Time for generics manufacturers to refocus on scale

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Overview

The market dynamics for US generics have been improving after a decline in prices that started in early 2014 and began to abate by the end of 2019. At the same time, generics manufacturers are moving more into complex, higher-value biosimilar treatments that offer relatively higher margins. The COVID-19 pandemic will cause companies to re-examine their global supply chain strategy and footprint. There are already opportunities for companies to reassess what products they want to compete in and invest in the capabilities they need to emphasize.

The opportunity is there to focus on building more scale in higher-value treatments to increase return on assets. Companies also need to rationalize manufacturing capacity and operations in conjunction with overall portfolio optimization efforts. To do this effectively, companies need to identify the most suitable targets to add to their portfolios, while also considering which lower-cost, lower-margin treatments to divest.

Improving pricing environment

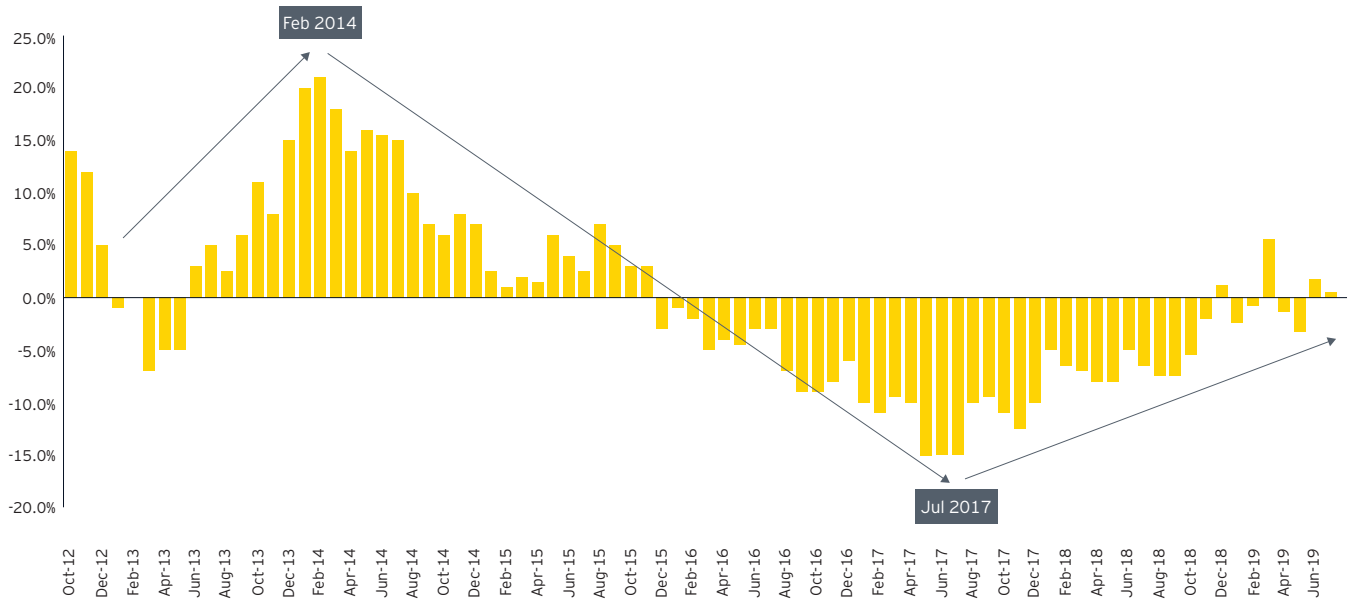
Generics pricing came under pressure in early 2014, when double-digit price increases ebbed, according to an August 2019 Barclay's research report.[1] In fact, from late 2015 through mid-2019, prices actually fell, the report shows. A double-digit increase in US Food and Drug Administration (FDA) approvals through the Abbreviated New Drug Application (ANDA) (17% increase over 2014 to 2018), competition from lower-cost products in India, regulatory and public scrutiny over prices, and consolidation of group purchasing organizations combined to pressure prices and created excess capacity.

