# Akorn Inc struggles amid intense competition and regulatory non-compliance By Anastasia Karina Kartikaputri

Akorn Inc is an American generic drug manufacturer which specializes in difficult-to-manufacture sterile and non-sterile dosage forms. Its key drugs include Ephedrine Sulfate injection, which is used for the treatment of clinically important hypotension occurring in the setting of anesthesia. This year, Akorn Inc has seen its market capitalization plunged by nearly 80%, as its merger deal with Fresenius SE fell through. In the same period, the RMI-CRI 1-year Probability of Default (PD) for Akorn Inc rose from 0.4bps to 255.3bps.

Last month, the Delaware corporate law court <u>allowed Fresenius to walk away from the USD 4.8bn merger deal</u>, stating that Fresenius' action is justified given the "sufficient" evidence that Akorn indeed experienced "material adverse changes". More importantly, the evidence highlighted include various compliance issues within Akorn's manufacturing plants, such as <u>Food and Drug Administration (FDA)'s findings</u> on metal shaving impurities on an anesthetic produced at Akorn's Somerset plant. Akorn's sterile eye drops also had to be recalled after failing quality testing.

This year, FDA has issued Form 483 to Akorn Inc's Decatur and Somerset manufacturing plants, which would cause supply disruptions in Akorn's plants. An FDA form 483 is normally issued when FDA investigators observe any conditions that may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. Evidently, Akorn Inc recently reported that FDA compliance-related improvement activities has increased the frequency of maintenance shutdown in its facilities and therefore its operating costs. The improvement activities are expected to affect Akorn Inc's profitability, at least until the end of 2018.

Akorn's struggle started in early 2017, where it stated that a <u>modest decline in its annual sales in 2017 is to be expected</u> due to pricing erosion and increased competition. Prices for generic drugs have fallen in a faster rate since last year, due to the <u>faster abbreviated new drug application (ANDA) approval</u>, as part of the government's effort to increase access to medications and reduce the cost of medicines for patients. The faster approval has led to greater pricing pressure and competition. However, in 2018, Akorn only received six new generic drug approvals so far, as compared to 26 in 2017, thus worsening its situation.

	2017Q1	2017Q2	2017Q3	2017Q4	2018Q1	2018Q2	2018Q3
Revenue (USD mn)	253.4	199.1	202.4	186.1	184.1	190.9	165.6
Net Income (USD mn)	41.0	2.5	-2.9	-65.2	-28.7	-88.0	-70.1
T12M EBITDA (USD mn)	400.8	322.4	244.7	66.8	-33.6	-140.6	-226.9
Total Debt/T12M EBITDA (X)	2.02	2.52	3.33	12.20	N/M	N/M	N/M

Table 1: Financial Information for Akorn Inc. N/M indicates not meaningful due to negative trailing 12 month EBITDA. Source: Bloomberg

Akorn has been facing increased competition for its key drug, Ephedrine Sulfate, from other drug manufacturers such as Endo International PLC. The impact of Akorn's loss of exclusivity for the drug, which generated 10% of Akorn's 2017 total net revenue, is reflected in its latest income statements. As shown in Table 1, Akorn's revenue and net income have continued to plunge in the competitive environment. In Q3 this year, Akorn reported its fifth consecutive quarter of losses in its latest financial results and its third quarter net revenue missed even the lowest analyst estimate of USD 178mn. In particular, Akorn mentioned that the increase in net revenue due to new products and product relaunches were not able to offset the decline in the existing portfolio. In the same report, Akorn also said that it is currently facing greater competition for three additional key products.

Akorn's worsening credit profile is reflected in the increasing trend of its Total Debt/T12M EBITDA, which reached 12.20x in the fourth quarter of 2017. In light of its high leverage (larger than 7x) as well as the decreasing likelihood that it will be acquired by Fresenius, Moody's downgraded Akorn to B3 from B1. With Akorn's product pipeline's inability to offset declines in the existing portfolio, Moody's said Akorn is likely to have weak cash flow over the next 12-18 months.

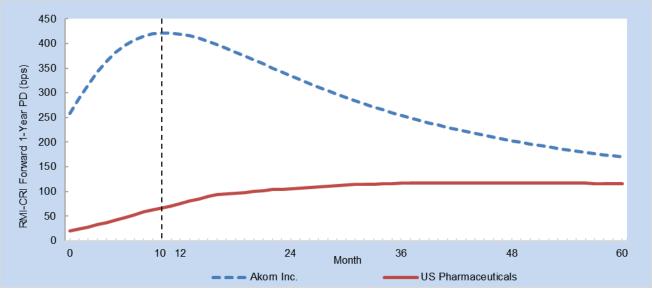


Figure 1: RMI-CRI Forward 1-year PD term structure for Akorn Inc and Forward 1-year Aggregate PD term structure for 297 US pharmaceuticals companies on November 8, 2018. Source: RMI-CRI.

Figure 1 illustrates the term structures of the RMI-CRI Forward 1-year Probability of Default (Forward PD) for Akorn Inc and the RMI-CRI Forward 1-year Aggregate Forward PD for US pharmaceuticals companies. As illustrated in the figure, based on the market information available as of November 8, 2018, the credit profile for Akorn Inc could deteriorate in the following 10 months. The Forward PD computes the credit risk of a company in a future period, which can be interpreted similar to a forward interest rate. For example, the 10-month Forward 1-year PD is the probability that the firm defaulted during the period from 10 months onwards to 1 year plus 10 months, conditional on the firm's survival in the next 10 months.

