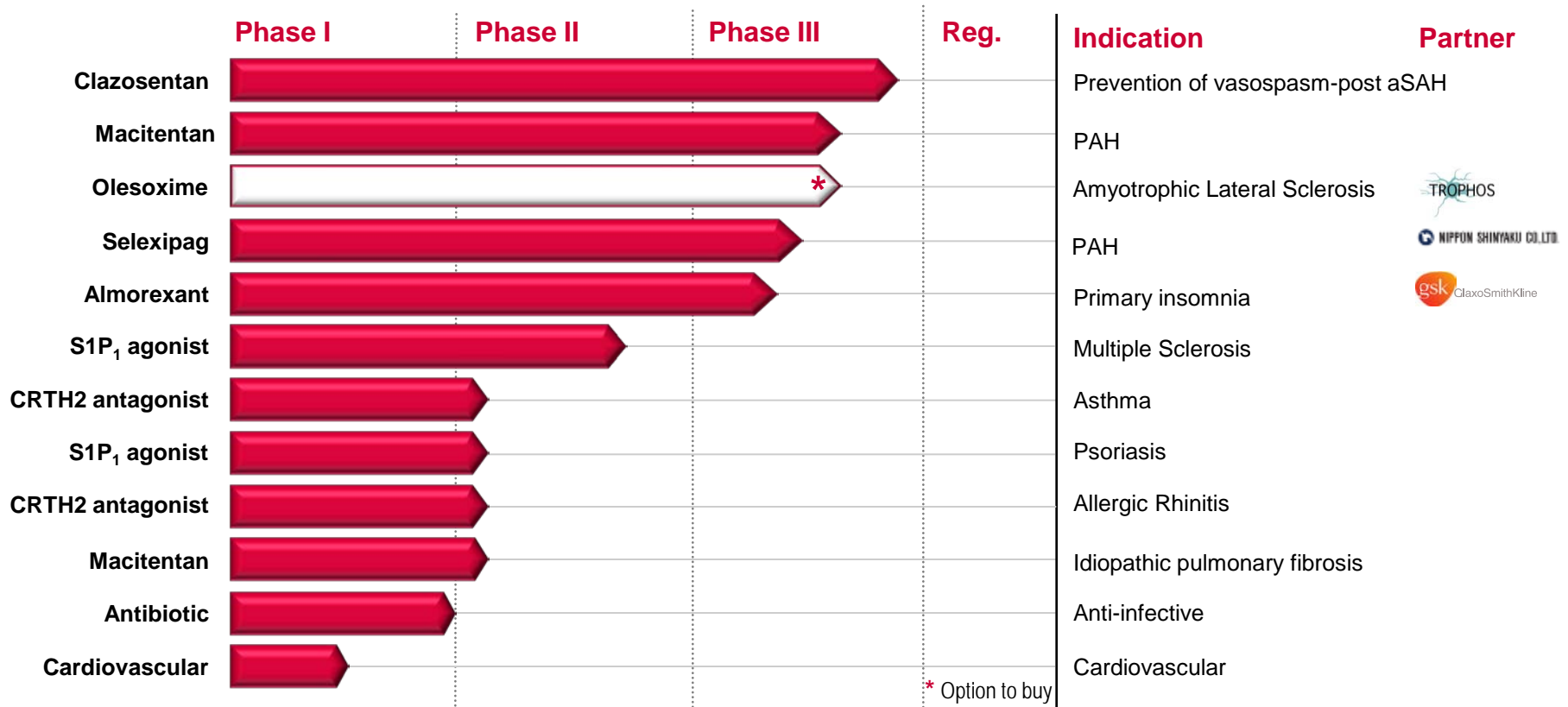
## **CRTH2 antagonist: Phase II initiation before year-end**

- Selective, orally available compound believed to block the inflammatory processes
  - Potential in allergic indications
  - Proof of concept achieved
  - Preclinical package updated
- Phase II studies to begin in asthma and allergic rhinitis
  - Results expected in allergic rhinitis in H1 2011
  - Results expected in asthma in 2012

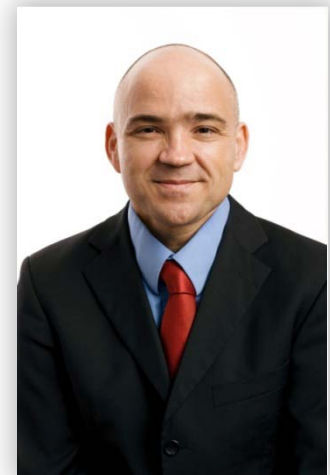
## **Antibiotic: Prepared to enter Phase II**

- Potent, novel antibiotic to enter Phase II in H2 2010
- Strong pre-clinical data
  - Shown to be highly active against problematic and multi-resistant pathogens
  - Demonstrated low propensity for resistance development
- Well tolerated in Phase I trial

# Actelion's pipeline overview



## Questions & Answers



## News Flow

---

**9M Results 2010**

Thursday, 21 October, 2010

---

**CONSCIOUS-2 in clipped aSAH**

expected October 2010

---