Since hitting the bottom in mid-2017, price declines have eased. By early 2019, there were even some months in which prices increased (see Figure 1).

A combination of factors has helped stem pricing declines. The onetime impact of large buying groups driving down prices has passed through the system. While prices are still lower, they aren't falling as steeply as they did in the middle of the last decade. At the same time, leading manufacturers have rationalized costs and pruned their product portfolios. For example, in 2018, one large pharma sold its European generics business to a private equity investor. Meanwhile, Teva has said it has cut costs for the past three years, reducing about $2.5 billion in cost out of a $3 billion cost-reduction goal.[2]

Companies have also discontinued less-profitable treatments. In fact, according to the FDA, the number of drugs discontinued in 2018 was 132, up from 18 in 2017.

Figure 1: Generics pricing



Source: IQVIA and Barclays Research, August 2019.

[1] "Drug pricing; generics remain relatively stable," Barclays, 29 August 2019.

[2] "Teva, amid massive restructuring, closes in on $3b cost-cutting goal," *FiercePharma website*, https://www.fiercepharma.com/pharma/teva-s-shaved-2-5b-costs-out-3b-goal-seeks-2020-growth, accessed 30 March 2020.

More generics approvals, but also more shortages

At the same time, more injectable treatments have reached generic status, helping to offset persistent deflation in generic oral solids. These treatments are non-commoditized and offer higher margins and long-duration opportunities to unbranded generics manufacturers. In some cases, patients take treatments for months or years.

Shortages of injectable treatments for diseases such as cancer, sepsis and other life-threatening conditions, in part due to manufacturing issues at specific companies, also have supported prices. The outbreak of COVID-19, which is disrupting the global supply chain for pharmaceuticals, also is resulting in shortages of generics, given China produces many of the active pharmaceutical ingredients used to make these products. For other diseases, pricing support comes from companies either withdrawing from treatments or delaying the launch of less-profitable treatments, even after ANDA approval is received.

