



FOCUS



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Pharma Industry Shows Resilience Despite Difficult Market Conditions

(Source: Two articles by Jessica Merrill for Scrip Intelligence)

Inflation, rising interest rates, market volatility, violence in Ukraine and a persistent pandemic has been wholly responsible for a difficult macroenvironment for doing business. Despite the challenges, pharma appears to be poised for growth.

When market conditions become unstable, pharmaceutical manufacturers usually rise above the chaos. However, the second quarter of 2022 has certainly put the industry's standard stability to the test, delivering one challenge after another – inflation, supply constraints, labor shortages, rising interest rates, the prolonged military conflict in Ukraine, and a pandemic that continues to disrupt communities and business operations.

Through this turmoil, drugmakers are still delivering modest growth, new drug launches, positive pipelines and focused business strategies, all while navigating through the continuing storms.

The bright spot is an array of dependable brands that continue to deliver growth on blockbuster-sized sales. Drugs like Merck's *Keytruda*, Pfizer and Bristol Myers Squibb's *Eliquis*, Johnson & Johnson's *Darzalex*, Novartis AG's *Cosentyx* and Sanofi/Regeneron's *Dupixent* have all shown to be resilient in the face of multiple headwinds. Additionally, there has been a top-line revenue boost from various vaccines and treatments for COVID-19, with Pfizer leading the way with their *Comirnaty* vaccine and antiviral *Paxlovid*. Other companies such as Moderna, BioNTech, Merck, Eli Lilly, GSK and Gilead Sciences have also benefitted.

It was expected that it would be a busy year for M&A, but that activity has yet to materialize, not unexpectedly. Ongoing market volatility and uncertainty have slowed any possible M&A activity. Merck is in late stage talks to buy cancer specialty company Seagen Inc. in a deal that could be the largest M&A acquisition of 2022 thus far.

Pfizer has also been an active acquirer and has more to invest in building out its pipeline. In fact, Pfizer has committed to using business development to add US\$25 billion to risk-adjusted revenues by 2030 and has completed several bolt-on deals, including the US\$6.7 billion deal to buy Biohaven Pharmaceutical Holding Company Ltd.'s migraine portfolio.

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In Brief...

◆ **AmerisourceBergen** reported third quarter 2022 revenue of US\$60.1 billion, an increase of 12.5% year-over-year, and diluted earnings per share (EPS) of US\$1.92, compared to US\$1.40 in the prior year quarter. Adjusted diluted EPS increased 2.13% to US\$2.62 from US\$2.16 from the prior year quarter. "AmerisourceBergen delivered another quarter of strong results, and we have raised our full year outlook, driven by our team members' continued strong execution, our differentiated solutions, and the resilience of our business," said *Steven H. Collis*, Chairman, President and CEO.

◆ **McKesson Corporation** announced first quarter financial results of US\$67.2 billion, an increase of 7% year-over-year, driven by growth in the U.S. pharmaceutical segment, resulting from increased specialty product volumes, including retail national account customer, and market growth, partially offset by lower revenues in the international segment as a result of planned progress with McKesson divestiture of its European businesses. First quarter earnings per diluted share from continuing operations was US\$5.25 compared to US\$3.09 from the prior quarter a year ago, an increase of US\$2.16.

◆ **Profarma Distribuidora** (Brazil) announced second quarter 2022 earnings, with gross revenues of R\$2.2 billion (US\$423.5 million), up 22.8% year-over year, and gross profits of R\$318.6 million (US\$61.3 million), up 32.2% from the prior year. Net profits were R\$66.2 million (US\$12.7 million), a record 96.3% higher from the prior year. Ebitda reached R\$148.0 million (US\$28.5 million), up 80.5% with

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The Issue of Single-Wholesaler Distribution in Japan

(Source: An article by Takashi Ohama and an article by Yuki Kato for Pharma Japan)

According to Japan Medical Association (JMA) executive member in charge of pharmaceutical affairs, Masaaki Miyakawa, distribution of certain drugs by a single wholesaler should be corrected not only from the viewpoint of ensuring proper price negotiations but also from a stable supply perspective.

The single-wholesaler distribution practices came under the spotlight when healthcare provider representatives raised the issue at a June meeting of the health ministry's "Ryukaikon" council for the improvement of the drug distribution environment.

At the council meeting, Dr. Miyakawa said that "some manufacturers select a single wholesaler to distribute their products," urging the ministry to address such practices. Nobuya Koyama, advisor of the Japanese Association of Private Medical Schools, also questioned the practices, pointing out that this

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Pharma Industry (cont.)...

Sanofi and Merck have been the most active acquirers since 2018. Sanofi has made 10 acquisitions and Merck has tallied 7.

One formidable challenge facing pharma manufacturers is the new legislation just passed by the U.S. Congress introducing drug price controls. This new legislation will allow the U.S. government to negotiate drug prices for the drugs it spends the most on under Medicare Part D beginning in 2026 and Medicare Part B in 2028. Industry leaders acknowledge they are prepared to navigate these new headwinds now that it has been passed and signed into law.

