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Nerlynx's setback in Europe creates uncertainty for Puma Biotechnology Inc

By Lin Li

Puma Biotechnology Inc (Puma) is a development-stage biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. Puma's product, Nerlynx, was approved by the US Food and Drug Administration (FDA) in July 2017 for treatment of early-stage HER2+ breast cancer. The FDA's approval was a huge boost to the company's outlook as it has been losing money for the past few years. However, the prospect of Puma is uncertain as Nerlynx is unlikely to gain the marketing approval in Europe. Combined with the company's history of operating losses, the share price of Puma slumped twice by more than 50% in the past 3 months and the RMI-CRI 1-year Probability of Default (PD) increased to 45.43bps on February 05, 2018 from 3.9bps at the end of October 2017.

On January 23, Puma announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has communicated a negative trend vote for Puma's Marketing Authorization Application for Nerlynx. A negative trend vote means it is unlikely that CHMP will provide a positive opinion at the formal decision vote scheduled in February 2018. CHMP indicated that, in its opinion, the benefit risk assessment is negative in two aspects. Firstly, the study results are based on evidence from a single pivotal trial. Secondly, the 2- and 5-year invasive disease free survival benefits observed to-date may lack sufficient clinical relevance.

In fact, Puma has no other approved product other than Nerlynx at this moment. Due to lack of a strong pipeline, the company is totally dependent on Nerlynx for growth. As for the drug itself, the main adverse side effect seen to date in clinical trials includes diarrhea, liver abnormalities and potential harm to fetal. These side effects make EMA reluctant to approve the marketing of Nerlynx. The uncertain clinical trial result of Nerlynx and the regulatory setback in EU seriously affect investor's belief about the company's growth prospects. Analysts from JP Morgan estimate that earnings per share for Puma will continue to be negative in 2018, around USD -3.11.

Profitability has always been a major concern for Puma. Early in November 2017, the company announced its Q3 financial statement and reported a loss of USD 77.2mn in the third quarter of 2017, slightly higher than a loss of USD 65.08mn in Q3 2016. Puma also registered the first revenue of USD 6.1mn from initial sales of Nerlynx after it gained FDA's approval. Total net income of the company continued to be negative due to huge operating expenses as the selling, general and administrative expenses increased 132% YoY to USD 32.5mn due to higher professional fees, payroll costs and other costs to support the commercial launch of Nerlynx.

	Q1 2017	Q2 2017	Q3 2017
Revenue (USD mn)	0.0	0.0	6.1
Operating Expenses (USD mn)	73.2	78.2	82.0
Net Income (Loss) (USD mn)	-72.9	-77.8	-77.2

Table 1: Financial Data of Puma Biotechnology Inc. *Source: Bloomberg*

Competition is also intense in the breast cancer drug market. Approved treatments include Roche Holding AG (Roche)'s main products, Herceptin and Perjeta and Kadcyla. Roche is the leading company in the treatment for the same type of breast cancer. Its product Herceptin has gained FDA approval in 1998 and enjoys strong market share. Roche also developed Perjeta and Kadcyla as adjuvant treatments and improves the drugs' performance a lot. This great competition puts Puma in a tough position. Even if approved, physicians and patients may not accept or use Nerlynx with the presence of other available therapies. In addition, quite a few companies are working on developing treatment targeting the breast cancer drug market.