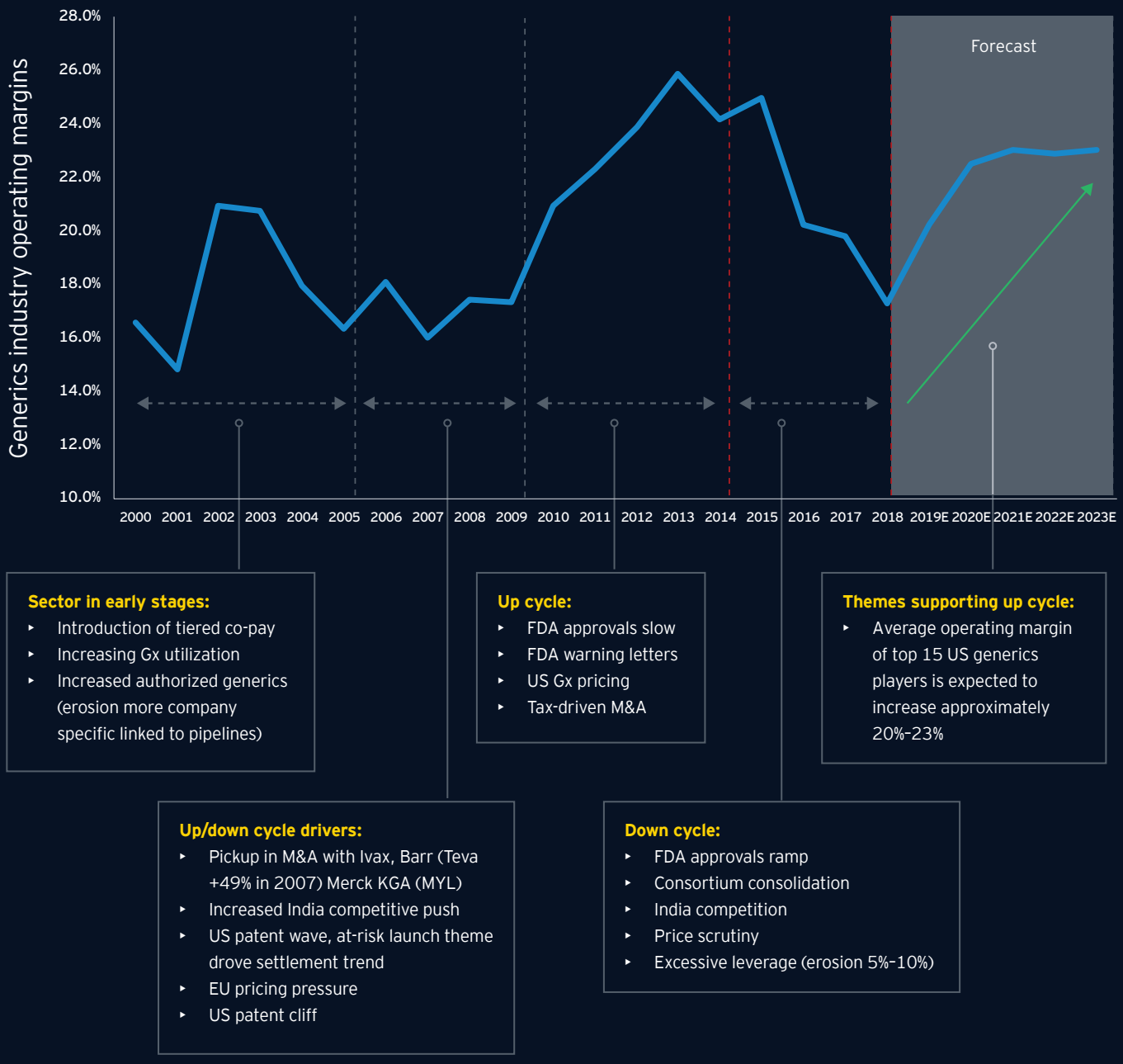
To be sure, not all pricing pressures have been eliminated. Branded players are responding with heavy rebating and patent protection strategies that could pare opportunities in the biosimilar space for generics competitors. Their relationships with pharmacy benefits managers also can block generics competitors, while some branded players have also introduced their own generic versions. Meanwhile, several major hospital systems in the US have combined to create a nonprofit company to produce a stable supply of generic drugs.

Pressure from the legislative landscape is also top of mind this election year. Drug pricing is likely to be a high-profile topic as issues such as "pay for delay" have put a stigma on the industry in the past.

Still, the average operating margin for the top 15 US generics manufacturers is expected to increase between 20% to 23% by 2023, up from 17% in 2018, according to an EY analysis (see Figure 2). This could give manufacturers more firepower to make acquisitions. Additional factors that could support consolidation are that many companies have worked to reduce the debt incurred in the last round of industry consolidation, while firms are also looking to fend off excess capacity that has been created by pruning less profitable commoditized products.

> The outbreak of COVID-19, which is disrupting the global supply chain for pharmaceuticals, also is resulting in shortages of generics.

Figure 2: Generics margins since 2000



Margins are based on top 15 players having approximately 60% market share in US generics market.

Source: Company filings, EY analysis.

