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Walgreens Boots Alliance is Now a Reality

Sources: Walgreens, Alliance Boots and Drug Store News

Walgreens and Alliance Boots completed the final phase, Step 2, of their strategic partnership to form Walgreens Boots Alliance, concluding the merger process launched in 2012. Under a reorganization merger agreement approved by Walgreens shareholders, Walgreens is now a wholly owned subsidiary of Walgreens Boots Alliance. Existing shares of Walgreens common stock were converted automatically into shares of Walgreens Boots Alliance common stock on a one-for-one basis. Walgreens Boots Alliance common stock trades on the Nasdaq stock exchange under the symbol "WBA."

The new global enterprise combines Walgreens, the largest drug store chain in the USA; Boots, the market leader in European retail pharmacy; and Alliance Healthcare, a leading international wholesaler and distributor. Together, Walgreens Boots Alliance spans more than 25 countries, with over 12,800 stores, over 370,000 employees and more than 340 pharmaceutical distribution centers serving more than 180,000 pharmacies and other points of care.

Walgreens Boots Alliance will be domiciled in the United States and headquartered in Deerfield, Ill. Overseen by an international management team, Walgreens Boots Alliance comprises of three Divisions: Retail Pharmacy USA, Retail Pharmacy International and Pharmaceutical Wholesale. In addition, the company operates a number of global cross divisional functions, including Global Brands and a Global Pharmacy Market Access group.

Walgreens and Alliance Boots announced their two-step strategic transaction in June 2012. They completed Step 1 in August 2012, when Walgreens invested approximately US$4 billion in cash and 83.4 million shares of its common stock in exchange for a 45% equity ownership stake in Alliance Boots. With the recent announcement of the completion of Step 2, Walgreens has acquired the remaining 55% of Alliance Boots in exchange for approximately US$5.3 billion in cash and 144.3 million shares of stock.

Walgreens also announced earlier that Greg Wasson, president and CEO, has informed the company's board of directors that he will retire shortly after the close of the second step of the Alliance Boots transaction. Following the transaction close and Wasson's retirement, Walgreens chairman James Skinner will become Walgreens Boots Alliance's executive chairman, and Stefano Pessina, executive chairman of Alliance Boots and a member of the Walgreens board of directors, will serve as its acting CEO, pending

SAVE THE DATE FOR IFPW'S
CEO ROUNDTABLE
May 18 & 19, 2015
The Corinthia Hotel
London, UK
Andrew Witty of GlaxoSmith Kline, Guest Speaker
For more information visit
www.ifpw.com/meetings/roundtable.htm

In Brief . . .

- Wholesaler **Cardinal Health** (US) and German pharmaceutical manufacturer **Bayer** have signed a 15-year agreement for the contract manufacturing of Xofigo (radium Ra 223 dichloride). Cardinal will build a dedicated facility in Indianapolis specifically for the manufacturing of Xofigo, the output of which will primarily be distributed in the USA and Canada, which will be supported by around 85 employees. The facility will be situated near Cardinal Health's existing Indianapolis radiopharmacy, one of the two US locations authorized by Bayer HealthCare to distribute Xofigo. Cardinal Health is the sole distributor of Xofigo in the US.
- The strategy shift by **AmerisourceBergen** (US) to focus on a few big clients rather than several smaller ones is proving to be both successful and lucrative. In October, the drug wholesaler reported another quarter of robust sales growth with sales jumping 29% to US$31.6 billion and representing the 5th straight quarter of 25%+ sales growth. Earnings growth also accelerated, for the fourth straight quarter, rising 36% to US$1.10 a share.
- **The European Commission** has conditionally approved **IMS Health's** plans to acquire part of **Cedegim SA's** customer relationship management and strategic data business. Approval of the €385 million (US$470 million) deal is conditional upon IMS' commitment to divest parts of its primary market research business and to grant third-party access to the structure underlying its sales tracking data for 10 years. Separately, IMS announced that *Mason Tenaglia* has been appointed vice president, **Payer & Managed Care Insights, IMS Institute for Healthcare Informatics**. In this newly-created position, Tenaglia is responsible for advancing the IMS Institute's payer and managed care thought leadership, as well as engaging with key leaders in the healthcare industry, academia and government.
- **Amgen** set the price for its newly approved leukemia drug *Blincyto* (blinatumomab) at US$178,000 for a standard treatment course, or $89,000 per treatment cycle – well above what most analysts had expected.
- The recent approval of **Roche's** cobas KRAS mutation test in China is a sign that the company is building up its diagnostics business in the market. Roche's diagnostics business, despite being the world's largest, has long been lying low in China, particularly compared to its drug business. However, Roche is now responding as China is opening to targeted drugs.
- The European Union's 28 member states have signed off an agreement to continue sharing information on medicine prices. The news comes after France rallied other EU member states to discuss the price of Gilead's Sovaldi (sofosbuvir), after which the French health ministry declared a new, lower price for the hepatitis C drug.

