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Investors' Cautious View of the Generic Industry

(Source: an article written by Allison Gatlin and published by Investor's Business Daily)

In the U.S., high prescription drug prices are considered a problem, but except for pharma stockholders, few people may realize that price cuts are actually rippling through the generic side of the industry.

Recent events represent a metric of problems facing the generic industry, among them are falling U.S. generic drug prices that erased billions of dollars in market value in August for the likes of Teva Pharmaceutical, Mylan and Dr. Reddy's Laboratories. The relatively small contingent of pharma companies that produce cheaper versions of brand-name drugs are being pressured by players in the value chain. For one, leading wholesalers are squeezing drugmakers for lower prices to undercut one another in the battle for pharmacy contracts. Meanwhile, group-purchasing organizations are consolidating and grabbing onto more negotiating power, representing a hurdle for generics which comprise a large chunk of those purchases.

Analysts say it could be six to nine months before prices stabilize, if they ever recover at all. While that means lower prices for patients, drugmakers are taking the brunt of the battle. Prices have clearly deteriorated in the aftermath of contract negotiations, Evercore analyst, Umer Raffat, said in an August 12 audio report. "And the question really is: What does that mean going forward?" he said. "Because if you look at the way Mylan and Teva stocks have behaved and you look at the way their estimates have been revised, it clearly suggests a material worsening in business." Teva stock lost 50.7% in August, though it has recovered 7.9% this month, and the No. 1 drugmaker by market cap is close to losing that status. Since July 31, Teva's market value has fallen by nearly half to US$17.56 billion. Comparatively, Mylan trails at a US$16.85 billion cap.

Teva isn't the only one with these challenges. Selling pressures shaved US$4 billion off Mylan's market capitalization in August, and its shares have fallen 19% since the beginning of August after particularly discouraging quarterly reports. As a whole, Investor's Business Daily's Generic Drugs industry group is down 6.6% year to date after nearing a four-year low in August. It's ranked No. 160 out of the 197 groups tracked by IBD.

The underlying cause of the price erosion stems back to 2013-14, when drugmakers increased prices based on shortages, monopolies and other opportunities, Credit Suisse analyst, Vamil Divan, told IBD. "If something was US$10 per day, you would see it up to US$15 per day because you're the only one making it and there was no competition," he said. "If there's no one else producing it, you have more flexibility (in how you price a drug)." "Now that card is gone," he said.

IBD's evaluation is that Teva has an IBD Composite Rating (CR) of 5 out of a best-possible 99, meaning it performs in the bottom 5% of all stocks in terms of key growth metrics. The top-ranked generic drugmaker is Ani Pharmaceuticals, which has a moderate CR of 61. That's not only because competition is fiercer, it's also that generics face another adversary: heavy scrutiny from the media and in Washington.

In January, then President-elect Donald Trump accused drugmakers of "getting away with murder" in their pricing. Now, he's aiming to use competition to undercut prices. Complicating matters, some drugmakers — Teva, Mylan and Perrigo included — are under investigation by the U.S. Department of Justice for alleged generic drug price fixing. Last month, two members of Congress sent letters to makers of multiple sclerosis drugs to probe rising drug prices. That's yet another wrench in the generic story, Divan says. "Investors are looking for cleaner stories," he said. "And there's too much unknown here."

Teva and Mylan, on their second-quarter earnings calls, projected price erosion in the high-single digits for the rest of

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- In an effort to assist with hurricane recovery efforts, The **AmerisourceBergen Foundation** has committed more than US$100,000 to the communities that have suffered due to hurricanes Harvey and Irma. Of the US$100,000 total, US$50,000 in targeted donations was given to regional relief organizations in Houston and across the Caribbean that are focused on building healthy communities and improving patient outcomes. AmerisourceBergen has also committed to matching funds up to US$100,000 for donations to the **American Red Cross** by customers and AmerisourceBergen associates.
- **McKesson Foundation** announced donations in cash, products, and equipment to victims of hurricanes Harvey and Irma, bringing their total commitment to more than US$600,000. Of the total amount, US$185,000 will go directly to **Americares**. McKesson employee contributions, now totaling more than US$125,000, will also be matched by McKesson Foundation. "Our hearts are with the people and communities dealing with the aftermath of these storms," said *John Hammergren*, Chairman and CEO of McKesson, "We have employees and customers in many of the areas impacted by the hurricanes and are proud of how our employees have responded to these disasters."
- On September 19th, **Walgreens Boots Alliance** announced that its amended purchase agreement of **Rite Aid** has been approved. The deal, totaling US$4.38 billion in cash and other considerations, secured regulatory clearance for Walgreen's takeover of 1,932 Rite Aid stores, three distributions centers and related inventory. Once all stores are acquired, they will be converted to the Walgreens brand in a phased approach over time. In an interview, Walgreens executive vice chairman and CEO, *Stefano Pessina* stated, "Combining Walgreens retail pharmacy network with a strong portfolio of Rite Aid locations is

