FOCUS

Vol. 24, No. 2 International Federation of Pharmaceutical Wholesalers January 19, 2017

2017: A Year of Significant M&A Activity for the Industry?

(Source: An article prepared by Julia Bradshaw and published by The Telegraph)

The pharmaceuticals industry is set for a surge in deal-making this year, as companies under pressure from weak drug pricing and higher costs take advantage of low valuations and a tax-friendly political climate in the US to bolster faltering sales growth. Even those with solid growth prospects may pursue M&A, leading to a sharp rise in the value of deals this year, according to a report from EY.

"This could be a banner year for deal-making, as industry and political forces converge," said Pamela Spence, a co-author of the report. "From a macro perspective, there was pent-up demand for deals in a holding pattern going into the US presidential election, but deal discussions in the last weeks of 2016 indicate much firepower could soon be unleashed in 2017." Global pharmaceutical firms have navigated a difficult environment in recent years. Increasing R&D costs have eroded margins while blockbuster drugs have lost their patents, hitting profit growth. Drug pricing and reimbursement have becoming thorny issues for Big Pharma.

Meanwhile, pricing pressure in the US and stricter reimbursement rules from health authorities in other countries have piled further pressure on companies such as Pfizer, Merck, AstraZeneca and GlaxoSmithKline. Political uncertainty in the US in the run up to the presidential elections weighed further on the valuations of these companies. That meant that the value of M&A deals in the sector fell to US$273.7 billion last year, a significant difference from the US$392.4 billion recorded in 2015, according to figures from Mergermarket.

"Biotech and big pharma valuations fell steadily throughout the year," the EY report said. "This trend may offer further clues to 2017's outlook. The last time biopharma valuations experienced such acute declines was during the 2008 financial crisis. This pronounced downturn was quickly followed by a handful of 2009 megadeals." Indeed, 2009 was the year in which Pfizer bought Wyeth, Roche bought Genentech, and Merck acquired Schering-Plough. "So, there's a precedent for big pharma ramping up deal-making in 2017, and potentially dominating M&A share for several years," said the report.

Expectations that Donald Trump's administration will relax corporate tax rates and allow US companies to repatriate the billions of dollars in cash stockpiled overseas at a low, one-off charge, will give US pharmaceutical companies a huge amount of financial strength with which to pursue acquisitions to bolster growth.

Jeffrey Greene, one of the report's authors, said: "You tend to see companies acting in advance of regulatory changes, rather than waiting, so I think we will see a few very large deals greater than US$20 billion or so. It's likely that we will have more mega mergers among the top 25 pharmaceutical companies in the world, but there will be deals all the way down the spectrum."

In Brief...

- The Supervisory Board of **Celesio AG** has appointed *Brian Tyler* to the position of Chairman of the Management Board, effective 1 April 2017. Tyler will succeed *Marc Owen,* who has decided to retire after 15 years with **McKesson**. Mr. Owen has been Chairman of the Management Board of Celesio for nearly three years. Mr. Tyler has also served as President of North American Pharmaceutical Distribution and Services for McKesson U.S. Pharmaceutical, McKesson Medical-Surgical, and McKesson Specialty Health, as well as Executive Vice President of Corporate Strategy and Business Development.
- In an effort to strengthen its logistics business, **Galenica Group** will assume control of the physicians wholesaler **Pharmapool Ltd.** Through **Galexis Ltd.**, Galenica's pharmaceutical wholesale company. Galenica plans to continue its service offerings under the current name, while management will be integrated with **Galenica Santé** as part of the Business Services sector, allowing Galenica to take advantage of potential synergies going forward.
- The **Pharmaceutical Research and Manufacturers of America** (PhRMA) has announced that **Johnson & Johnson** worldwide chairman, *Joaquin Duato* will succeed *George Scangos* (outgoing CEO of **Biogen**) as PhRMA's board chairman. Duate has held regional chairman roles and leading local market businesses across the globe during his 28 year career at J&J.

