# Novartis
# Our Next Phase of Growth

**Joseph Jimenez**

**CEO Novartis**

JP Morgan Healthcare Conference, January 7th, 2013

NOVARTIS

# Disclaimer

The following presentation contains forward-looking statements that can be identified by terminology such as “next phase of growth,” “strategy,” “strategic,” “pipeline,” “expected,” “potential,” “planned,” “expect,” “about to enter,” “next growth phase,” “confident,” or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products; or regarding potential future sales or earnings of the Novartis Group or any of its divisions; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Group regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any new products will be submitted or approved for sale in any market, or that any new indications will be submitted or approved for any existing products in any market, or that any submissions or approvals will occur at any particular time, or that any such potential new products or existing products will achieve any particular revenue levels, or at any particular time. Nor can there be any guarantee that the Group, or any of its divisions, will achieve any particular financial results. In particular, management's expectations could be affected by, among other things, the inherent difficulties and uncertainties involved in making predictions about events expected to take place in the medium- to long-term future; unexpected clinical trial results, including additional analyses of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays or government regulation generally; government, industry, and general public pricing pressures; uncertainties regarding future demand for our products; uncertainties involved in the development of new healthcare products; competition in general; the Group's ability to obtain or maintain patent or other proprietary intellectual property protection, including the ultimate extent of the impact on the Group of the loss of patent protection on key products and the potential timing of any such losses; uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation and investigations regarding sales and marketing practices, shareholder litigation, government investigations and intellectual property disputes; unexpected product manufacturing and quality issues, including the potential outcome of the Warning Letter issued to us with respect to three Sandoz manufacturing facilities, the potential outcome of efforts to restart production of products formerly produced at the Consumer Health manufacturing facility at Lincoln, Nebraska, and the potential outcome of our efforts to improve quality at other Group manufacturing sites; uncertainties regarding the effects of the ongoing global financial and economic crisis, including the financial troubles in certain Eurozone countries; uncertainties regarding future global exchange rates; the impact that the foregoing factors could have on the values attributed to the Group's assets and liabilities as recorded in the Group's consolidated balance sheet; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. 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. Novartis is providing the information in this presentation as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

# Today's discussion

- **Our Company and Performance in 2012**
- Our Next Phase of Growth



NOVARTIS

# Novartis' strategy is to win through science-based innovation, in growth segments of healthcare

**Environment**

**Patient needs**

- Innovative medicines
- Prevention
- Affordable options
- Self-care

Full range of healthcare options

**Novartis**

- Pharmaceuticals
- Eye care (Alcon)
- Generics (Sandoz)
- Vaccines and Diagnostics
- Consumer Health (OTC, Animal Health)



NOVARTIS

# Our strategic priorities are clear...

1. **Extend our lead in innovation**
   - Ensure best in class pipelines in all divisions
2. **Accelerate growth**
   - Translate innovation into sales and profit growth
3. **Drive productivity**
   - Lower costs to improve margins

# ...and we delivered on these in 2012

## 1 Innovation

- **17 key approvals in 2012[1,2]**, incl.
  - Afinitor® in EU and US
  - Jakavi® in EU
  - Flucelvax® in US
  - Dailies Total 1 ® in US
- **Positive CHMP opinion for Bexsero®**
- **9 positive phase III trials[1]**

## 2 Growth

- **29% of Group sales from recently launched products[3] at Q3**
- **China growth +22% CC** in Q3 vs. PY

## 3 Productivity

Over first 9 months 2012:

- **Procurement:** USD 900M in savings
- **Manufacturing**: 15 sites divested or restructured
- **Marketing and sales spend as % net sales** down -0.9% pts vs. PY in CC

*1 Across Pharmaceuticals Division, Alcon and V&D in EU and USA*
*2 Approvals counted as indication – regulator combinations; exclude label updates and minor approvals*
*3 Products launched since 2007 except Sandoz (products launched in last 24 months)*



NOVARTIS

# The progress of our Pharmaceutical Division's pipeline in 2012 has been strong



[1] *In US and EU*
[2] *Approvals counted as indication – regulator combinations; exclude label updates and minor approvals*



