

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

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## 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

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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-denied- 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

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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 reflected in revenues

The impact of competition on Faslodex

Late stage development program update: I) Selumetinibii) Lesinuradiiii) Olaparibiv)  
Benralizumabv) Brodalumabvi) Moxetumomabvii) Trolokinumabviii) MEDI4736 (anti-  
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## **KEY MILESTONE Table**

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Table 3: Generic exposure thru 2018

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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**

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Supporting Diabetes Market Offers a sigh of Relief

Necitumumab offers sigh of relief but commercial significance limited

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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

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Detailed data on Olanecicab – 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, Pembrolizumab 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

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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 CAPIA 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

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## **KEY MILESTONES**

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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  
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### **KEY MILESTONE Table**

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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

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Strong late stage pipeline will offer potential sustainability and growth

Superiority of Gazyva against Rituxan in CLL

Ramp up of Kadcyla 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

Etrolizumab ( 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)

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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)

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### **KEY MILESTONE**

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