(continued on page 3)

Ms. Spence also expects a wave of divestitures, where companies sell off parts of their business, as well as further asset swaps, in a similar vein to the one carried out by GlaxoSmithKline and Novartis in 2015. "There will also be several smaller, specific straight bolt on acquisitions that fuel the R&D pipeline, which tend to go under the radar, as well as further joint ventures between pharma and technology companies, such as Alphabet, which did a deal last year with GSK." This year could also see some M&A from cash-rich Asian companies looking to gain a foothold in US and European markets. The Chinese are eyeing western pharmaceutical assets.

"I think we will see acquisitions from Asia inbound to the US and Europe," Ms. Spence said. "But because of the nature of the capital, which is mostly private equity, it is difficult to estimate how much funding there is for inorganic growth, but it's certainly an area to watch." She added: "I see this as a potential tipping point. Companies have been cautious over the last 18 months, especially big pharma, but they know which assets they want and it is going to be a first mover advantage…. So, there will be a little bit of a price war as some assets are more desirable than others. My advice to the industry is don't hold back if you know what you want, go and get it."

Changes are Forthcoming for Canada's Private Pharmaceutical Market

(Source: Edited excerpts from an article prepared by Francesca Bruce and published by Scrip)

Manufacturers and private insurers are increasingly entering into Product Listing Agreements (PLAs) to get drugs to patients in Canada. The Canadian private market was once a haven for companies with few constraints on pricing, but recent agreements may bring forth important changes to which manufacturers will eventually have to adjust, according to research from PDCI Market Access and H3 Consulting. Firms may have to adapt their economic arguments and think about greater transparency.

Canada's private pharmaceutical sector accounts for more than half the country's total spend on drugs, so a shift in dynamics could have a big impact on drug company business. Private insurers pay out some C$10 billion (US$3.75 billion) for medicines and out of pocket spending is worth around C$5 billion (US$3.75 billion.) Meanwhile government payers, which have been trying to reduce spending through Product Listing Agreements (PLAs) for some years, spend around C$11 billion (US$8.25 billion.) H3 Consulting founder Chris Bonnett says that the private market has traditionally been a "safe place for companies to ensure market access with virtually no restrictions." A recent report indicates that this is changing.

So far, says Bonnett, private payers have been "tinkering around the edges" when attempting to control costs, without tackling prices or addressing utilization or economic arguments to determine whether drugs are delivering value. For example, they have implemented measures such as cost shifting so plan members pay more towards their drugs, or they have introduced case management for patients taking specialty drugs to make sure treatments go according to plan. But bigger changes are coming now that private payers are increasingly coming to share the concerns of public payers over high drug prices and are beginning to use more sophisticated cost-control tactics.

PLAs have become a mainstay of the public market. The pan-Canadian Pharmaceutical Alliance (pCPA) negotiates PLAs on behalf of provincial and federal government drug plans and companies have been negotiating deals since the pCPA' s inception in 2010. By the end of November 2016, 127 deals had been finalized. Prior to the creation of the pCPA, each province negotiated its own listing agreements with manufacturers. According to the analysis of the companies and private payers survey, the "private sector PLA agreements are in their infancy, similar to the public plans dating back 5-8 years."

Both PDCI and H3 Consulting expect that PLAs will become increasingly common in the private market. The survey attracted responses from 25 pharmaceutical companies and five private payers and revealed several benefits for manufacturers, including: securing a listing in the drug plan; more timely listing; and protection from genericization. It also showed a growing interest in such agreements. Fourteen manufacturers (56%) reported that they had taken part in a successful PLA with a private payer, and four (80%) of the responding private payers indicated the same. "The number of PLAs has been increasing year over year … Both groups reported an increase - almost double – in the number of private PLAs completed or underway in 2016 compared with the number completed in 2015, which emphasizes the growing importance of this mechanism."

