# Lawsuit against FDA brings Endo's future into further uncertainty by Yu Ning

On Oct 27, the shares of Endo International, one of the largest generic drug makers in the world plunged nearly 14% after two of its subsidiaries filed a lawsuit against the US Food and Drug Administration (FDA) for ignoring the Drug Quality and Security Act of 2013. The RMI-CRI 1-year PD for the company increased to 1126.83bps a day after the announcement. In a District of Columbia court filing, the Endo subsidiaries accuse the FDA of allowing the bulk compounding of hundreds of drugs and request the immediate removal of vasopressin, a key ingredient in one of Endo's important drug Vasostrict, from the Category 1 nomination list. By keeping vasopressin in the list, pharmacies would be allowed to freely compound a custom-made generic drug of Endo's blood pressure product Vasostrict.

Endo International may be keen to keep the competition away from Vasostrict as it helped <u>generate USD 194.9mn of revenue</u> for the firm during 1H 2017, which accounted for 10.19% of Endo's total revenue. Not enforcing the Drug Quality and Security Act of 2013, which heavily restricts the practice of bulk compounding, would not be beneficial to Endo as it allows other pharmaceutical companies to easily manufacture make-ups of special pharmaceuticals and thereby competes against the high-price drug.

It's been a tumultuous year for Endo International PLC. The company, formerly known as Endo Health Solutions Inc, is a <u>specialty healthcare company</u> headquartered in Ireland that manufactures, markets and distributes pharmaceutical products and generic drugs. Over the past year, the company lost nearly 69% of its market capitalization to USD 1.33bn by the end of October. The RMI-CRI 1-year Probability of Default (PD) for Endo International, which started from 314.28bps in December 2016 soared to 1024.418bps in November 2017.

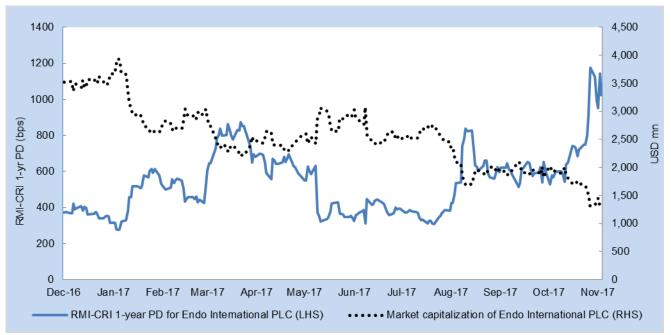


Figure 1: RMI-CRI 1-year PD for Endo (LHS) and Market Capitalization for Endo (RHS) Source: RMI-CRI, Bloomberg

Endo's high PD trend partly resulted from boomed problems in 2017. For example, earlier this year, Endo announced a voluntary recall of Edex (alprostadil for injection) in February due to potential lack of sterility assurance. In June 2017, the FDA asked the company to withdraw its opioid pain drug Opana ER from the US market on concerns of a burgeoning opioid epidemic. The drug recall resulted in a 13.6% drop in market capitalization on June 6. President Trump also said in January that he would take action to lower drug prices after expressing concerns that Americans are paying multiples of what other countries are paying for the same

drugs. Confronted by a series of nasty shocks, Endo <u>lowered its full-year revenue forecast</u>, sending the company's stock price and market capitalization to its lowest since 2009.

	Q4 2016	Q1 2017	Q2 2017
T12 Net Income (USD mn)	-3347.07	-3387.03	-5127.12
T12 EBIT (USD mn)	-3471.52	-3446.31	-3984.67
Net Debt / Equity (%)	286.98	348.75	947.52
EBIT / Interest Expense (x)	-7.61	-7.62	-8.61

Table 1: Financial information for Endo International PLC. Source: Bloomberg

By the end of June 2017, the company's net debt-to-equity ratio reached 947.52%, which is significantly higher than the industry median of 10.80%. Endo's high debt load partly resulted from the firm's continuous expansion in 2014 and 2015. During those two years, the company made a spree of acquisitions, including Par Pharmaceutical Holdings Inc, Innoteq Inc, and Litha Healthcare Group Ltd. The company's trailing 12-month net income meanwhile plunged further during the first six months of 2017, together with its T12 EBIT dropping to USD -3984.67mn. The firm's ability to cover its interest expenses, represented by the ratio of EBIT-over-interest expense fell to -8.61 in Q2 2017.

Endo's Q3 preliminary results on Oct 30 may be better than Q2 but there are lingering concerns about the FDA's lawsuit and the firm's poor financial conditions. Analysts say that another lawsuit filed by forty-six US state attorneys accusing the industry of conspiring to fix drug prices creates an uncertain outlook for the US pharmaceutical market. Investigations are ongoing, and the sector would likely to get hurt if the lawsuit will involve more companies.

