AtonRā Partners

Biotech And Pharma Madness

After huge pressure on the Pharma and Biotechnology names in October (including our Biotech actively-managed-certificate), the first week of November did not give any sign of relief.

This time around, the political rhetoric was followed by some hard facts.

The US DOJ's (Department of Justice) two-year investigation in the generics pharma industry (including large players such as **Teva Pharmaceuticals** and **Mylan**) is reportedly nearing to a close, leading possibly to criminal charges by year-end for price-collusion. In a separate probe, a group of state attorneys general are investigating generic-drug companies for price-fixing.

We have no exposure to this subgroup, but this piece of news badly hit an already fragile Biotechnology sector.

As often is the case in the US, criminal price-fixing investigations (and many other criminal cases) are settled out of the courts with hefty fines. Eventually, shareholders of those companies will end up having to support a one-time charge that is likely to eat the companies' FY2017 earnings.

In our October Biotech monthly update, we argued that "while the outrageous pricing hike (5'500% in a single day) made by a stupid 32-year-old greedy VC on a 62-year old life-saving drug (Daraprim) needs to be for sure monitored and punished (the Pharma industry should have been the most vocal on this matter, this was unfortunately not the case), the continued bashing of the industry (reminiscent of what happened in the financial industry over the last few years) won't lead to a better world but rather to regression".

We remain convinced, even more now with the DOJ investigation in the generics industry, that the best plays in the sector are not the largest Pharmaceutical and Biotechnology companies, which for sure are trading in the lower range of historical valuations, but the specialty-driven biotechnology companies, which are to benefit from some unmet medical treatments and drugs.

In addition, M&A could be a major catalyst going forward as the smaller biotech names need cash while the larger players could use the opportunity of tumbling valuations across the board to put at use their significant cash positions. Hence, once the dust settles, positive catalysts for smaller niche companies are well identified.

Last week, we also had one of our largest positions in the Biotechnology portfolio (**Cempra Inc.**) which got badly hit.

Fortunately on Friday, during one of the most epic Advisory Committee we've ever seen, the Antimicrobial Drugs Advisory Committee of the FDA voted 7/6 that Cempra's leading drug's (solithromycin) efficacy outweigh the risks for the treatment of community-acquired bacterial pneumonia (CABP). The PDUFA (Prescription Drug User Fee Act) target date is December 28, 2016.

While the FDA is not obliged to follow the Advisory Committee, it usually does so. In the last five years only 10% of Advisory Committee's decisions have been partially turned down (more data were requested) but none has been rejected. Solithromycin would be the first macrolide antibiotic with an oral and IV (intravenous) formulation in over 20 years.

As a reminder, the stock lost 80% of its value last week on two sets of different news. The first one had to do with solithromycin's manufacturing issues which sent the stock down more than 20% in a single day.

In fact, during the 3Q earnings conference call, the company's CEO stated that based on an in-person meeting held with the FDA in late October, she believed the FDA may not allow the use of API (active pharmaceutical ingredient) produced by Wockhardt (India) for approval and commercial supply of solithromycin.

She further stated that the company was preparing to provide the FDA with data from another API supplier, based in Mexico. The big news here is that the FDA hinted that the manufacturing of this API in India was not appropriate.

As of late, the FDA has heightened scrutiny of Indian drugs which are to be shipped to the US, but has also approved generic drug applications from the country's firms at a record pace.

The problem with this news is that even if Cempra gets the approval in time, the 2016/17 influenza & pneumonia season is gone for them if the Wockhardt manufacturing is not allowed by the FDA and this represents a one-year delay for the company, which just hired 20 sales and 12 medical science liaisons who are responsible for communicating medical information to physicians and to national account directors who are responsible for establishing and maintaining relationships with payors.

Furthermore, the FDA could withhold or defer potential approval until they are satisfied that commercial supplies of solithromycin meet their CMC (chemistry, manufacturing and controls) requirements.

While the first news was quite shocking for us, the second one, which came out only four days after, was completely unexpected.

Two days before the long-time scheduled AdComm, the FDA released the briefing documents for the upcoming meeting, expressing concerns over the safety of Cempra's pneumonia antibiotic due to potential liver damage.

This is something everyone (including the FDA) knew as solithromycin is a derivative of Ketek (Sanofi), which was approved by the FDA in 2004 but later linked to dozens of serious fatal liver problems and largely withdrawn. We took the 60% haircut in the share price as an opportunity and added to already existing positions.

Cempra constructed the same drug (Ketek) but without the elements it believed were responsible for the side effects associated with Ketek.

We believe that Cempra has some of the best assets in the Biotechnology space and the above example shows how difficult it is for investors to fully forecast the unexpected, whatever the amount of diligence, care and study is put into it.

We believe that solithromycin is going to be approved, as antibiotic resistance to current macrolides for the treatment of CABP is reaching alarming rates across the globe (more than 40%), and that despite a likely black-box warning and a huge post-marketing safety commitment by Cempra, this drug will be a success and represents a multi-billion opportunity for the company.

Whether the company wants to pursue the journey alone after two heart-attacks like these ones or to sell itself to a larger company is something we are currently weighing.