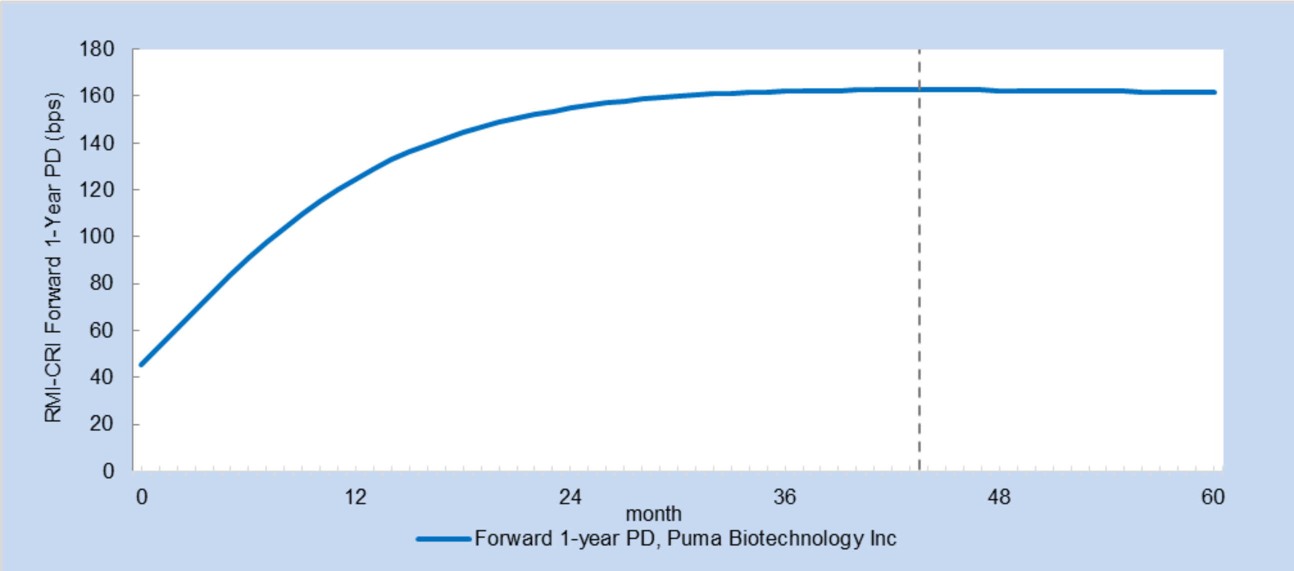

Figure 1: Term structure of RMI-CRI Forward 1-year PD of Puma Biotechnology Inc on February 05, 2018. *Source: RMI-CRI*

Effective on October 31, 2017, Puma entered into a credit facility with Silicon Valley Bank and Oxford Finance for a term loan of up to $100 million. Puma intends to use the funds for general corporate purposes and to further support Nerlynx commercial initiatives. The loan will mature on October 31, 2022. Puma's new debt may further test shareholders' and creditors' patience as it has yet to turn a profit amid uncertainties on Nerlynx's approval in Europe. As seen in Figure 1, the RMI-CRI Forward 1-Year Probability of Default (Forward PD) of Puma will climb to peak at 180bps in more than 3 years. Intuitively, the Forward PD computes the credit risk of the firm on a future period, which works like a forward interest rate. For instance, the 3-month Forward 1-Year PD is the probability that the firm defaults during the period from 3 months onwards to 1 year plus 3 months, conditional on the firm surviving the next 3 months. The Forward PD term structure suggests that based on the market information available as of February 05, 2018, Puma's credit profile is likely to deteriorate in the near future.

Net income for the next few quarters are projected to be negative though on a decreasing trend, according to Bloomberg. The expected improvement could be due to the efforts to commercialize Nerlynx to other parts of the world. Puma has entered into several executive licensing agreements with giant biopharmaceutical companies in China and Israeli and appointed them to be responsible for seeking the requisite regulatory approval and commercialization of Nerlynx upon approval. Puma will also report Phase III trial results in the first half of 2018. If more promising clinical data are provided, Nerlynx still stands some chance to gain approval in Europe. With a history of operating loss, the future sales of Nerlynx in the United States and regulatory approval in other parts of the world will be quite critical for Puma.

Credit News

Concern grows over long-term stability of Italian sovereign debt

Feb 4. Italian banks are selling off their domestic sovereign debt at unprecedented rates. According to analysis by investment advisory firm Jeffries, Italian banks reduced their holdings of sovereign debt by EUR 12.6bn in December and by EUR 40bn in the final quarter of 2017. The sell-off comes as Italy is going to run the general election on March 4. There are fears that Italian exports, which are the main driver of economic growth, will dampen as the euro gains strength. There are also growing concerns about the long-term stability of Italian sovereign debt. Economy Minister Pier Carlo Padoan warned that the proposals from senior European Union officials, which differentiates risk scores to government bonds of different countries that banks hold in their portfolios, would encourage banks to sell off riskier bonds. (The Telegraph)

Subprime auto debt is booming even as defaults soar

Feb 2. Sales of subprime auto bonds are booming despite a pickup in defaults. These subprime loans packaged into securities have rarely been so popular a decade after risky mortgage lending toppled the US financial system. However, the collateral behind the bonds is getting less safe. According to JP Morgan, Wall Street has supplied USD 3bn worth of subprime auto asset-backed securities to satisfy the demand of investors so far in 2018, compared to USD 1.8bn worth sold in the same period last year. A combined gauge of both prime and subprime auto bonds shows spreads have dropped to the lowest 4th percentile of their seven-year ranges, according to Goldman Sachs. Nevertheless, it is unlikely to trigger new financial crisis even with a wave of defaults, as the amount of bonds issued was far less than the USD 1.2tn of bonds backed by home loans sold in 2005 and 2006 prelude to the credit crisis. (Bloomberg)

