

# Global Pharmaceutical & Biotechnology Outlook 2014: Major US and EU

<https://marketpublishers.com/r/GDD04D388BBEN.html>

Date: January 2014

Pages: 113

Price: US\$ 2,500.00 (Single User License)

ID: GDD04D388BBEN

## Abstracts

Strategy Diversification Divested: Productivity measurements, Divestment of non-core assets resulting in healthy Cash position- Will accelerate Next wave of targeted acquisition

In the recent years several new therapies have been approved in the area of diabetes (SGLT-2, GLP-1 agonists), Multiple Sclerosis, HCV, melanoma and breast cancer from major pharmaceutical companies. Many of them are expected to reach multibillion dollars peak sales in the near-term which is likely to compensate the patent expiry loss in top-line revenue. Novel mechanisms like anti-PD1, anti-PCSK9 and CDK inhibitors have also got exclusive attention by large cap Pharma companies. Most companies are in race to acquire assets in these hot therapy areas. Companies who already have these assets are investing heavily in clinical development programs. The interest in pursuing opportunities in Oncology therapy is unhindered for all major Pharma companies. Research investments in oncology likely to continue for several more years due to the significant unmet need exist in this area.

But for a few companies, patent expiry impact continues to haunt the top-line and they are finding it difficult to replace declining sales with Proprietary pipeline products. Beyond 2013, the impact of patent loss will further aggravate the revenue decline. They have chosen strategies of prioritization pipeline assets, cost efficiency measures, divestment of non-core assets which yield poor margins and increase focus on therapy areas where they have already proven its mettle. Increase in dividend payout and share repurchase are some near term measures where they are actively participating. Gain in financial strength through divestment of non-core assets (OTC, Animal Health, Consumer health, Diagnostics) will be utilized in pursuing opportunities in high margin therapy areas. At the same time it has becoming more difficult to find such lucrative

assets because they are scarce and if available are trading at very high premium in speculation of getting acquired (ex. Roche-Alexion). Going forward, Economies of Scale will also play a major role in swapping the non-core business among major pharma including Vaccines, OTC and animal health to improve margins.

Global Pharma continues to remain attractive due to management efforts on the restructuring of entire business model, cost efficiency measures, de-consolidation, acquisition of high value targeted assets, share repurchase program and dividend policy.

Global Biopharmaceutical Outlook 2014-Global Pharma, released by MP Advisors provides analyses of individual large cap companies, promising drug candidates in their late stage pipelines, competitive landscape, and important therapy areas where new innovation will create leadership, forecast for major marketed drugs where competition/regulatory scenario will change the dynamics, and the potential impact of several important upcoming milestones on the industry

## Contents

Macro Analysis: Strategy Diversification Divested: Productivity measurements, Divestment of non-core assets resulting in healthy cash position- Will accelerate Next wave of Targeted

### ACQUISITIONS

New Drug Filing Declining but compensated by faster approval with Break through

### DESIGNATION

FDA Break through designation allowed faster market reach

R&D strategy re-dened- More focus on early development to improve late stage success

Recent Restructuring efforts of Major Pharma companies

Cost efficiency measures and divestments

Financial Environment favourable for the Next Wave of acquisition

Table 1: Pharma Pipeline allocation changes: 2010-2013

Table 2: Global Pharma –Head count reduction & Share repurchase program

Table 3. Cash, Debt and Mkt Cap Of Global Pharma/ Biotech Companies

Table 4: Cash, Debt and EV of Rising star companies

### Chart 1: CASH AND DEBT OF GLOBAL PHARMA/ BIOTECH COMPANIES

### COMPANY ANALYSIS:

#### 1. ASTRAZENECA: EARLY STAGE PIPELINE STRONG; BOLD INITIATIVES OFFER SOME RELIEF BUT ARE NOT

Enough To Hold Pressure

Long term clinical studies and R&D outlook

Strengthening business in diabetes: Acquisition from BMJ

Outlook of respiratory franchise going forward: Symbicort and PT003

Brilinta/Brilique –Prescription Trend and formulary adoption improving but not reected in revenues