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Generics (cont.)...

2017. Mylan specified that erosion would take place in its North American generics unit, which followed lackluster quarterly reports from September 26. Generic drug makers face pricing issues unlike other pharmaceutical companies; Mylan's North American sales declined 9%, while Teva's numbers were helped by the acquisition of Actavis Generics. Moreover, both Teva and Mylan cut their 2017 forecasts.

On their investor calls, executives from the two companies acknowledged an increase in generic approvals from the U.S. Food and Drug Administration. New FDA Commissioner Scott Gottlieb is looking to speed up generic approvals even more to help ease drug prices, which is in line with President Trump's vision. "During the quarter, we saw increased competition resulting from FDA's focus on accelerating the approvals of third, fourth or fifth generics," Mylan President Rajiv Malik said. "Unfortunately, we have not seen the same for the first generics nor for more complex and niche products." As a result, Mylan said it would delay launching generic versions of the GlaxoSmithKline (GSK) asthma drug *Advair* and Teva's multiple sclerosis drug *Copaxone* amid the "uncertain U.S. regulatory environment."

Teva's former interim chief executive, Yitzhak Peterburg, cited customer consolidation, an increase in FDA generic-drug approvals and products that were either delayed or subject to more competition for accelerated price erosion and decreased volume" in the second quarter. FDA approval complications were cited across second-quarter reports, a Mizuho analyst said in an August 17 report to clients. Though generic approvals are catching some wind under the FDA's new goal, complex generics (a molecular copy that also has a complex active ingredient, formulation, route or device combination) have been subject to administrative delays. Mizuho sees Mylan as best-positioned to rebound despite its tie to the challenged generics sector. The firm has a pipeline of complex generics and biosimilars, guidance is now more realistic and it's less levered than its peers, meaning it could pursue acquisitions of companies whose stocks have dropped. "The risks are that pricing pressure in the U.S. may not abate, and the overall profitability of the company is declining as it expands into lower-margin international markets that now comprise a greater percentage of its revenue," the analyst said.

A few drugmakers seemingly escaped the second-quarter uneasiness exhibited by others. But those reports were somewhat misleading, CFRA analyst, Jeffrey Loo, told IBD. Perrigo issued a "beat-and-raise" that helped its stock increase 16% in a day. Though Perrigo's generic drug sales toppled 13% year over year, its separate consumer health segments had smaller 4% and 9% declines in the U.S. and internationally, respectively. Valeant Pharmaceuticals beat second-quarter profit views, though sales came in slightly light. The firm also cut its 2017 revenue target, but kept its earnings before interest, taxes, depreciation and amortization forecast. "A lot of people consider Valeant as a generic play, but the bulk of the business is now Bausch & Lomb eye-care products," Loo said. In the quarter, revenue from Bausch & Lomb as well as Salix, its gastrointestinal-drugs division, represented 73% of total sales. Its smaller generics unit, on the other hand, fell by 33%. "If you exclude Valeant from the generic space and Perrigo, none of these generic drugmakers really bucked the trend in the second quarter," Loo said. "I think that it [pressure on the group] will likely continue going forward for the next two quarters."