Saudi Arabia and UAE tops for tough debt collection, report says

Feb 1. According to new research from a credit insurance company Euler Hermes, Saudi Arabia and the United Arab Emirates (UAE) are the hardest places in the world to collect unpaid debts. In UAE, the new insolvency law in 2016 has not delivered on its promise to make debt collection easier. While in Saudi Arabia, court proceedings are still extremely long and uncertain. China, Russia, Malaysia and South Africa also scored badly when judged on the complexity of debt collection. US came towards the middle of the pack with its particularly complex court system and relatively pro-debtor insolvency procedures. Countries in the EU fared better, with eight countries in the top 10 list. (FT)

Refiner bankruptcy adds to pressure to overhaul biofuel program

Feb 1. The bankruptcy of Philadelphia Energy Solutions LLC (PSE), the biggest refiner on the US East Coast, has added pressure to overhaul the controversial Renewable Fuel Standard (RFS) that forces PES and other refiners to use biofuel. Costs to obtain required credits have skyrocketed, with last year's USD 218mn tab more than twice the PSE payroll and representing the company's single largest expense after crude oil. Some politicians and refiners that wanted a RFS overhaul say the PSE bankruptcy is fresh evidence for change, while biofuel backers indicate that the business model is the reason for the PSE bankruptcy instead of the current policy. Officials are currently working on possible solutions to use robust volumes of biofuels without bankrupting domestic refiners, but efforts would need time to take effect due to difficulty in passing the biofuel legislation in Congress. (Bloomberg)

Debt payment behavior of Singapore SMEs worsened in 2017

Feb 1. Debt payment behavior of Singapore's small and medium-sized enterprises (SMEs) worsened last year, with the proportion of severely delinquent debts increasing to 14% in 2017 from 12% in 2016. The construction sector has the highest proportion of severely delinquent debts at 24%, up from 18% in 2016. The information and communication sector came in a close second at 23%, down from 27% in 2016. Despite the uptick in 2017, Dev Dhiman, managing director for South-east Asia and emerging markets at Experian, pointed out that there is a downward trend in severely delinquent debts since 2014, which could have been a result of better trading conditions in the local and global economies together with better exports and tourist numbers. (Straits Times)

Bon-Ton is preparing for bankruptcy (Bloomberg)

Patriot National files for chapter 11 bankruptcy protection (Insurance Journal)

Noble shares fall after proposed debt-for-equity deal (Straits Times)

Regulatory Updates

Euro zone bailout fund could handle future debt restructuring—ESM

Feb 2. The European Stability Mechanism (ESM) could in the future define a Sovereign Debt Restructuring Framework, under which the ESM could provide debt sustainability analysis, and help organize negotiations between creditors and the debtor, with the aim of a fair solution for all stakeholders. Such a framework will make settlements with private creditors more effective and transparent, as compared to the current arrangement of lending cash to governments that have been cut off from markets in exchange for reforms that put their economies back on track. Several northern European countries advocate the implementation of the Sovereign Debt Restructuring Framework, as the framework would help improve government fiscal discipline through market pressure. However, some southern euro zone countries with high debt strongly opposed, fearing that such discussions may lead to markets selling off their bonds and triggering another crisis. (Reuters)

European banks to face tougher stress tests in 2018

Feb 1. According to the European Banking Authority (EBA) regulator, European's biggest banks will face stringent tests of their resilience against economic shocks in 2018. Some 48 institutions representing 70% of European banking sector assets will be involved in the exercise. The tests include four different types of risks that regulators have identified as the most dangerous to financial stability in Europe, with "confidence shock", a speculative scenario caused by major political uncertainty, regarded as the biggest risk. In a worst-case simulation, the EBA will work out the effects of a two-year recession in the EU, with economy shrinking by 1.2% in 2018 and 2.2% in 2019, followed by mild growth of 0.7% in 2020. Economic risks linked to Britain's departure from the EU have been included and results will be released in November. (Channel NewsAsia)

China cracks down on tech credit scoring (FT)

Deutsche Bank to pay USD 70mn to settle US rate-rigging probe (FT)

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Contributing Editor: Liu Hanlei