Similar to the PLAs agreed with the pCPA, a typical private-sector agreement involves a rebate and a specialty drug, and lasts for three years. Bonnett predicts that agreements will only become more complex, for example by including more risk-sharing elements, when insurers invest more in their infrastructure to understand the impact of the agreements and whether they are "delivering the goods." Moreover, the private plan sponsors (typically employers) will be looking for lower overall drug costs with impacting employee health or productivity, says PDCI President and Principal Consultant Neil Palmer.

A typical private-sector agreement involves a rebate and a specialty drug, and lasts for three years. Although currently there appears to be similarities between the public and private sector PLAs, private agreements may evolve differently as the very nature of PLAs present some difficulties for insurers. PLAs are strictly confidential, which makes it hard for insurers to market them as a competitive advantage through which they can make significant savings. Indeed, current agreements do not allow payers to make many claims about agreed upon drug prices; for example, whether they are the lowest or how they compare to prices paid by provincial plans for the same product. Added to this, drug plan members will have very little awareness of the agreements and whether they deliver savings, all of which means there may be moves towards somehow making the agreements more transparent, says Bonnett. "Ultimately payers will have to demonstrate they are a good use of resources. Palmer believes that outcomes-based listing agreements hold promise as the most effective form of risk sharing, although the fragmented Canadian health care system makes these challenging to implement in both the private and public sectors. Some drug manufacturers are looking for innovative approaches to implement such agreements, he says.

It can take a significant amount of time to negotiate a deal, sometimes between six months and a year, notes Bonnett, during this period there is no access to the treatment under discussion and plan members could see their health decline. This is significant as employers are important clients for private health insurers and provide insurance as part of their benefit packages. As Bonnett explains, those plan members are much closer to the employer who pays the insurance company than individual citizens are to the governments that negotiate in the public sector. "So, private payers might not be willing to wait months for access to a drug that will improve health.

Private payers will accelerate their PLA activities and resources and "the future of private reimbursement is expected to be markedly different," says the survey analysis. This means that both manufacturers and private payers must get ready for the "significant changes already arriving in their environment." Per Bonnett, one thing companies need to understand is that they must present a different case to the private sector. "The economics are not the same for employers as they are for provincial governments, it will be really important to include how their product will affect productivity, absence from work or return to work," he says. Palmer, moreover, points out that private insurers are learning with each

(continued on page 3)

Canada (cont.)...

PLA they negotiate. "Processes are evolving such that recent deals with private insurers may not serve as reliable analogues for future negotiations," he says. Bonnet advises companies to keep deals simple, as this will help ensure that there are enough resources and time to complete a deal. The survey showed that deals can take up to a year, "a crazy amount of time," says Bonnett. In addition, companies should go into talks being realistic about their prices, Bonnett adds. According to OECD figures, Canada has the third highest per capita drug spending globally. This is not proportional with the size of the country's economy, and payers in Canada are not happy with the situation. Bonnett believes Canadian prices will move towards the OECD median… an important prediction as pharma prepares for significant change in the marketplace.

Currency Exchange Impacts WBA's International Operations

(Source: an article prepared by Sonya Bells)

In the last couple of quarters, Walgreens Boots Alliance's (WBA) fiscal 1Q17 top line was adversely affected by negative currency exchange rates. The top line fell 1.8% year over year in fiscal 1Q17. WBA's Retail Pharmacy International and Pharmaceutical Wholesale divisions, which account for about 30.0% of the company's top line, bore the brunt of unfavorable exchange rates. The company acquired these two businesses as part of the Alliance Boots transactions in 2015.

WBA's Retail Pharmacy International segment saw sales fall 14.4% year over year to US$3.0 billion, primarily due to unfavorable exchange rates. Had it not been for currency headwinds, the segment would have risen 0.50% in total sales. Comparable store sales fell 0.10% with the 0.20% rise in retail comps (comparables) was reduced by a 0.50% fall in pharmacy comps. Pharmacy comps were negatively impacted by the reduction in government pharmacy funding in the United Kingdom. Currency fluctuations also impacted the segment's gross profit, which fell 17.4% year over year during the quarter. On a constant currency basis, gross profit fell 2.7%. Adjusted operating income fell a significant 32.4% year over year to US$213.0 million, with the company recording a 1.1% year over year rise in its SG&A (selling, general, and administrative) rate.