Aiming for strategic position for impending consolidation

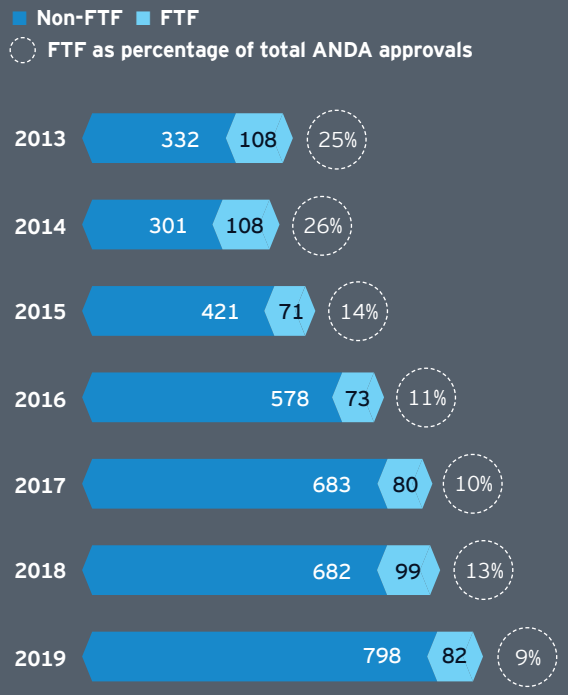
The deal announced in July 2019 for Pfizer to combine and spin its Upjohn off-patent drug business with generics manufacturer Mylan set the stage for more consolidation. More recently, Akorn announced it is exploring a sale that is expected to address its capital structure and litigation-related issues with a new owner that seeks to invest in the future growth of the business.

Disruption and consolidation opportunities are ripe across the value chain, from oral solids to ophthalmics to injectables. In 2019, Aceto asked for bankruptcy court permission to sell its generics business to Shore Suven Pharma Inc. In October of the same year, Zentiva agreed to acquire Alvogen's Central and Eastern European business as Alvogen's private equity owners consider options for the company.

The generics manufacturing market still remains highly fragmented, with the top four companies supplying only 28% of total prescriptions, while three primary buyers held 90% of prescriptions[3] (see Figure 3). The key for pharma industry CEOs, CFOs and their boards is to determine the best strategy and act while opportunities still exist. One or more of several options may be beneficial.

[3] "Global/US Generics and Biosimilars: Trends, Issues and Outlook," *IQVIA*, https://accessiblemeds.org/sites/default/files/2019-02/Doug-Long-Access2019.pdf, 5 February 2019.

Figure 3: ANDA approvals – first to file (FTF) vs. non-FTF
The market has witnessed a declining FTF rate with players reflecting the declining number of LOEs, resulting in crowding and pricing pressure.



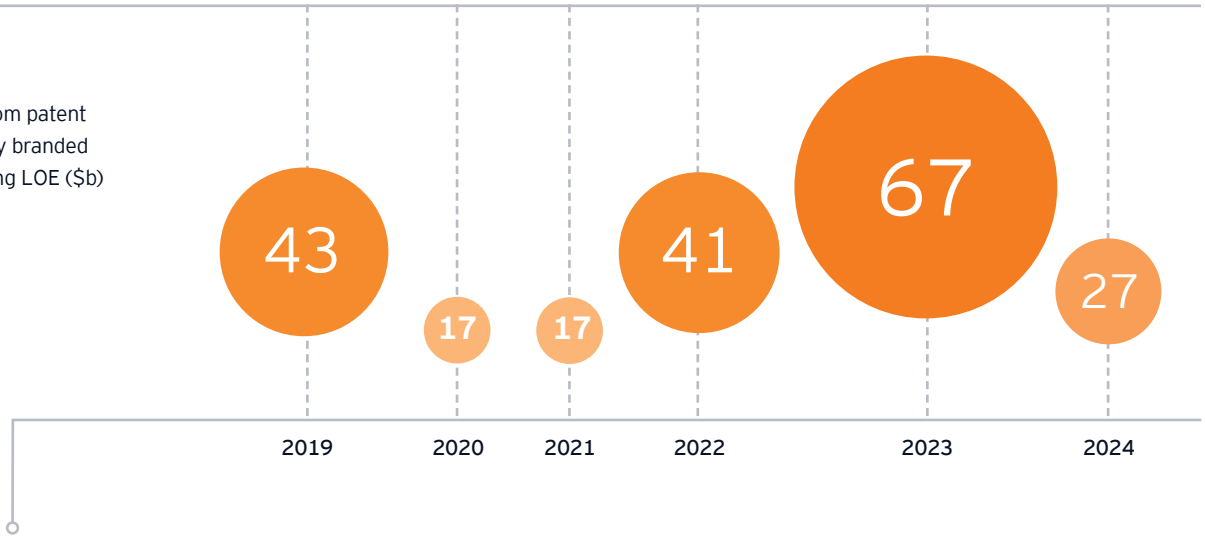
Source: FDA website, secondary source, EY analysis.