Given the uncertainty of the court appeal, risks associated with Akorn's compliance issues as well as the tough generic-pricing environment, there is a pressing need for Akorn to deleverage and drive its business back to profitability to regain market's trust, especially in the short term.

#### **Credit News**

### China developers face USD 55bn of maturing onshore debt in 2019

**Nov 12.** Chinese property developers are facing difficulties to finance their existing and future obligations. A wall of onshore debt worth tens of billions of dollars issued by Chinese property developers is due to mature next year, raising concerns over defaults amid a decade low economic growth, instable financial sector and tightening liquidity. Property developers also struggle to issue new debt and thus face problems to refinance maturing bonds this year as the Chinese government attempts to control the runaway credit-fuelled growth that has helped power the sector in recent years. A crackdown on shadow banking also makes it hard for developers to gain capital since companies were often able to access credit through China's shadow banking industry in past years. (FT)

#### Turkish banks report rise in bad loans

**Nov 12.** As the Turkish lira crisis in August begins to hit the country's indebted corporate sector, Turkish bank are reporting an increase in non-performing loans (NPLs) and a slump in lending. Analyst are warning that the NPL rate is likely to increase in the months ahead from its current September rate of 3.22%. The earnings of Turkish banks are also down 12.6% quarter-on-quarter due to a sharp increase in provisions. Even though the lira has strengthened following the large interest rate increase, it is still down almost a third against the dollar as of early 2018. Turkish banks' ability to refinance maturing external debt is also at a higher cost. Economists are predicting that Turkish banks will be challenged as the economy faces headwinds. (FT)

#### Alternatives to scandal-ridden Libor are slow to catch on

**Nov 12.** Thousands of interest rate swaps, mortgages, consumer loans and credit card contracts are still pegged to Libor despite efforts by the world's largest financial regulators to push banks off the benchmark. The key problem with Libor, a measure of the cost of unsecured borrowing between banks, is that it remains incredibly easy to manipulate. The Financial Conduct Authority has announced that it will phase out the London Interbank Offered Rate by 2021 but data from ISDA showed that 63 percent of interest rate derivative contracts are using Libor rates as reference, in contrast to 15 trades based on the Secured Overnight Financing Rate or Sofr, introduced by the Federal Reserve. (FT)

### Smaller deals emerge in Asia USD bond market

**Nov 8.** A trend toward smaller deals emerges in Asia USD bond market, creating headaches for companies with super-sized funding needs as smaller issues also tend to be taken up by local investors who prefer to hold to maturity. Amid the challenging background where the China-US trade war is dragging on and the increasing corporate default risks in China, Asian corporate bond yields are the highest in nearly 7 years. Consequently, only 12 Asian borrowers priced deals that met the USD 1bn threshold in the second half, down from 35 issuers during the first half of this year and 91 issuers in 2017. Some issuers are paying a much higher premium to price deals as investors are demanding more new concessions to compensate for a potentially higher mark-to-market loss on their portfolios if the US Treasury yields increase in the future. (Business Times)

### Russian lenders wrestle over capital rules drive

**Nov 7.** The attempt to clean up Russia's inefficient state banking sector has failed due to a conflict of interest between the central bank and government. The central bank has asked the top 11 "systemically important" banks to create a buffer of 1 per cent of risk-weighted assets to comply with Basel III capital adequacy regulations but the finance ministry demanded state-run companies to pay 50 per cent of profits in dividends to fund the state's budget. Some Russian lenders find it difficult to meet these Basel III requirements as risk-weighted assets can reach as high as 91% of the total. Banks also find it difficult to raise capital from the market because of US and EU sanctions on long-term debt. (FT)

Fitch Solutions cuts loan growth forecasts for Singapore banks, saying outlook weaker (<u>Straits Times</u>)

Green bond sales stutter after rapid growth (FT)

IMF warns Italy vulnerable amid rising interest rates (Business Times)

#### **Regulatory Updates**

## Australia's banking regulator flags higher capital requirements

**Nov 9.** Australia's banking regulator's third request in three years to raise capital requirements is heaping pressure on companies already bracing for tighter regulation. The Australia Prudential Regulation Authority (APRA) wants to increase the country's four biggest lender's capital requirements by four to five percentage points by 2023 from the current 14.5% of total risk-weighted assets, requiring the lenders to raise between AUD 67bn to AUD 83bn in extra capital over 4 years. The regulation is aimed to barricade the banking sector against global shocks and bring Australian banks in line with new international standards developed by the Basel Committee on Banking Supervision. S&P Global stated that if implemented, the new regulation can trigger an upgrade in its credit outlook on the four biggest lenders to "stable" from "negative". (Business Times)

#### Fed unveils plans to reduce stress of Wall Street's stress tests

**Nov 9.** Wall Street banks will have to wait till at least 2020 as the Fed plans to revamp its stress tests, first implemented after the 2008 financial crisis. The Fed plans to improve the transparency of the testing process by disclosing additional detail about the supervisory stress test models and results and regarding scenarios and scenario design. It also plans to delay a related rule change to the stress capital buffer which will force the biggest banks to hold more capital. The Fed will also let banks know their stress test outcomes before they plan their capital distributions, which will help the banks allocate the right amount of capital to return to shareholders through dividends. (Bloomberg)

China unveils more funding support for private firms (Business Times)

EU regulators monitor big tech's financial services foray (FT)

Published weekly by <u>Risk Management Institute</u>, NUS | <u>Disclaimer</u> Contributing Editor: <u>Dexter Tan</u>