(Sources: Investor's Business Daily, Reuters, Scrip and thePharmaLetter)

Top Regulatory Changes in China for 2014

Sources: An article prepared by Brian Yang and published by Scrip; PharmaAsia News

The top five regulatory changes in 2014 as selected by PharmAsia News were:

1. *Drug Registration Law:* China is poised to release an important Drug Administration law as well as a regulation on registering drugs. The pace of the Drug Registration Regulation has notably accelerated and CFDA has released three drafts, first in November 2013 and subsequent drafts in February and May 2014. Key is a provision on generic drug application filing. In the second draft, CFDA said that makers could file generic applications at any time and the CFDA could approve an application. However, approvals would come into effect only when originator patents expire. The third revision apparently exempts the CFDA from responsibility to review patent status and to let generic makers decide the timing of a launch of products that could potentially be subject to dispute, legal experts say.

2. *Free Drug Pricing:* China's price setting body, the National Development and Reform Commission, has proposed dropping price ceilings for all drugs, effective January 2015. The move comes after the agency dropped price caps for low cost drugs in May 2014. But introduced are reimbursement prices, which will be decided by the Ministry of Human Resource and Social Security (MOHRSS) and related parties. For high cost drugs and those not listed on the National Reimbursement Drug List (NRDL), the prices will be decided via a negotiation mechanism among the MOHRSS and drug makers. So far, industry associations have voiced their suggestions to set a medium reimbursement price, instead of the lowest tender price. High cost and non-NRDL listed drugs should not be subject to the negotiation, and a rolling reimbursement listing for innovative new drugs, they say.

3. *Further New Drug Approval Delays:* China has seen four to five year delays in approval domestically after a new drug is approved in overseas markets. Now the drug lag may get longer. China FDA is looking to solve the problem by raising new drug review fees and procuring third party services to boost review efficiency and solve a severe shortage of drug reviewers. The reviewer shortage is often cited as a stumbling block for new drug approvals in China. Although the CFDA's drug review wing, the Center for Drug Review, is actively hiring for 20 some reviewers on contract basis, the short-term relief is expected to be limited. Meanwhile, the third party service procurement has not yet materialized, noted industry experts. Adding to the industry anxiety is the CFDA's review of multiregional clinical trials (MRCT), a pathway for imported new drugs from multinational drug companies. The change is expected to add an additional 30 months to an already lengthy process.

4. *CFDA Intensifies GMP Inspection:* Product quality is high on the regulator's agenda as it released a draft regulation on announced inspections in November 2014. Notably, the agency plans to increase the frequency of the "just show up" inspections to a certain ratio, normalizing it as a method of routine random checks. Also, the regulators are widening discretion and stepping up enforcement, via bringing media and police to the inspection sites. Overseas inspections are also on the rise. In a move demonstrating regulatory assertiveness, China FDA has significantly increased inspections of foreign drug manufacturing sites, growing from seven international drug manufacturers' sites in 2011 to 24 in 2014. The list could be further expanded by a separate notice, cautions the agency.

5. *First Chinese Biosimilar Guideline:* Although Chinese companies have been investing heavily in producing copies of biological products for many years, only now have the regulatory authorities completed a first draft guideline. The guideline is close to the approach taken by the EU, US and World Health Organization and should therefore improve the competitiveness of Chinese companies in the global community.

Walgreens. . . (cont.)

a board search for a successor. In addition, William Foote will serve as the lead independent director of the Walgreens Boots Alliance board of directors. Wasson stated, "When I became CEO six years ago, I had three goals – to transform the front end of Walgreens drug stores, to advance the role that community pharmacy plays in healthcare and to find the right partner to take Walgreens global…with the creation of Walgreens Boots Alliance, it is now time for new leadership to move that vision forward building on the global platform we have created, executing on the company's many opportunities and creating long-term sustainable value for our customers and shareholders. I could not be more proud of our company or more grateful for the opportunities I have had to work with so many incredible people since joining Walgreens over 35 years ago, and I am committed to doing my best to achieve the smoothest possible leadership transition."

"The completion of the merger between Walgreens and Alliance Boots and the establishment of the first global pharmacy-led, health and wellbeing enterprise, are a fitting tribute to Greg's exceptional leadership and legacy at Walgreens," Pessina added. "Through his strategic vision, Greg has done more than transform an iconic company – he has truly helped to change an entire industry for generations to come. I look forward to working with James Skinner and all the leaders of the future enterprise when we launch the combined group."

In addition to Walgreens, Wasson is on the boards of Alliance Boots, AmerisourceBergen and Verizon.