Increase scale in higher-margin biologics

As mentioned, several well-known blockbuster biologic treatments for rheumatoid arthritis, cancer and other diseases are close to coming off patent (see Figure 4). This may present an opportunity for some generics manufacturers to shift production into these higher-margin, harder-to-manufacture treatments if they can receive FDA approval. To make this shift, though, companies need to free up capital to invest in this capital-intensive manufacturing. One way is for generics manufacturers to sell lower-margin businesses. The funds from the sale of the Alvogen European business, for example, were used to invest in biosimilars.

The list of potential buyers includes both private equity investors and overseas investors that may want to build up manufacturing in the US market to mitigate against potential tariff threats and regulatory roadblocks and as a preventive measure from getting disrupted by future pandemic-like situations. Companies will need to build in optionality and may be looking for assets to build out localized supply chains in the US and other markets.

Figure 4:
Sales at risk from patent expiration – key branded drugs witnessing LOE ($b)



- The biopharma industry is expected to witness a more than $200b opportunity in the coming years due to LOEs of some of the biggest blockbuster drugs.
- This wave of LOEs is expected to drive the generics market, especially for biosimilars and complex generics, which form the bulk of the large opportunities going off patent in the next five years.

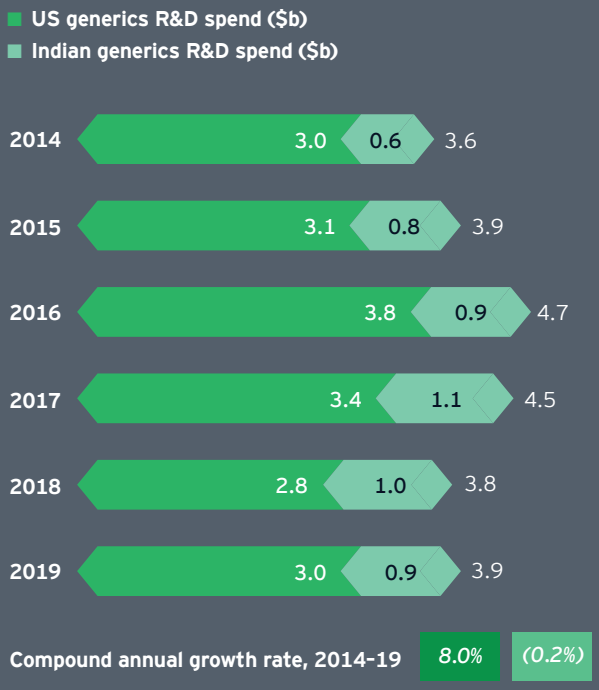
Focus on scale for first-to-file (FTF) and first-to-market (FTM) lower-cost products

These products can still be very profitable, with FTF offering a six-month window of market exclusivity. The number of companies with necessary capabilities such as navigating the PIV filing and litigation processes is still limited, though it is growing as certain Indian companies have added these skills (see Figure 5). According to studies, the first generics entrant into a market has an 80% market share advantage over the second entrant and a 225% market share advantage over the third entrant.

The generic drug market is less influenced by consumer choices than by buying habits of wholesalers and pharmacies that get the drugs from manufacturers to consumers. These buying habits and reluctance to switch manufacturers confer a major first-mover advantage and make speed to market a key determinant of how well a generic drug will perform in the marketplace.

Figure 5: Cumulative R&D spend by top US and Indian generics companies ($b)

While US-based generics players have been reducing their R&D spends, key Indian companies have demonstrated renewed focus on R&D investments.



Note: R&D spend represents cumulative R&D spend for key US generics players.