The impact of competition on Faslodex

Late stage development program update: I) Selumitinibii) Lesinuradiiii) Olaparibiv)  
Benralizumabv) Brodalumabvi) Moxetumomabvii) Trolokinumabviii) MEDI4736 (anti-  
PDL1)ix) AMP-514

## **KEY MILESTONE Table**

Table 1: PhIIb combo data of lesinurad in gout pts – allopurinol-inadequate responders

Table 2: Recent acquisition /partnership deals done in 2013

Table 3: Generic exposure thru 2018

## **Chart 1: CHINESE MARKET GROWTH: GLOBAL PHARMA IN 2013**

## **2. BRISTOL-MYERS SQUIBB: SPECIALTY BIOPHARMA WITH ONCOLOGY FOCUS CAN GIVE RETURNS:**

Nivolumab and Eliquis Success Important

Snapshots Review on Late stage pipeline assets

Divestment of diabetes business to AZN – Deal review

Eliquis Ramp up would be central to BMY's stock price performance in 2014

Yervoy's potential could be limited by emerging competition Ipilimumab status in other indications

Anti-PD1 antibody (Nivolumab, BMS-936558, PhIII) Immunotherapy (NSCLC, Melanoma)

Other key Pipeline assets: Elotuzumab

Impact of generization in topline revenue

## **KEY MILESTONES**

Table: 1: Anti PD-1 pipeline molecules

Table 2: Ongoing PhIII clinical studies on Anti-PD1

Table 3: Peak sale potential of future blockbusters

Table: 4: Generic exposure thru 2018

## **3. ELI LILLY: PATENT PRESSURES AGGRAVATED WITH UNDIFFERENTIATED PIPELINE ASSETS BUT**

Supporting Diabetes Market Offers a sigh of Relief

Necitumumab offers sigh of relief but commercial significance limited

Late Stage Assets Review: PEG-Lispro, LY2963016, Dulaglutide, Empaglifozin, SGLT2 + DPP4 FDC, Solanezumab, Baricitinib, Ixekizumab, Cixutumumab, Ramucirumab  
Litigation of marketed products update: Evista and Alimta

## **KEY MILESTONES**

- Table 1: Competitive landscape – GLP-1 agonist
- Table 2: SGLT2 inhibitors- competitive landscape
- Table 3: Ongoing PhIII clinical studies of Ramucirumab
- Table 4: Patent expiry impact through 2018

## **4. GLAXOSMITHKLINE: BASE BUSINESS PROVIDES SUSTAINABILITY; SEVERAL BLOCK BUSTER'S WILL OFFER GROWTH!**

Multiple blockbusters emerging in Melanoma, Respiratory and HIV  
MAGE-A3 vaccine in NSCLC

Anoro (Umeclidinium/Vilanterol, LABA/LAMA FDC-Ellipta device) positioning becomes stronger than LABA+ICS or LABA or LAMA mono in COPD

Relvar/Breo Ellipta (Vilanterol/Fluticasone FDC): Efficacy and safety data in Asthma and COPD

Eperzan (Albiglutide): Superior efficacy, better tolerability, ease of administration and compliance benefits should position Albiglutide better than competition in earlier lines of treatment

## **KEY MILESTONES**

- Table 1: Clinical data of BRAF Inhibitor in Metastatic Melanoma
- Table 2: Bydureon, Albiglutide & Victoza- DURATION 6 vs. HARMONY 6,

## **5. MERCK: RESTRUCTURING IMPACT AND TARGETED FOCUS ON ONCOLOGY AND HCV WILL DRIVE GROWTH!!**

Detailed data on Olanacatib – Upside lies in the safety profiles of this drug  
Completion of Mega-trials should ensure R&D cost savings to the tune of \$1 billion  
R&D Pipeline Update: HCV combo, Lambrolizumab and Corporate Restructuring

## **PROGRAM**

Growing evidence base on CV safety of DPP-IV inhibitors

TECOS should help DPP-IV expand their share in a fast growing but highly genericized diabetes market

Once weekly DPP-IV - MK-3102 should help Merck carve a share in the 1st line setting in type 2 diabetes