NOVARTIS

# We reported key phase III results for QVA149 and RLX030

**Example major clinical trial results in 2012**

## QVA149 in COPD

ENLIGHTEN A2307 · ILLUMINATE 2313 · BRIGHT 2305 · SHINE A2303 · SPARK A2304

- Potential to be the first LABA / LAMA combo to market
- Demonstrated superiority to both Spiriva® and Seretide®
- COPD market segment USD 11.8 bn in 2012 expected to grow at a CAGR of ~4.6%

## RLX030 in Acute Heart Failure


- Improved dyspnea and increased survival when administered in acute heart failure
- Submission in Europe and US expected in H1 2013
- Investments planned in launch preparation throughout 2013

*Note: Spiriva® and Seretide® are registered trademarks of Boehringer Ingelheim Pharmaceuticals and GlaxoSmithKline, respectively."*
*Source: ILLUMINATE trial*



NOVARTIS

# Vaccines and Diagnostics and Alcon have advanced their innovation platforms

## Vaccines and Diagnostics

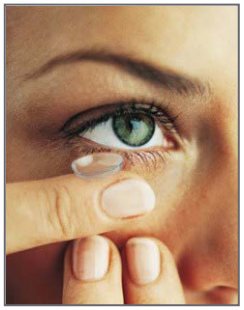
FLUCELVAX® Influenza Virus Vaccine

- First cell-based flu vaccine in the US
- Controlled manufacturing environment, reducing risk of impurities and contaminates

BEXSERO® Meningococcal Group B Vaccine (rDNA, component, adsorbed)

- First broad coverage MenB vaccine for all age groups, including infants*

## Alcon



- Dailies Total 1 ®
- First water gradient silicone hydrogel contact lens, improving patient comfort