Option 3

Focus on innovation through 505(b)(2) approvals

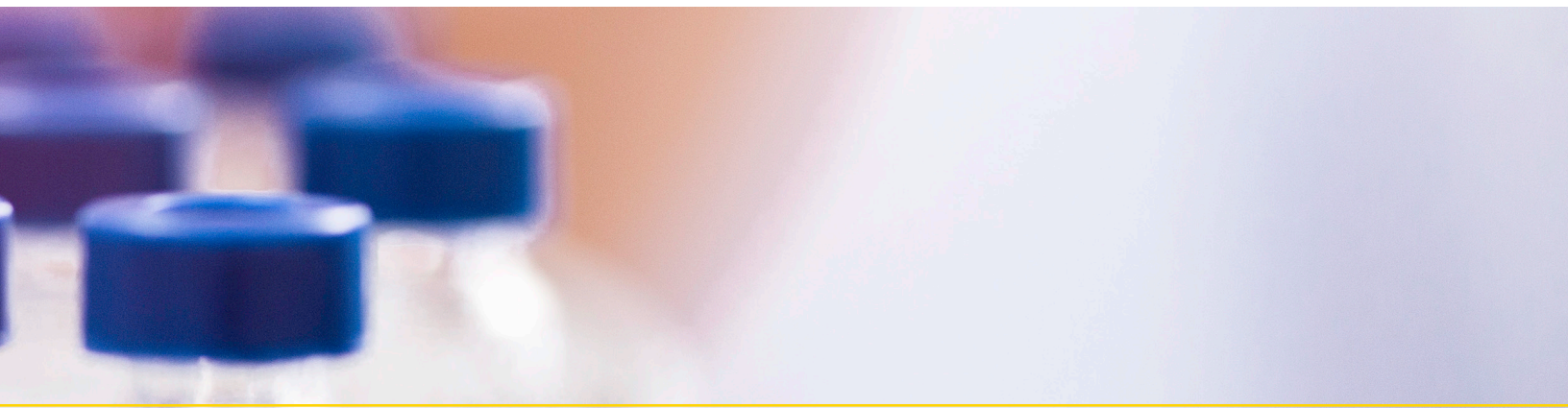
Approvals for 505(b)(2)s, which build upon and provide differentiation from previously approved products, has risen in recent years. In fact, the FDA approved more than 300 such products from 2013 to 2018 – comprising 50% of all ANDA approvals. For many generic drug companies, the 505(b)(2) pathway for a new product is an attractive business model as it takes much less time, cost and risk to get a product in the market compared to innovator drugs. These drugs are generally more expensive than the generic version of the innovator drug. Key factors for a successful launch strategy through the 505(b)(2) pathway include (i) the extent of modification to dosage form, new route of administration, etc.; (ii) careful analysis of reference studies; and (iii) a strong selling arrangement. Companies with the right product selection, strong R&D and cost advantages should benefit from the current wave of loss of exclusivity. Beginning in 2019 and running through 2024, drugs representing more than $200 billion in sales will go off patent, including some of the biggest blockbuster drugs like Humira, Enbrel and Revlimid. This creates the need to innovate quickly to take advantage of the opportunity.

Option 4

Leverage digital transformation

Generics players have lagged in terms of their digital efforts, in comparison to their innovator counterparts. But there are opportunities to use digital tools and data analytics for managing data, developing treatments, interacting with patients and medical professionals, and improving the supply chain.

> The key for pharma industry CEOs, CFOs and their boards is to determine the best strategy and act while opportunities still exist.



Conclusion

The recent market condition and business cycle offer a unique window of opportunity for the generics manufacturers to reshape their business by optimizing their portfolios, building scale and utilizing improving firepower to help accelerate growth over the next several years. Those companies moving quickly will have their pick of acquisition targets (both products and businesses). They also had been participating in a stronger deal market to divest treatments now considered to be less strategic or no longer desirable. When the market normalizes, this can provide the funds to invest in complex high-margin products, such as biosimilars.

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