#### **Credit News**

#### DBS profit sinks as bank tries to put bad loans behind it

**Nov 6.** DBS Group Holdings, the largest bank in southeast Asia, announced a 23% drop in net income to SGD 822mn which is mainly due to the increased bad-loan allowances in the third quarter. DBS's bad loan allowances raised more than sixfold because the management group decided to classify more non-performing loans from soured energy-industry. Singapore banks have been struggling with the troubled regional oil and gas sector since Swiber filed for judicial management last year. Energy-services industry is still under stress according to the quarterly reports of Oversea-Chinese Banking Corp. and United Overseas Bank. Although DBS's earnings missed the average of analysts' estimates of SGD 1.14bn, net fee income rose 12% from a year earlier attributed to the growth in income from wealth management. (Bloomberg)

### China's central bank chief warns of 'sudden, contagious and hazardous' financial risks

**Nov 4.** China's central bank governor, Zhou Xiaochuan, issued warnings on the vulnerability of China's financial system due to high leverage. He cautioned that latent risks are accumulating even though the overall financial system remains healthy. In response, Zhou called for tougher regulations and deeper reforms in China's financial markets. Comments by Zhou are widely regarded as a signal that policy makers remain committed to their deleveraging efforts in the Chinese economy. Despite so, credit is still expanding with aggregate financing reaching a six-month high of RMB 1.82tn. Chinese corporate debt climbed to 159% of the economy in 2016, a sharp rise from the 104% ten years ago. (Bloomberg)

# Venezuela to restructure foreign debt, default looms as possibility

**Nov 3.** Venezuelan President Nicolas Maduro vowed to make a USD 1.1bn payment on a bond maturing and announced plans to create a commission to study restructuring of its burgeoning foreign debt. However, Venezuela has few avenues to restructure its debt. Its sanctions imposed by the US bar US banks from participating in or even negotiating such deals, and a restructuring plan without a clear plan to create a functioning market economy would not get investors' support. Currently, the Venezuelan government and state-owned companies such as PDVSA owed some USD 1.6bn in debt service and another USD 9bn in bond servicing in 2018. For PDVSA, the next hard payment deadline is an USD 81mn bond payment that was due on Oct 12 but on which the company delayed payment under a 30-day grace period. Failing to pay that on time would trigger a default, which would in turn make countries less willing to do business with Venezuela and create further problems for its vital oil industry that is already hobbled by under-investment. (Reuters)

## Falling junk bond spreads trigger sense of foreboding

**Nov 2.** For the USD 1.3tn US junk bond market, the spread, which is the premium that investors demand over US government bonds, has fallen by almost a fifth this year, and has reached 338 bps, just 3bps above a 2014 nadir that remains the lowest since the financial crisis. Consequently, junk bonds have outperformed investment-grade bonds, generating a total return of 7.4% this year. Many analysts believed that spreads could continue to tighten to record lows, as the European Central Bank (ECB) and the Bank of Japan (BoJ) continue with their bond purchases. The looser constraints on borrowers in the loan markets have also provided an incentive for companies to tap the loan markets, thus reducing high-yield supply and keeping a lid on the spreads. However, fears are growing over the risks of such falling spreads, as some investors are worried that bond buying from the ECB and BoJ has distorted corporate credit markets, and at the same time, investor protections in the form of covenants that can restrict a company's level of indebtedness have been whittled away. (FT)

# Another China company defaults on bond payment as borrowing costs jump

Oct 31. Dandong Port Group Co is next on the list of Chinese company defaults after it failed to repay notes sold back to the company by investors. The RMB 1bn five-year bond, issued by Dandong Port in 2014, had an initial coupon rate of 5.86% and an option for investors to sell them back to the company early. All investors had exercised the option but Dandong Port was only able to pay back part of the principal. However, the company managed to pay RMB 58.6mn in interests to its bondholders. The rising borrowing costs in China sparked concerns about the high corporate borrowings in China and bond yield surged after the Chinese central bank echoed this sentiment. (Bloomberg)

Reliance Communications shares jump on debt revamp plan (FT)

China's HNA selling short-dated bond at "scary" high 9% coupon (Reuters)

Marks & Spencer poised to announce more store closures (The Guardian)

## **Regulatory Updates**

### Corporate affairs ministry considering multiple changes to Insolvency and Bankruptcy Code

**Nov 4.** The Ministry of Corporate Affairs of India is considering changes to the Insolvency and Bankruptcy Code. According to senior officials, the review is conducted based on feedback received and how the law has worked in the past few months. One of the possible changes includes preventing an insolvent founder from getting back the reins of a company through a shell company while escaping liabilities. The government has also received a suggestion to make the code more comprehensive to cover entities such as trusts, societies and Hindu Undivided Families as well. Another proposal is easing compliance requirements regarding routine disclosures while the insolvency process is on, in addition to the establishment of a framework to deal with cross-border insolvencies. (Economic Times)

#### Trump kills class-action rule against banks, lightening Wall Street regulation

**Nov 2.** US President Donald Trump has signed a Congressional resolution that kills a Consumer Financial Protection Bureau (CFPB) rule. The CFPB rule stopped banks, credit card issuers and other financial companies from requiring customers to sign away their rights to join group lawsuits and agree to take the potential disputes to closed-door arbitration as a condition to opening accounts. The rule was set to go into effect next spring but critics say that the lawsuits will only benefit attorneys and argue that arbitration is faster and may lead to larger rewards. This is considered President Trump's first concrete action to lighten financial regulation in the US since taking office earlier this year. (Reuters)

Greece is planning a EUR 30bn debt-swap exercise (Bloomberg)

Bank of England raises UK interest rates for first time since 2007 (The Guardian)