HCV Therapy: MK-5172 and MK-8742 combo, Once daily

Lambrolizumab (MK-3475, anti-PD1) in Second-line NSCLC; Potential additional Indications for anti-PD1

Merck restructuring Impact going forward is positive for Investor

Januvia franchise - Reason for de-growth in the US and outlook for the DPP-IV market

–Emerging competition from SGLP-2 inhibitors

Impact of Gardasil and V503: JP Govt. scheduled to review the withheld decision of Gardasil in early 2014

View on Remicade Biosimilar approval in Europe

Key Milestone

Table 1: Ongoing clinical trials of Lambrolizumab

Table 2: Competitive landscape of anti-PD1

Chart 1: Late stage pipeline in HCV therapy

## **6. PZER: DEPENDENT ON PALBOCICLIB AND PREVNAR-13 IN ADULTS TO SUSTAIN BUSINESS!**

Restructuring: Three Major Business Segments

Xeljanz (tofacitinib)-RA broader label but slower uptake: Limited Opportunity for Xeljanz and forecast \$1.2b in peak sales with competition Following

Prevnar 13 US growth will be driven by approval in adults and outcome of the CAPiTA study data is the key

Eliquis Superiority claim in Stroke will give an edge over competitor

Palbociclib (CDK4/6 cell cycle inhibitor, PhIII, ER positive and HER2 negative Breast cancer) - Blockbuster potential -PFE leading the race: Competitors are 1.5 y behind in development

Dacomitinib (PhIII, secondline NSCLC) –Low potential

Hypercholesterolemia) – Third entrant will lose its relevance if others succeed

Advantages and Risks vs. Competitor in anti-PCSK9 area

### **KEY MILESTONES**

Table 1: Xeljanz: Efficacy comparison with baricitinib

Table 2: Select oral RA drugs in development

Table 3: Ongoing clinical trials: CDK inh.-Palbociclib

## **7. NOVARTIS: PIPELINE STRENGTHENING : DE-CONSOLIDATION WILL PROVIDE TARGETED FOCUS**

Respiratory sales ramp to drive sales; Patent expiry pressure immense

Oncology targeted and cellular therapy approach

Divestment of blood transfusion unit to Grifols

String of Pearls- LDK378, Serelaxin followed by breakthrough designation for BYM338 (bimagrumab)

Gilenya ramp up in Multiple Sclerosis much faster than expected but market ramp up

Tecdera (BiogenIdec) is extraordinary

SERELAXIN (RLX-030) in Acute Heart Failure – Unmet need would allow an approval-

FDA breakthrough designation granted - LCZ696 in chronic heart failure

Secukinumab in Plaque Psoriasis - Trying To Be Different in a Crowded Space

Competitive Scenario in Plaque Psoriasis

PASPORT-Cushings Head to Head Study positive: Sandostatin LAR Replacement ready in active acromegaly

Signifor/ Pasireotide will penetrate in patients inadequately controlled on Sandostatin. Signifor

LAR will take up market share from Sandostatin LAR before the patent expiry in 2017

Panobinostat in RRMM

Sandoz growth to be driven by biosimilars and respiratory generics

### **KEY MILESTONE Table**

Table 1: Competition in Acromegaly

Table 2: PASPORT-Efficacy and safety comparison: Signifor LAR vs. Sandostatin LAR

Table 3: Select late- & mid-stage pipeline: Plaque Psoriasis

Table 4: PhIII Clinical data on Plaque Psoriasis of marketed products

## **8. NOVO NORDISK: GLP-1 AND INSULIN MARKET BECOMING TOO COMPETITIVE; RELIEF SHOULD**

Come From Victoza in Obesity

Novothirteen targets rare, autosomal, niche market

Competitive pressures on Victoza

Dulaglutide Phase III data suggests slightly better efficacy with once weekly advantage over Victoza



Levemir under threat from SAN's U300  
Bio-similar insulins impact cannot be neglected  
Liraglutide 3mg obesity regulatory overhang persists  
Regulatory concerns of pancreatitis, thyroid cancer & CV risk for high dose regimen in obesity  
Haemostasis Franchise  
Key Milestone Table

