The Health Care Credit Beat: Has The U.S. Generic Pharma Sector Hit Rock Bottom?

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The U.S. generics pharma industry is certainly not in the best of health these days. Generic price deflation in the U.S. market, the largest generic drug market in the world, has hurt generic drug companies' EBITDA and cash flows, leading to higher-than-expected leverage for longer periods and contributing to negative ratings actions in the sector.

At the end of 2018, we believed that the U.S. generic drug market had begun to stabilize, as consortiums had already squeezed pricing and generic drug players had exited select markets, lessening competition.

However, so far in 2019, we continue to see negative rating actions among the major generic players. The most recent occurred when S&P Global Ratings downgraded Amneal Pharmaceuticals LLC (B/Stable/--) two notches from (BB-/Negative/--), following a steep downward earnings revision on the heels of continued challenges and uncertainty in the core U.S. generics business. In May, we revised our outlook on Mylan N.V. (BBB-/Developing/A-3) to negative from stable. However, we affirmed the ratings and revised the outlook to developing on Mylan's recent announcement of its planned merger with Upjohn Co., Pfizer Inc.'s established branded pharmaceutical segment. Earlier in the year, we revised the outlook on Teva Pharmaceutical Industries Ltd. (BB/Negative/--) to negative from stable, after we downgraded the company out of investment grade in 2018.

Have we hit bottom yet in the U.S. generic drug industry?

Five Key Takeaways

Pricing has stabilized, but pressure continues

- U.S. generic drug pricing has settled into a steadier level of pricing deterioration (mid-single digits). We think pricing pressure has decelerated and the pace of new generic approvals has leveled out, lessening the strain on generic drug companies. However, the normal revenue growth dynamic in the generic industry persists, as companies must offset pricing pressure with a consistent flow of major new product approvals.

Generic players deleveraging is at risk

- The more competitive generic market creates uncertainty for participants' operating results and cash flows at a time where many of them are struggling to de-lever following acquisitions in the past several years. Debt repayment is balanced with continuing investment in the business to keep up with constantly evolving industry trends (e.g., sterile injectable, biologics, gene therapy). We believe deleveraging plans will remain vulnerable to further industry setbacks, such as unexpected further pricing pressure or delays on key drug approvals, and we believe deleveraging at many of the generic drug makers we rate could be slower than expected.

FDA generic approval rate remains accelerated

- Even with the surprise departure of Food and Drug Administration (FDA) commissioner Scott Gottlieb, who headed the agency for only roughly two years and helped staff up the Generic Drug Program, we believe approvals for generic drugs will continue at its faster pace. The agency set consecutive records in 2017 and 2018 for annual generic approvals, and we think the pace of approvals will remain high. We believe the current pace of approvals means competitive pressure will continue and that there are fewer opportunities for an above-average return on generic products.

Delevering will occur without the help of key specialty franchises

- A number of generic drug players with key high-margin branded franchises were able to generate high levels of free cash flow, such as Teva with Copaxone and Mylan with EpiPen. Both these franchises have since declined and both companies will increasingly have to rely on their core U.S. generics businesses and new launches to generate EBITDA growth and deleverage. On the positive side, Teva and Mylan believe that 2019 is a trough year for revenue and EBITDA, and a smaller impact from the loss of exclusivity of Copaxone and EpiPen translates to a smaller hurdle for growth.

Generic pricing/opioid litigation are additional wildcards

- The generic drug industry also faces a number of lawsuits, regarding collusion on generic drug pricing and litigation on generic drug companies' sale and promotion of opioids. The timing and settlement amounts are uncertain. And while litigation liabilities could be in the billions they could be years away because a clear path for a universal settlement has not been set. We believe that Teva, Mylan, Amneal, Mallinckrodt PLC, and Endo International PLC have limited capacity at the ratings level for large fines or settlements.