While there are plenty of drawbacks for the industry to consider, it also includes a redesign of the Medicare Part D benefit, including a cap on out-of-pocket spending, which has been a policy priority for pharma. Another positive outcome may be some much-needed clarity on policy and the possibility that drug pricing reform would be off the table for a while.

One major risk of this legislation is its effect on R&D investment. Industry has cited the potential for reduced R&D and fewer innovative drugs as a consequence of price limitations, which was included in the Congressional Budget Office's evaluation of the price negotiation legislation. Pfizer CEO Albert Bourla told the company's second quarter sales and earnings call that while he supports the cap on patient out-of-pocket costs, the other provisions will force the industry to reduce R&D spending.

"It is very disappointing that they are choosing to single out one industry," he said, pointing particularly to the timing coming after the pharmaceutical industry has delivered so many solutions to help ease the COVID-19 pandemic. "We would be in a very different point in this global economy if we didn't have the investment and the thriving life sciences sector."

Single-Wholesaler(cont.)...

"essentially makes it impossible to (fairly) negotiate prices." In response to these comments, the council agreed to set up a working team to determine which ethical drug products are currently being distributed by a single wholesaler.

Dr. Miyakawa stressed that single-wholesaler distribution poses concerns in the area of price negotiations and drug supplies. "If the characteristics of medicines are considered, it's obvious that single-wholesaler distribution is necessary for a select type of products such as orphan drugs, which we fully understand. But the thing is that we also see such practices with other products that wouldn't require special handling, and that is why we raised the issue (at Ryukaikon)."

There are concerns for unpredictable supply disruptions. Considering such circumstances, regulators should keep tabs on the actual status of single-wholesaler distribution and take corrective measures as needed, he added. "If any additional distribution costs arise to safely deliver medicines to clinics (by eliminating single-wholesaler distribution), we would accept that because that is the price of efforts to wipe out supply concerns."

In a separate interview, Dr. Koyama of the Japanese Association of Private Medical Schools has told the publication Jiho that single-wholesaler distribution would be reasonable for products like COVID-19 vaccines that require special transport techniques, orphan drugs, and expensive medicines. If products not in these categories are distributed by a single wholesaler, drug makers should make clear why they opted for a single wholesaler. Dr. Koyama said that if this practice continues, a new forum

should be created where medical institutions, drug makers, and other stakeholders can discuss how to determine whether single-wholesaler distribution is appropriate whenever a new product is proposed for single-wholesaler distribution.

But Yoshitoshi Imoto, a partner at the Tokyo law firm Nagashima Ohno & Tsunematsu and an antitrust expert, said during an interview with Jiho, that the single-wholesaler distribution does not overstep the principle of free trade, one of the foundations of the civil law. Though this principle could conceivably be modified by the antimonopoly law, single-wholesaler distribution in itself would not qualify as "abuse of a dominant position", "private monopoly" or "refusal to deal" prohibited under this law, according to Imoto, and would only violate the antimonopoly law in very exceptional cases.

Mr. Imoto said that a company with an extremely high market share could be charged with violating the antimonopoly law from the standpoint of "private monopoly" or "refusal to deal" if it eliminates competitors by refusing contracts for a socially essential service. He said, however, that he was not aware of any drug with such an overwhelming impact that a wholesaler could not continue its business unless it receives a single company designation. He also pointed out that medical institutions are in a strong position as drug buyers. "When buying drugs, they have options such as buying from other drug makers, which gives them leverage in negotiations. It would be difficult to make the case that a drug maker is violating the antimonopoly law based on single-wholesaler distribution itself," he said.

In Brief (cont.)...

7.7% margin.

- ♦ **Cardinal Health** reported 4th quarter 2022 revenues of US\$47.1 billion, an increase of 11% from the 4th quarter last year. The company also announced that the company's current CFO, *Jason Hollar*, will assume the role of CEO, succeeding *Mike Kaufmann* effective September 1st. Hollar will also join Cardinal's board of directors. *Patricia English*, Cardinal's current chief accounting officer will serve as interim CFO while the company conducts an external search for a permanent CFO.

- ♦ **Pfizer** will acquire **Global Blood Therapeutics** for US\$5.4 billion in a cash deal to boost their presence in the field of rare hematology diseases. The proposed acquisition complements and further enhances Pfizer's 30-year heritage in rare hematology and reinforces Pfizer's commitment to bring expertise and a leading portfolio to help address the full spectrum of critical needs in the underserved sickle cell disease community.

- ♦ **CVS Health** beat expectations with Q2 2022 revenues of US\$80.6 billion, up 11% compared with the prior year period. Year-to-date revenues increased to US\$157.5 billion, up 11.1% compared to the prior year. Separately, the company plans to become a major player in the primary care arena by the end of 2022. CEO *Karen Lynch* indicated that the company wants to team up with a provider that has a strong management team and tech background, as well as the ability to grow quickly. "We have a strategy that is we are expecting to enhance our health services in three categories...primary care, provider enablement and health," she said.

(Sources: Company Press Releases, Drug Store News, Fierce Pharma, and World Pharma News)