- CE Marks in EU for new advanced technology intra-ocular lenses

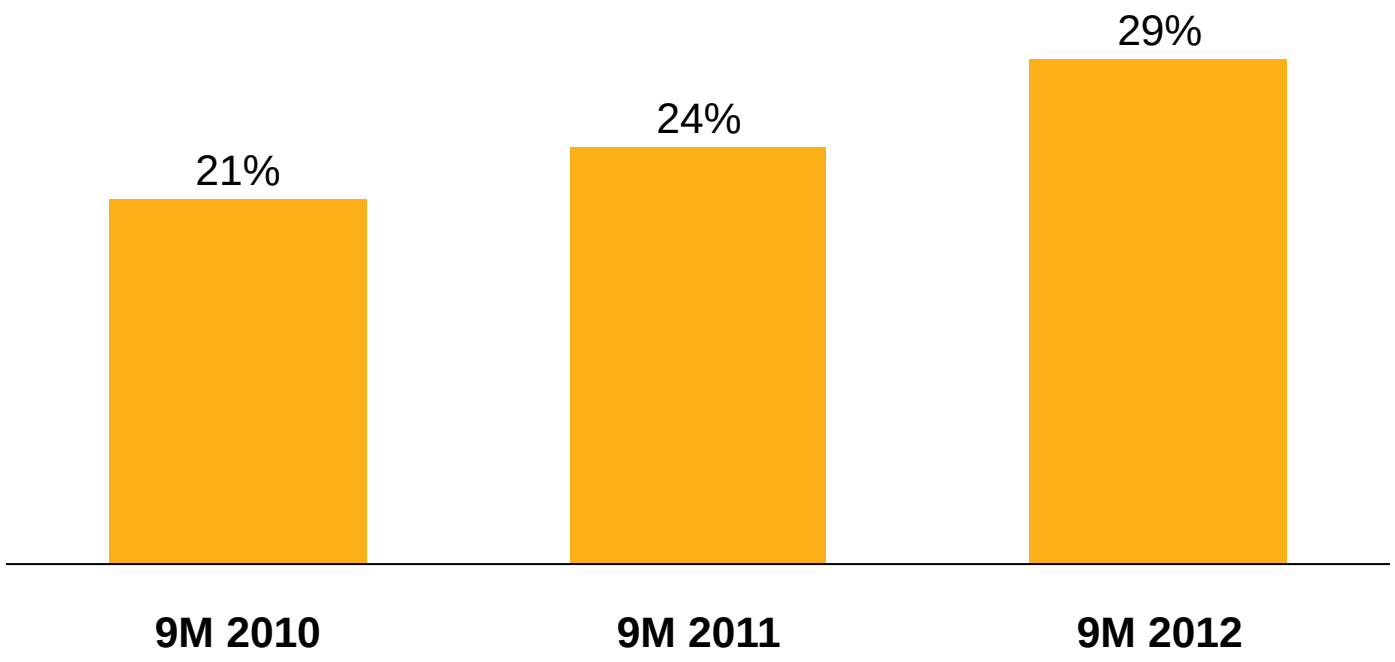
**Upon approval*



NOVARTIS

# Recently Launched Products[1] account for 29% of our sales

## % of net sales from Recently Launched Products[1]



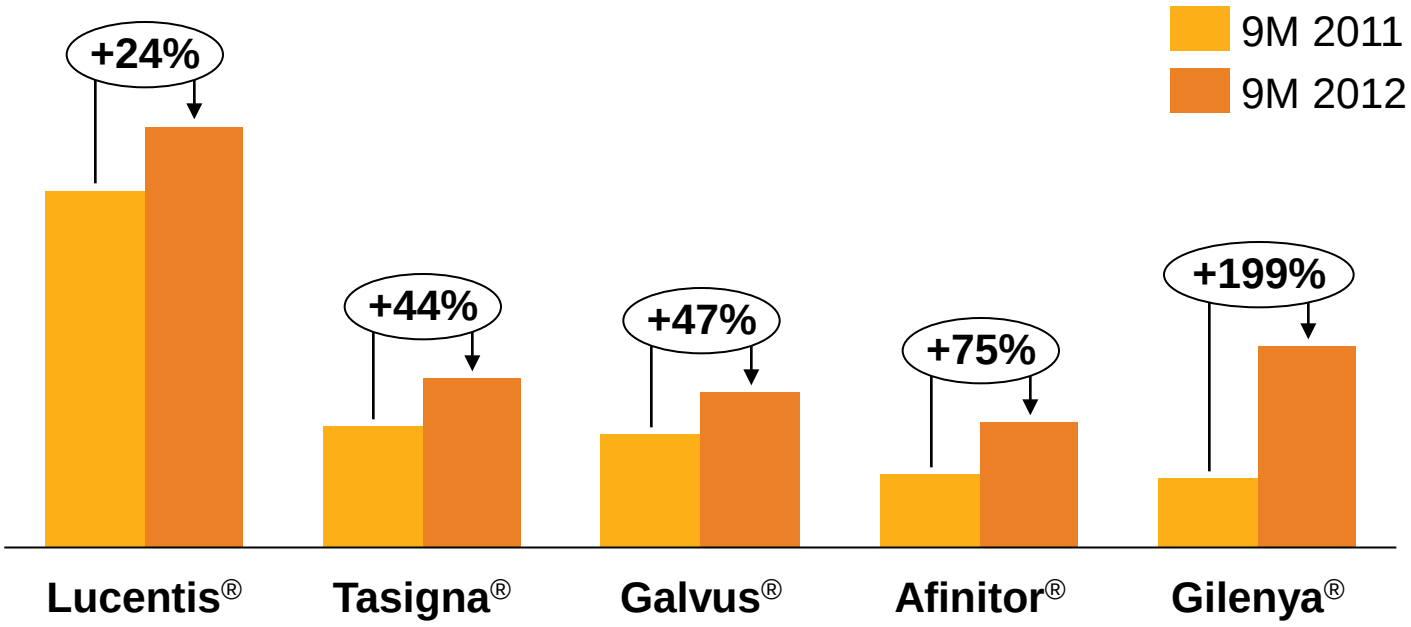

[1] *Major products launched since 2007 including Alcon, except Sandoz (all launches in the last 24 months) excluding A(H1N1)*