Pricing In The U.S. Generics Market Is Stabilizing

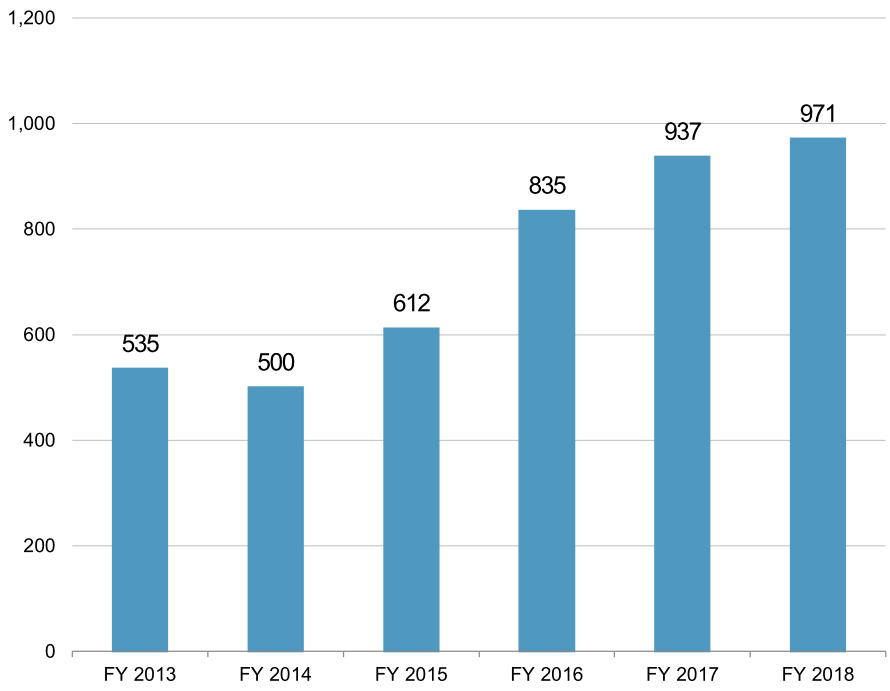
We believe that U.S. generic drug pricing, which has been problematic for the industry over the past several years, has stabilized to a more "normal" rate of price deterioration, based on earnings calls and commentary from generic drug makers, pharmacy chains, and drug distributors. The pressure from the three main drug-buying consortiums has subsided for now, with most of the major buyers in the U.S. already a member of one of the consortiums. We don't think the

consortiums can further merge, so this is no longer a major driver of price declines. Also, generic drug companies are exiting select products where it no longer makes economic sense, leading to more rational prices in commodity products and slowing the rate of price deterioration. We have even seen price increases in products in shortage. Although the decline in U.S. generic drug pricing has stabilized, we believe many products that were highly profitable now have competition, and we think there will be fewer opportunities for above-average profits from limited competition.

The FDA Continues To Fast-Track Generic Approvals

Part of the U.S. government's drive to lower drug spending is to increase competition in the generic drug industry by accelerating the approval times on generic drugs. The FDA has focused on improving generic approval times by instituting a "Competitive Generic Therapy" pathway in which it gives priority status to generic drug applications in markets where it deems there is a limited number of generic competitors. We see the faster, more streamlined approval process for generics as a long-term positive for the sector, especially if it enables first-time generics or complex generics to reach the market quicker. However, the increased pace of approvals has also had the collateral impact of accelerating price deterioration in existing generic markets.

FDA Approvals Per Year



Sources: FDA; S&P Global Ratings.

Indeed, the FDA approved a record number of generic drugs in 2018, totaling 971, after setting a previous record in 2017 with 937. This reflects an uptrend since 2014. However, we did not see an increased number of branded drugs going generic during this 2014-2018 period, meaning that the

generic drug industry saw increased competition (and lower prices) in existing generic drug markets.

Leverage Remains High For The Ratings

A number of the major generic drug companies we rate levered up in the 2016-2017 timeframe, mainly to expand their generic drug franchises (Teva, Amneal Pharmaceuticals LLC, and Endo International PLC) as well as to increase their international presences (Mylan). However, given the challenges the industry has faced, deleveraging has been slower than expected for all the aforementioned companies. Also, we believe that, while conditions have improved a bit (stabilizing pricing, more moderate pace of generic approvals), generic drug companies will find it tougher to compete than in the years since they made the original acquisitions.

Table 1

Generic Drug Company Comparisons

					--Leverage (S&P Global Ratings- adjusted)--		
Company	**Rating**	**Business risk**	**Financial risk**	**Median leverage for financial risk**	**2018**	**2017**	**2016**
Mylan N.V.	BBB-/Developing/a-3	Satisfactory	Significant	3-4	4.2	4.3	4.9
Teva Pharmaceutical Industries Ltd.	BB/Negative/--	Satisfactory	Aggressive	4-5	5.8	6.4	5.7
Amneal Pharmaceutical LLC	B/Stable/--	Weak	Aggressive	4-5	5.5	5.6	4
Endo International PLC	B/Stable/--	Fair	Highly leveraged	5+	6.3	6.6	6.1

Source: S&P Global Ratings.