Teva leads the U.S. generic drugs sector, but it's also under the most pressure, Steven Schoenfeld, chief information officer of BlueStar Indexes, told IBD. BlueStar Indexes tracks Israeli equities. Cybersecurity play Check Point Software Technologies is now bigger than Teva in terms of market cap, at US$18.18 billion. Former Teva Chief Executive Erez Vigodman stepped down in February amid a bribery investigation. Since then, management has been shaky and the firm's strategy has been "out of kilter", Schoenfeld says. This followed its loss of several key patents protecting MS drug Copaxone in January. In September, Teva named former Lundbeck and Novo Nordisk veteran, Kare Schultz, as its new chief executive officer. Still, Teva is splitting its focus between generic and branded drugs, Schoenfeld says. "They need a strategy," he said. "They need to see if they want to expand or continue to invest in blockbuster drugs. They've now got some early-stage Alzheimer's assets and other drugs. They have to decide if they're going to be 'X' percentage generic and, if so, do the profits go into innovation?"

Meanwhile, debt has skyrocketed and investors are no longer sure the US$40.5 billion Teva paid to acquire Actavis Generics from Allergan was a good price, he says. As of June 30, Teva had US$35.1 billion in debt, rising from US$34.6 billion at the end of March. Under Schultz, Teva recently avoided a covenant violation on its debt. On September 19, Teva said it amended several term loans and revolving credit facilities, providing Teva greater flexibility in its financial leverage ratio covenants.

The question at the forefront now is whether the U.S. generic drugs sector has hit a bottom. In recent history, Mylan has come under scrutiny for the pricing of its emergency allergy injection, EpiPen. Turing Pharmaceuticals' former chief executive, Martin Shkreli, drew criticism for spiking the price of a decades-old HIV drug. Teva is among those being looked at for MS drug prices. "Popular culture has turned against it," BlueStar's Schoenfeld said. "Secular trends aren't going to go away. Teva is trading where it had major support in the 2001-03 time frame. But I wouldn't recommend anyone plunge into Teva." Most firms are now trading at four to five times their earnings, CFRA's Loo says. Amid continuing price erosion, he sees the stocks trading sideways for the next six months. He notes there aren't many drugs going off patent in the near future, causing somewhat of a roadblock for new generics. "I would like to hope they've hit a bottom," he said. "There are not that many catalysts for them going forward. You might see some buyers step in and buy shares of these companies. Four to five times earnings is an awfully attractive valuation."

Cardinal Diversifying Its Portfolio in Response to Market Changes

(Source: Equities.com)

Cardinal Health chairman and CEO George Barrett, in a recent interview to discuss the future of what he called the "largest company you've never heard of," said the company sees significant growth in 2019 and beyond despite a downturn of the company's stock of 9% for 2017 and 20% for 2016. Cardinal's products are distributed to 80% of hospitals and 60% of pharmacies in the U.S..

He stated that Cardinal has been focusing on diversifying its portfolio to focus more on the health care system and less on areas that are susceptible to swings, like the generic drug industry.

The CEO said the swings in generic drugs were bigger than

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Cardinal (cont.)...

expected, which hurt the company in the most recent quarter. But looking ahead to 2019, he says the company expects to see significant growth. In its fourth-quarter, earnings came in at US$274 million; during the same period last year, earnings were US$333 million. Revenue was at US$33 billion, up from US$31.4 billion for the quarter. The most recent quarter included a profit decrease in its "pharmaceutical segment" and in growth of its pharmaceutical distribution sector. The full-year revenue increased 7% to a record US$130 billion.

In April, Cardinal said it expected profit decline in its pharmaceutical business. When reporting its earnings for the fourth quarter, the company also noted that it would be taking "discrete actions" that would affect fiscal year 2018 and their "trajectory for 2019 and beyond."

As part of the Company's diversification program, Cardinal Health recently announced that it has completed the acquisition of Medtronic's Patient Care, Deep Vein Thrombosis and Nutritional Insufficiency business for US$6.1 billion. The Patient Care, Deep Vein Thrombosis and Nutritional Insufficiency business encompasses 23 product categories across multiple market sites of care, including numerous industry-leading brands, such as Curity, Kendall, Dover, Argyle and Kangaroo – brands used in nearly every U.S. hospital.

The medical supply and drug company was also under pressure earlier after the city of Cincinnati filed a lawsuit against them. The city has accused Cardinal [and others] of shipping excess millions of opioid dosages to the area over the years, which, they say, has contributedto the opioid epidemic. The lawsuit states that Cardinal failed to investigate suspicious orders.