NOVARTIS

# Key products maintain rapid growth...

**9M 2012 Sales vs. PY**
Growth in CC



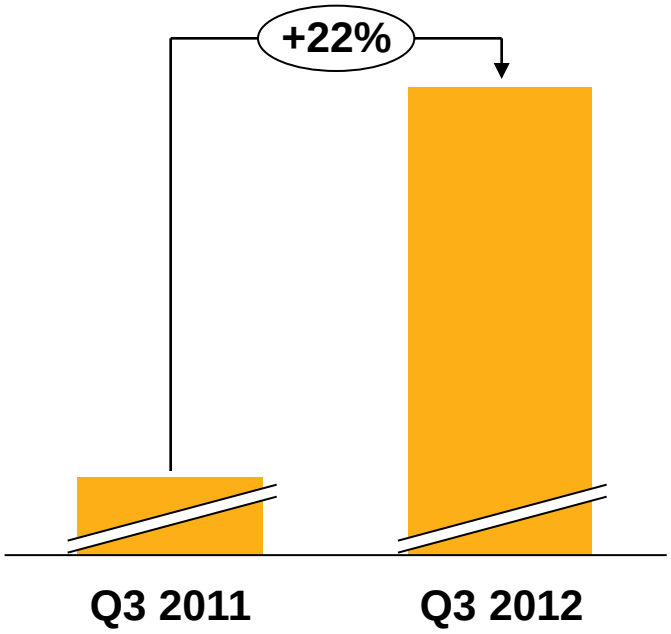

| | | | | | |
|---|---|---|---|---|---|
| **Launch year** | 2007 | 2007 | 2008 | 2009 | 2010 |



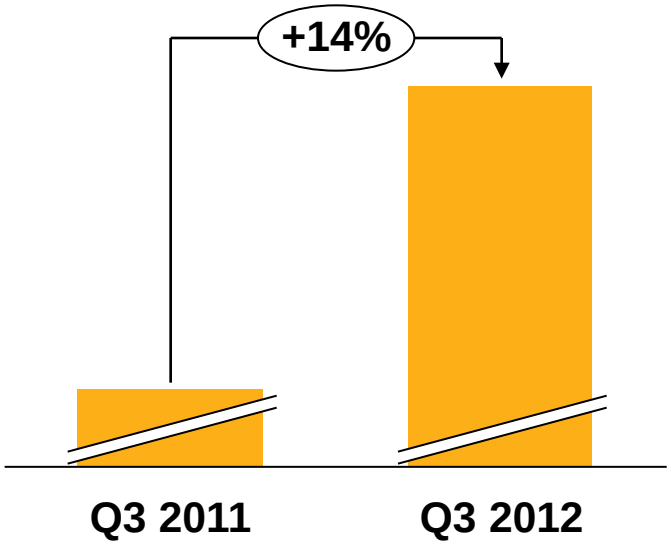
NOVARTIS

# … and our emerging markets growth is accelerating

## China sales




## Russia sales






NOVARTIS

# We have an aggressive productivity agenda

| | |
|---|---|
| ***Procurement*** | ▪ Leveraging scale<br>▪ Global category management<br>▪ Country Centers of excellence |
| ***Manufacturing Footprint*** | ▪ 15 sites divested or in a process of restructuring since beginning of the program |
| ***Marketing & Sales*** | ▪ Geographical resource reallocation<br>▪ Simplification of processes<br>▪ Reduction as % of net sales |

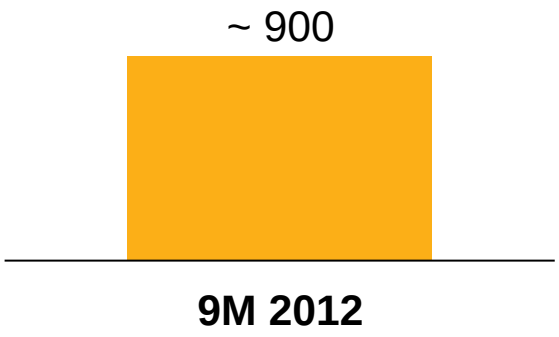
# We have reorganized Procurement across the company, to operate cross-divisionally

## Novartis Procurement organization

- Accountable for a global spend of over USD 20 billion per year
- Coordinates activities cross-divisionally to drive value and efficiency from scale, including across:
  - Global category management
  - Shared Country Procurement teams
  - Talent management

**Performance gain associated with cross-divisional model**

**Procurement savings**
(in USD m)






NOVARTIS

# Not everything went to plan in 2012

| | Setbacks | Actions taken |
|---|---|---|
| **Sandoz and Consumer Health** | **Supply constraints due to Quality remediation** | ▪ Investments into Remediation<br>▪ Focus on Quality |
| **Vaccines and Diagnostics** | **Supply constraints** | ▪ Investment in technical operations and modernization of manufacturing footprint |