Although Specialty Franchises Are Key, The Cupboard Seems Bare

Many of the generic drug companies we rate had significant branded, patented product franchises that generated relatively higher margins and cash flows, enabling them to deleverage more quickly after large acquisitions. Major players such as Teva (Copaxone) and Mylan (EpiPen) were also able to offset competition in their core U.S. generics business with their specialty franchises. However, going forward, these companies will not have as strong of a specialty franchise, as both Copaxone and EpiPen sales have declined steeply due to generic competition and Teva and Mylan have also had to lower pricing to preserve what market share they were able to retain. While both companies have new specialty products, such as Teva's migraine medication, Ajovy, we do not believe they will approach the same revenue levels as prior franchises over the next couple of years. Indeed, looking at other major rated U.S. generic players, such as Amneal (BB-/Negative/--) and Endo (B/Negative/--), we also place limited weight on the prospects of their respective specialty franchises.

Complex Generics Are The Future

Given limited specialty opportunities and heightened competition in simpler generic drugs, many manufacturers are turning to complex generics. These medications are somewhere in between branded specialty drugs and simple to manufacture generics in terms of margins and competition, but they are also have risks--primarily in development (and approval) and marketing expenses. Because complex generics are inherently more difficult to develop, we believe there is greater risk to their timely approval, although we think the largest, most experienced manufacturers are better positioned to develop complex products. Additionally, complex generics may not be directly interchangeable with branded comparators, so generic companies will have to spend more on sales and marketing expenses, which add risk to launches and represent a generally unproven business model.

The Latest Pricing Lawsuit And Opioid Litigation Adds More Uncertainty

As if the U.S. generic drug industry needed any more uncertainties and challenges, Connecticut and 43 other states recently amended a civil complaint against subsidiaries of Teva, Mylan, Endo, Amneal, and Novartis, among others on allegations of price collusion on generic drugs. While the lawsuit has been a long-running development (since 2014), the latest amendment expanded the number of drugs to around 120 (up from a few), adding another difficulty to companies that are struggling to reduce debt amid a stabilizing, but still tough operating environment.

On the opioid litigation front, Teva recently settled with the state of Oklahoma an opioid-related litigation for $85 million. The amount was higher than expected and it remains to be seen what this may mean for future opioid litigation for Teva and other companies, such as Endo and Mallinckrodt.

- Teva Pharmaceutical Industries Ltd. Oklahoma Settlement Negative To Rating; Limited Capacity For More Liability, May 29, 2019
- The Pharma Industry Outlook Is Negative On M&A, Pricing Pressure, Regulatory Scrutiny, And Opioid Litigation, March 11, 2019

Recent Rating Actions

Table 2

Recent Rating Actions

Date	Company	Action	To: Rating	From: Rating
7/29/2019	Mylan N.V.	Affirm, Outlook Developing	BBB-/Developing/A-3	BBB-/Negative/A-3
7/23/2019	WP CityMD Bidco LLC	Affirm, Outlook Positive	B-/Positive	B-/Stable
7/22/2019	DaVita Inc.	Affirm, Outlook Negative	BB/Negative	BB/Stable
7/19/2019	Alcami Corp.	Downgrade, Outlook Negative	CCC+/Negative	B-/Stable
7/15/2019	Mallinckrodt PLC	Affirm, Outlook Negative	B+/Negative	B+/Watch Neg
7/15/2019	Amneal Pharmaceuticals LLC	Downgrade, Outlook Stable	B/Stable	BB-/Negative
7/12/2019	Teleflex Inc.	Affirm, Outlook Negative	BB+/Negative	BB+/Negative

Source: S&P Global Ratings.

Mylan N.V. (BBB-/Developing/A-3)

We affirmed the ratings and revised the outlook to developing from negative following the announcement of the proposed merger with Pfizer Inc.'s Upjohn Co. legacy branded pharmaceutical business. The addition of the business not only adds a number of high-margin products and greater diversity to Mylan's portfolio, but more importantly is immediately deleveraging upon consummation. The previous negative outlook on Mylan primarily reflected leverage that was persistently over 4x for the past several years as its core U.S. pharmaceutical business, like many of its peers, struggled. If the merger is completed, we would affirm the ratings and revise the outlook to positive. If the merger is not completed, we would revise the outlook back to negative or consider a lower rating.

Primary Analyst: Matt Todd

Mylan N.V. 'BBB-' Issuer Credit Rating Affirmed On Proposed Merger With Upjohn Co.; Outlook Developing, July 29, 2019

WP CityMD Bidco LLC (B-/Positive/--)

New York and New Jersey regional urgent care provider WP CityMD is merging with New Jersey-based Summit Medical Group. Given CityMD's increased size, scale, and capabilities following the merger and its growing track record of performance, we believe CityMD's competitive position has improved. However, the company has yet to establish a solid track record of positive free cash flows and we project free cash flows of only $10 million to $20 million annually in 2020 and 2021, translating to free cash flow to debt below 3%. Still, the improvement and maturation of CityMD's business sets up the possibility of an upgrade over the next year.