The company does distribute and fulfill orders for painkillers and other prescription drugs for pharmacies and clinics. But Cardinal denies that it was lax in its policing of suspicious orders.

"We are industry leaders in implementing state-of-the-art controls to combat the diversion of pain medication from legitimate uses, and have funded community education and prevention programs for a decade," the company said. The company also stated the "copycat lawsuits" were "misguided and do nothing to stem the crisis." Cardinal is not the only company the city is targeting. They are also seeking damages against McKesson Corp. and AmerisourceBergen Drug Corp. Cincinnati is seeking unspecified damages in the suit, which may run millions of dollars. The city is looking to triple damages under its RICO law and also wants compensation for the care of residents addicted to opioids.

Japanese Wholesaler, Medipal, to Develop a U.S. Joint Venture

(Source: Pharma Japan)

Japanese pharma wholesaler Medipal Holdings and JCR Pharmaceuticals intend to establish a joint venture in the US by the end of this year, the CEOs of the two companies told reporters on September 22, a day after they announced a capital and business tie-up deal that envisioned an expansion into the world's largest drug market.

"We'd like to discuss ways to bring them to the global market as soon as possible," JCR CEO Shin Ashida said at a press conference, referring to the company's eight lysosome disease treatments being developed based on its proprietary 'J-Brain Cargo' blood-brain barrier (BBB)-penetrating technology.

On September 21, the two partners said that Medipal would become the largest shareholder of JCR by acquiring over 7 million shares from the current top owner GlaxoSmithKline, while announcing a plan to form a joint venture in the US. Through the JV, the two companies will initially pursue the development of two drug hopefuls for the treatment of types of lysosome disease called Hunter syndrome and Pompe disease.

At the press conference, Mr. Ashida indicated his company hopes to also develop other lysosome disease pipelines via the new JV. Medipal will support the development by introducing development researchers and CROs in the country.

Speaking about the distribution of products once approved in the US, Medipal Holdings President, Shuichi Watanabe, expressed his company's readiness to perform the logistics function, depending on the scale of logistics activities. "Small-molecule drugs are normally distributed by wholesalers in large volumes, but that's not the case for the drugs being developed by JCR. We might go for it if we are to only deliver these drugs to 10 or so medical institutions, he said.

Regarding the background of GSK's divestment of JCR shares, Mr. Ashida said, "As GSK has shifted away from the rare disease arena, we have been discussing the dissolution of our capital partnership." With respect to Medipal, he said, "If we partner up with a drug maker, we would have to accommodate our plan to their policy, and development would take longer. We want to speed up the development. I think Medipal is a very good partner."

Speaking about a collaboration between a wholesaler and a pharmaceutical company on the drug development front, Mr. Watanabe said, "Even if a drug is developed, it won't reach patients without a distributer. In future drug development, we need to prepare for the distribution of drugs together with their manufacturers."

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expected to help us achieve enhanced, sustainable growth while enabling us to broaden our reach and provide greater access to convenient, affordable care in more local neighborhoods across the United States."

- The president of the **Federation of Japan Pharmaceutical Wholesalers** (and IFPW Vice Chairman) *Ken Suzuki*, requested that the Central Social Insurance Medical Council initiate guidelines to encourage all parties involved in drug purchases to abide by prices settled in single-product, single-price transactions until the end of the fiscal year. The request was made at hearings held by Chuikyo's drug pricing subcommittee. No objections were raised by subcommittee members. Separately, *Hideyuki Hirano*, head of sales at Daiichi Sankyo has been named pharma industry representative of the Central Social Insurance Medical Council, replacing Shionogi senior executive, *Yoshiaki Kamoya*.
- **Teva Pharmaceutical** (Israel) has named *Kåre Schultz* as the company's next president and CEO, replacing interim CEO *Dr. Yitzhak Peterburg*. Mr. Schultz brings with him nearly 30 years of experience in the pharmaceutical and healthcare industries, most recently serving as president and CEO of H. Lundbeck where he was instrumental in the company's restructuring iniatives. Prior to that he served as COO of NovoNordisk.

(Sources: Bloomberg, Company Press Releases, Drug Store News, Pharma Japan and Scrip)