# Our system-wide focus on quality is paying off

**Over 250**
Health authority Inspections

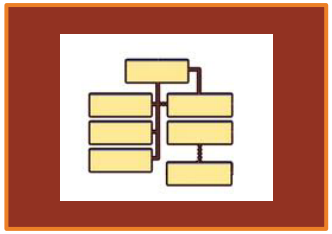
**1st of 3**
Sandoz sites under Warning Letter now compliant

**Over 50**
FDA Inspections – vast majority good or satisfactory

- Our governance is working
- Systematic upgrades to build quality as competitive advantage
- However, upgrades not yet complete at all sites, therefore some GMP compliance issues remain

# We are strengthening Sandoz quality via four priorities

**Deliver on FDA commitments**



**Strengthen leadership, organization, and governance**

**Upgrade facilities and systems**


**Culture: Quality on the shop floor**

# Progress at Lincoln OTC plant was slow during 2012. First products returned to market in Q4.

## Progress on Lincoln remediation

- Lincoln validation of production lines continues
- Focus throughout 2012 was on upgrading equipment, training, and validation

## Return to market independent of remediation, via third party manufacturers


#1 Neurologist Recommended OTC Migraine Remedy


Pediatric cough and cold


#1 Doctor and Pharmacist Recommended Athlete's Foot Remedy

# We are on a journey to make quality a competitive advantage, shifting from remediation to prevention

## KEY STEPS TAKEN

- ✓ Strong management involvement
- ✓ New governance structure, with Quality Head reporting to CEO
- ✓ Common standards and “Quality Metrics” across divisions
- ✓ Doubled Audit programs and assessments
- ✓ Official Quality objectives at all levels
- ✓ People & Capabilities upgrade

# Today's discussion

- Our Company and Performance in 2012
- **Our Next Phase of Growth**



NOVARTIS

# In 2013-15 we expect to enter a growth phase driven by three factors

| Key growth drivers | Examples |
|---|---|
| **A** Launch products [1] | GILENYA (fingolimod) capsules 0.5mg; AFINITOR (everolimus) Tablets; LUCENTIS RANIBIZUMAB; Galvus vildagliptin; Tasigna (nilotinib) 200mg capsules; Xolair omalizumab |
| **B** Emerging growth markets [2] |     |
| **C** Lower impact of patent expirations | ▪ Expected reduction of impact on sales of patent expirations |

[1] *Includes products launched since 2007, plus products expected to be approved in future*
[2] *All markets except the US, Canada, Western Europe, Australia, New Zealand, and Japan*