Primary Analyst: David Peknay

WP CityMD Bidco LLC 'B-' Rating Affirmed On Summit Medical Merger; Outlook Revised To Positive From Stable, July 23, 2019

DaVita Inc. (BB/Negative/--)

We affirmed the ratings, but revised the outlook to negative from stable based on a more aggressive-than-expected financial policy. The company plans a $1.2 billion share repurchase plan by year end. We had expected the company to use its proceeds from the sale of its DMG business to deleverage and maintain its adjusted leverage in the 3.5x-4x range. Given the potential for stepped-up share repurchases and what we believe are deteriorating industry fundamentals, we think net adjusted leverage may climb above 4x longer term.

Primary Analyst: Ji Liu

DaVita Inc. Outlook Revised To Negative On Greater Tolerance For Higher Leverage; 'BB' Issuer Credit Rating Affirmed, July 22, 2019

Alcami Corp. (CCC+/Negative/--)

We downgraded pharma contract development and manufacturing organization Alcami based on its falling revenues and cash flows, which placed pressures on liquidity. Despite a diverse client list (no customer contributes more than 10% of revenues), a number of the company's oral solid

business clients have experienced product delays, cutting into EBITDA and resulting in double-digit (11.5x-12.5x projected for 2019-2020) adjusted leverage. Alcami is undergoing a restructuring, with a number of key management changes. We expect the company to generate mid-single-digit revenue growth in 2020, that combined with working capital improvements, will result in some minimal free cash flow generation. However, the company needs to demonstrate it can generate revenue growth and positive cash flow generation over a longer term before we deem the company's capital structure sustainable over the long term.

Primary analyst: Viral Patel

Alcami Corp. Downgraded To 'CCC+' On Cash Flow Deficits And Weaker Performance; Outlook Negative, July 19, 2019

Mallinckrodt PLC (B+/Negative/--)

We expect cash flows to remain strong (upward of roughly $600 million annually), enabling the company to maintain adjusted debt leverage in the 4x-5x range. Yet the business remains pressured, with four of the top five key branded products facing threats, such as the looming patent expiration on Amitiza in 2021 and potential competition to Acthar Gel and INOmax. The company is also seeking to spin off its generics business and is dealing with opioid-related litigation. Still, with a stated focus on deleveraging, we believe Mallinckrodt will be able to maintain leverage under 5x longer term.

Primary analyst: Matt Todd

Mallinckrodt PLC 'B+' Rating Affirmed, Off CreditWatch; Outlook Negative On Weaker Business Assessment, July 15, 2019

Amneal Pharmaceuticals LLC (B/Stable/--)

We downgraded the company following its announced revision of its adjusted EBITDA guidance by 30% and a restructuring program. The steep drop raises questions on the predictability of Amneal's business and the extended challenges facing the beleaguered U.S. generics industry. Adjusted debt leverage, which we projected to be 4.5x by the end of 2019, will now likely be in the 6.5x area. However, the company generates solid cash flows and we expect leverage to remain under 7x. We believe the company is comparable to 'B' rated peers, such as Endo (B/Stable/--) and Bausch Health Cos. Inc. (B/Stable/--).

Primary analyst: Matt Todd

Amneal Pharmaceuticals LLC Downgraded By Two Notches To 'B' On Weak Performance, Outlook Stable, July 12, 2019

Teleflex Inc. (BB+/Negative/--)

We affirmed our 'BB+' rating on medical device manufacturer Teleflex and maintained a negative outlook given the potential for a more aggressive acquisition policy. Teleflex has made progress in deleveraging, to 3.5x from the 4.1x, following two major acquisitions in 2017, as it sought to add higher-margin product lines to its portfolio. We believe the company is on track to bring this measure to the 2x-3x range; however, if leverage remains above 3x, we could lower the rating.

Primary analyst: Alice Kedem

Teleflex Inc. Issuer Credit And Debt Ratings Are Affirmed On Deleveraging; Outlook Remains Negative, July 11, 2019

Aegis Toxicology Sciences Corp. (B-/Stable/--)

We downgraded toxicology laboratory company Aegis Toxicology on lower EBITDA and cash flow expectations and a write-off of large accounts receivables in its restatement of 2016-2018 financials due to billing issues. The stable outlook is based on our expectation that the company will resolve billing and receivables issues and that the recent positive momentum in the company's underlying business will result in marginally positive free cash flows and leverage in the 6x-7x range over the next several years.

Primary analyst: David Peknay

Aegis Toxicology Sciences Corp. Downgraded To 'B-' On Accounts Receivable Write-Off, Off Watch; Outlook Stable, July 11, 2019

This report does not constitute a rating action.