## **9. ROCHE: PRICING POWER WITH STRONG FOOT HOLD IN ONCOLOGY WILL DRIVE GROWTH**

Strong late stage pipeline will offer potential sustainability and growth  
Superiority of Gazyva against Rituxan in CLL  
Ramp up of Kadcylla in second-line advanced breast cancer patients  
Perjeta -First approved therapy in preoperative, early stage, and rst-line HER2 positive breast cancer strengthening its breast cancer franchise  
Further Indication expansion for Perjeta  
RoActemra monotherapy Superior to Humira: ADACTA Study  
Kadcyla: MARIANNE, EMILIA AND APHINITY trials will lend sustainable growth to breast cancer franchise  
Roche to retain all of its current Herceptin sales beyond Patent Expiry in US and EU; Rituxan Biosimilar threat is negligible  
Etolizumab ( Ulcerative colitis and Crohn's Disease)  
Avastin outlook - 2014 onwards  
Bitopertin (Schizophrenia-negative symptoms)  
Onartuzumab (MetMab, MET positive NSCLC (2nd and 3rd line) and triple negative breast cancer)  
Zelboraf ramp up to get impacted by competition from GSK MPDL3280A (anti-PDL1 mAB, PhIII, NSCLC, Melanoma)

### **KEY MILESTONE Table**

- Table 1: Major pipeline molecules with expected ling
- Table 2: Efcacy and safety comparison of Kadcylla vs. trastuzumab+docetaxel in rstline BC (PhII)
- Table 3: Ongoing important clinical studies of Kadcylla in late stage HER 2 positive cancer
- Table 4: Ongoing clinical trials on biosimilar rituxan
- Table 5: Efcacy target prole of Gazyva in clinical studies



Table 6: Clinical data of BRAF inhibitor in metastatic melanoma

## **10. SANO: SUSTAINABLE BUSINESS BUT INNOVATIVE PIPELINE NOT IMPRESSIVE**

R&D Pipeline: Upside limited due to Strong Competition; but orphan indication approval to improve the top-line growth

Anti-PCSK9 antibody and Dengue Vaccine are potential mega blockbuster candidates, and could make all the difference for SAN's investor but it will take long to deliver

Lemtrada ramp up in Europe (CR received in the US)

Lyxumia (Lixisenatide) –US ling withdrawn due to want of CV outcome data from FDA and ELIXA outcome and head to head Victoza data

New Lantus formulation (Insulin U300)

Lantus/Lixisenatide combination update

Patent Expiry Impact to continue in 2014

Aubagio: Except for oral administration and lower discontinuations, there is no differentiation for Aubagio vs. existing treatment options

Sarilumab ( anti-IL-6R mAB, Rheumatoid arthritis)

Dengue Vaccine (PhIII)

Alirocumab anti-PCSK6, Hypercholesterolemia) –CV outcome study will push the ling in 2018

### **KEY MILESTONE**

Table 1: Sarilumab ACR results at week

Table 2: Alicromumab PhIII ODYSSY Program

Annexure I: Clinical and Regulatory Milestones In 2014

Annexure II: Global Pharma- PhII and PhIII Pipeline Candidates

Annexure III: Pipeline Peak Sale Potential Thru 2018

Annexure IV: Impact of Patent Expiry Thro 2018

Annexure V: Drugs Losing Patent Protection By 2018

## I would like to order

Product name: Global Pharmaceutical & Biotechnology Outlook 2014: Major US and EU

Product link: <https://marketpublishers.com/r/GDD04D388BBEN.html>

Price: US\$ 2,500.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

[info@marketpublishers.com](mailto:info@marketpublishers.com)

## Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/GDD04D388BBEN.html>

To pay by Wire Transfer, please, fill in your contact details in the form below:

First name:  
Last name:  
Email:  
Company:  
Address:  
City:  
Zip code:  
Country:  
Tel:  
Fax:  
Your message:

**\*\*All fields are required**

Customer signature \_\_\_\_\_

Please, note that by ordering from marketpublishers.com you are agreeing to our Terms & Conditions at <https://marketpublishers.com/docs/terms.html>

To place an order via fax simply print this form, fill in the information below and fax the completed form to +44 20 7900 3970