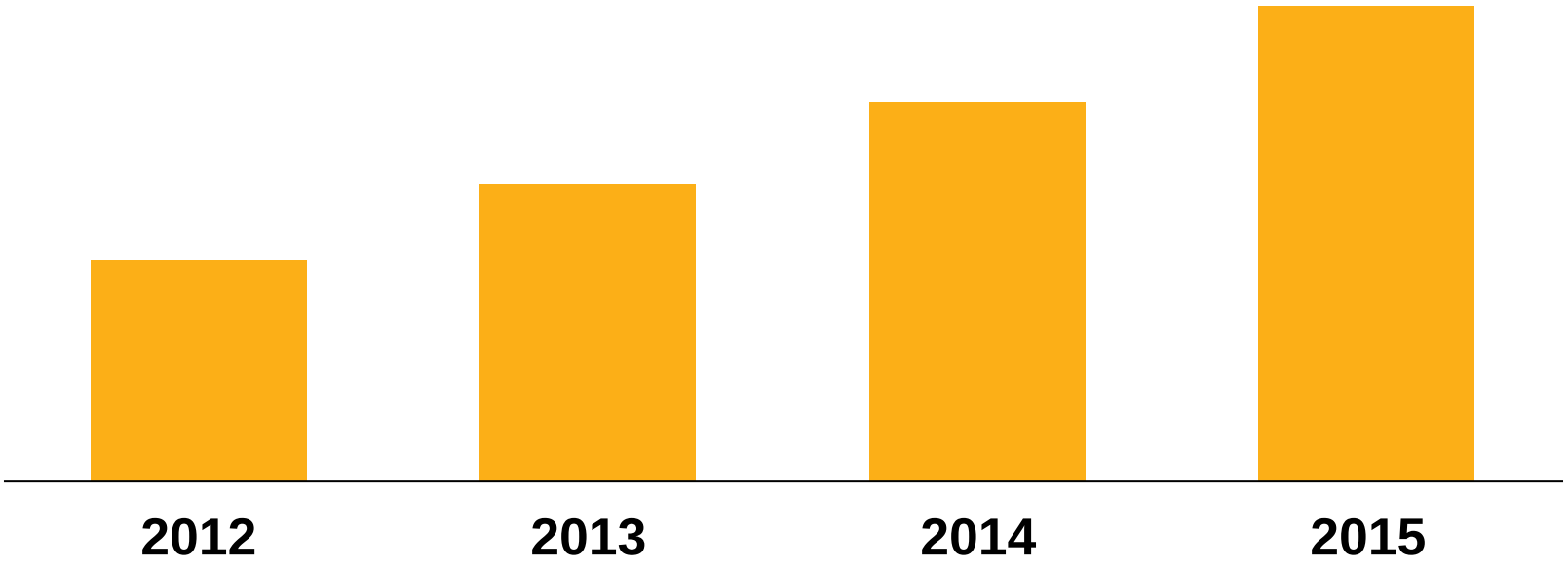


NOVARTIS

# Launch Products are expected to drive growth

## Expected sales from launch products[1]

Illustrative




[1] *Includes products launched since 2007, plus products expected to be approved in future*



NOVARTIS

# Over the next two years, we expect 24 pivotal study readouts, up to 20 filings and 18 approvals...

| Expected milestones [2] | Next 12 months | 13-24 months |
|---|---|---|
| **Pivotal study read-outs** | **13**<br>▪ Xolair® - Urticaria<br>▪ Seebri®- COPD (US)<br>▪ AIN457 - Psoriasis<br>▪ LCQ908 - Metabolic diseases<br>▪ LCZ696 - Hypertension<br>▪ AFQ056 - Fragile X Syndrome<br>▪ Afinitor® – HCC<br>▪ LBH589 - MM<br>▪ Afinitor® - HER2+ breast cancer 2nd/3rd line<br>▪ PKC412 - AML<br>▪ Tasigna® - c-KIT Melanoma<br>▪ TKI258 - RCC<br>▪ PKC412 - ASM | **11**<br>▪ AIN457 - Arthritides<br>▪ LCZ696 - Heart Failure<br>▪ QMF149 - Asthma<br>▪ QVA149 - COPD (US)<br>▪ Tekturna® - Heart failure<br>▪ LDE225 - BCC<br>▪ Afinitor® – Lymphoma<br>▪ Afinitor® - HER2+ breast cancer 1st line<br>▪ Afinitor® - non functioning carcinoid<br>▪ INC424 - PV<br>▪ LDK378 - NSCLC |
| **Filings** | **10**<br>▪ QVA149 - COPD: EU<br>▪ AIN457 - Psoriasis: US, EU<br>▪ ACZ885 - SJIA: US, EU<br>▪ Xolair® - CIU: US, EU<br>▪ Signifor®- Acromegaly : US, EU<br>▪ Afinitor® - HER2+ breast cancer 2nd/3rd line: US, EU<br>▪ LBH589 - MM: US, EU<br>▪ Afinitor® - HCC: US, EU<br>▪ TKI258 - RCC: US, EU<br>▪ LLX030 - AHF: US, EU | **10**<br>▪ LCQ908 - Metabolic diseases: US, EU<br>▪ LCZ696 - Heart Failure: US<br>▪ AFQ056 - Fragile X Syndrome: US, EU<br>▪ LDE225 - BCC[7]: US, EU<br>▪ INC424 - PV: US, EU<br>▪ LDK378 - NSCLC: US, EU<br>▪ Afinitor® - HER2+ breast cancer 1st line: US, EU<br>▪ Tasigna® - c-KIT Melanoma: US, EU<br>▪ PKC412 - AML: US, EU<br>▪ PKC412 - ASM: US, EU |
| **Approvals**[1] | **7**<br>▪ Certican® - Liver Transplantation: US<br>▪ QTI571 - PAH: EU<br>▪ ACZ885 - SJIA: EU<br>▪ ACZ885 - Refractory gout: EU<br>▪ Lucentis® - PM: EU<br>▪ Signifor® - Acromegaly: US<br>▪ Exjade®- non transfusion-dependent thalassemia: US | **11**<br>▪ AIN457 - Psoriasis: US, EU<br>▪ QVA149 - COPD: EU<br>▪ Xolair® - CIU: US, EU<br>▪ TKI258 - RCC: US, EU<br>▪ LDE225 - BCC: US, EU<br>▪ PKC412 - AML: US, EU<br>▪ PKC412 - ASM: US, EU<br>▪ LBH589 - MM: US, EU<br>▪ Afinitor® - HER2+ breast cancer 2nd/3rd line: US, EU<br>▪ Afinitor® - HCC: US, EU<br>▪ Signifor® - Acromegaly: EU |