WBA's Pharmaceutical Wholesale sales fell 6.5% to US$5.4 billion. On a constant currency basis, there was a 0.60% year over year rise in total sales. Sales comps stood strong at 4.7%, ahead of the company's estimates. The adjusted operating margin for the segment was 3.1%, excluding AmerisourceBergen (ABC). The segment rose 30 basis points in constant currency from the same quarter last year. Adjusted operating income rose 45.2% YoY on a constant currency basis, primarily due to equity earnings from ABC. WBA has a about 24.0% stake in ABC. Excluding ABC, operating income rose 10.2%.

In Brief (cont.)...

- **Ariad Pharmaceuticals**, a leading developer of the cancer therapy *Iclusig (ponatinib)*, will be acquired by **Takeda** in a deal worth US$5.2 billion. It is speculated that the acquisition will give Takeda a desirable operation in the U.S. and help to expand Takeda's geographical presence. In addition to *Iclusig*, Ariad's oncology portfolio also includes a handful of other promising oncology drug candidates. The deal was announced at J.P. Morgan's Healthcare Conference earlier this month.
- Leading wholesaler, healthcare services and information technology company, **McKesson Corporation** and **Change Healthcare Holdings Inc.** (a leading provider of software and analytics, network solutions and technology-enabled services) have announced their previously announced new healthcare company will be named Change Healthcare. The newly-formed entity will combine McKesson Technology Solutions with virtually all of Change Healthcare's business. Rollout of the new brand will occur over the 12 months following the close of the transaction.
- On January 13th, the U.S. House of Representatives passed a budget resolution to draft a repeal bill aimed at overhauling or repealing the *Affordable Care Act* (also known as Obamacare.) The repeal must still be written, debated and come up for a vote on the Senate floor before appearing on President-elect's desk. A draft of the repeal bill is expected to be completed by January 27th. Speaker of the House, *Paul Ryan,* stated "This is a critical first step toward delivering relief to Americans who are struggling under this law...We are on a rescue mission from making Obamacare even worse."
- On January 13th, the **Japan Generic Medicines Association** took action to correct quarterly generic share data. This data (erroneously reported due to an error found in the calculation method) gives volume-based generic use rates. Share data was corrected as far back as three years and past generic rates were revised upwards 3-4 points. Rates for April-June of 2016, which were previously reported as 60.1%, were revised to 63.7%. The generic rate for the quarter July-September came to 65.1%.
- **Valeant Pharmaceuticals International's** affiliate **Dendreon's** cancer business unit will be purchased by **Sanpower Group Co., Ltd.** (China) for US$819.9 million. Dendreon manufactures the prostate cancer drug, *Provenge*, which received U.S. FDA approval in 2010. Valeant continues to divest its non-core assets to repay its debt load. "With this sale, we are better aligning our product portfolio with Valeant's new operating strategy by exiting the urological oncology business, which is one of our non-core assets," Valeant CEO *Joseph Papa* said in a statement.
- *Dr. Carsten Brunn*, previously head of **Bayer Pharmaceuticals'** commercial operations in Japan (since 2013), has been named President of **Bayer's** pharmaceuticals business in the Americas, including the United States, Canada, Central America and South America. He will report to *Dieter Weinand*, member of the Board of Management of **Bayer AG** and President of the Pharmaceutical division.
- The **U.S. FDA's Center for Drug Evaluation and Research's** number of approved drugs for 2016 was 22, down by half year over year, and at an all time average low over the last ten years. *Dr. John Jenkins*, Office of New Drugs director, attributes the low number to a smaller pool of applications and 14 instances of deficiencies in submitted applications.

(Sources: China Daily, Company Press Releases, Drug Store News, PR Newswire, Pharma Japan, and Scrip)