*Note I: Key clinical read-outs consists of pivotal studies only*
*Note II: Approvals / Filings in US and EU only; pediatric approvals / filings / read-outs excluded; CHMP positive opinion considered as EU approval*

[1] *Approval counted for each indication*

[2] *Expected milestones for our Pharmaceuticals Division*

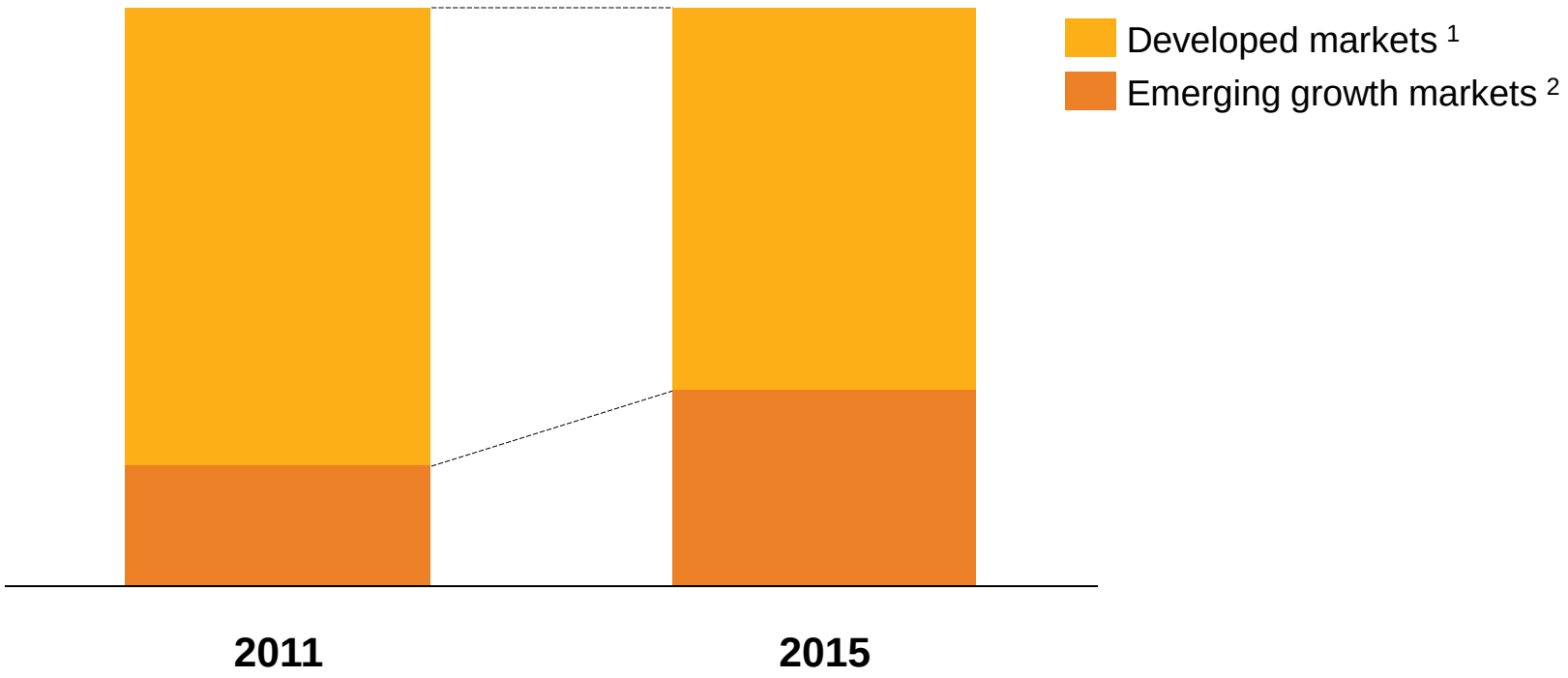


NOVARTIS

# ... while our center of gravity is expected to shift toward fast growing markets...

## Geographic distribution of Group sales

Illustrative



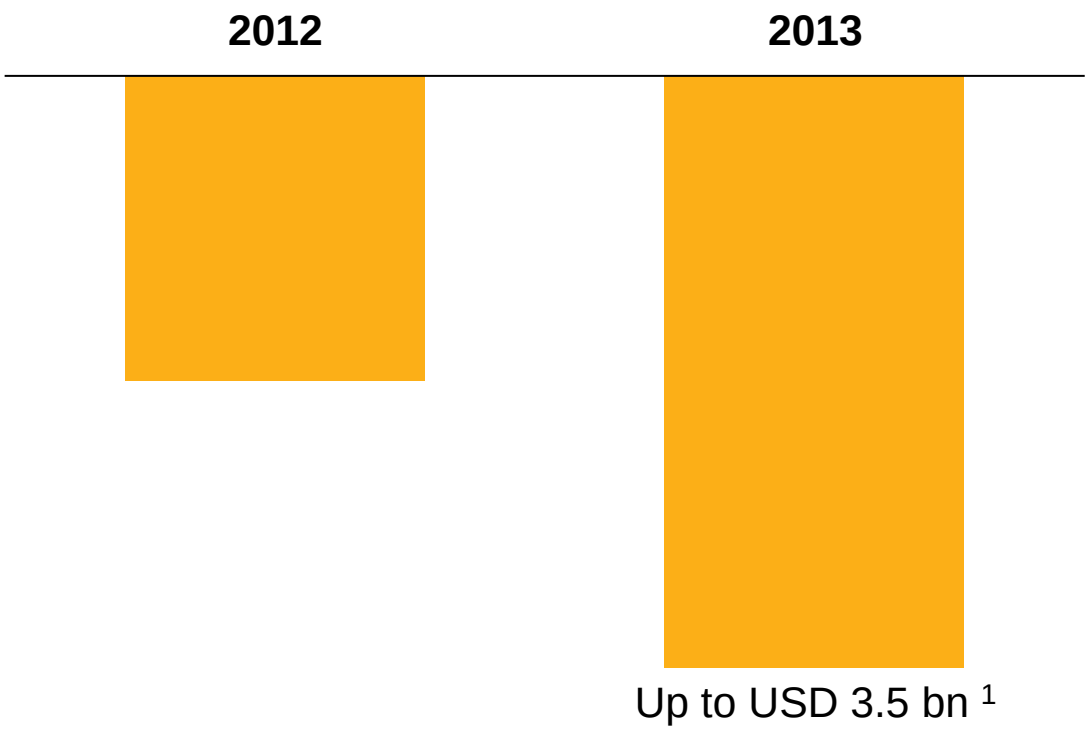

[1] *Developed markets include US, Japan and Europe*
[2] *Emerging markets include the rest of the world*



NOVARTIS

# … and our exposure to patent expirations is expected to decline

**Expected impact of patent expirations on Novartis Group sales**
Illustrative




**2014-15**
- Lower impact of generic erosion expected at ~2-3% of net sales (e.g., Zometa®, Reclast ®)

[1] *Uncertainty due to timing of Diovan ® monotherapy*



NOVARTIS

# Summary: Key messages

- Strategy to win through science-based innovation, focusing on high growth segments of healthcare
- As of Q3 2012
  - On target to meet expectations
  - Strong innovation delivery across divisions
  - Aggressive management of Quality remediation
- About to enter our next growth phase[1]
  - Launch products
  - Emerging growth markets
  - Lower impact of generics after 2013
- We’re confident of our prospects beyond 2013

[1] *Barring unforeseen events*

# Q & A

**Joseph Jimenez**

**CEO Novartis**

JP Morgan Healthcare Conference, January 7th, 2012

NOVARTIS