SIGNS OF LIFE

By and large, pharma companies are still walking the cliff. But with some of their biggest patent expiries due to pass in 2013, the next two years will be important in terms of the industry's return to growth, says Sanford Bernstein's **Dr. Tim Anderson**, who's been named Institutional Investor's top large-cap pharma stock analyst for the fourth consecutive year. Noah Pines reports

How would you assess 2012 for the companies in your coverage universe? Is the end of the patent cliff carnage yet in sight?

TIM ANDERSON: Yes, I would say that we are still seeing some slow fundamental improvement in the sector and issues of the past dying down. 2012 will still show the financial impact of the cliff, and that will spill into 2013, but the biggest bolus of patent expiries will have passed by the middle of next year. Fundamentals are slowly getting better. In terms of pipelines, you are continuing to see some signs of pickup in output. 2013 and 2014 will be important years to firm up that assessment. One challenge facing the sector continues to be drug pricing, mostly outside of the US. I doubt that the pricing outlook in ex-US regions is going to improve. That is the biggest headwind.

Industry-wide, what were the big successes of 2012?

TA: In diseases like Alzheimer's, the science seems to be advancing. This category drives home the point that while you have saturation in a lot of primary care disease areas, there remains substantial unmet medical need. And as the industry continues to sink dollars into R&D, they continue to make progress. There also have been major advances in the hepatitis C virus (HCV) pipeline. Given the wealth of data across a variety of compounds, it looks like you could actually cure the disease. There are large patient numbers and a lot of progress being made.

What about failures in 2012?

TA: I don't feel there were major failures—there were no categories where you have had a sudden about-face that demonstrated the industry was making a wrong bet. Failure is always going to accompany success in pharmaceutical R&D. In 2012, I don't think we saw any situation where an entire category of products was doomed. Right now, I am seeing more success than failure. Another area I might spotlight is the PCSK9 inhibitors. Despite numerous medications available for cholesterol lowering, there is still an unmet need. You have a high-science approach that could yield good efficacy.

Your reports have cited research showing big pharma pipeline success rates have been slowly worsening or at best staying flat, but that success rates are better for biologics. Are several more lean years in store, or can specialty revive things?

TA: Yes, I anticipate a slow shift in improving odds of R&D success,

driven by biologics. Biologic product success rates are higher, and that makes up a higher proportion of the industry pipeline. However, I continue to attest that you will never see these companies go "all-biologic," because biologics are not relevant for all diseases. There will still be areas where the only feasible approach is a small-molecule one. The KMR data from a couple months ago may show that things are getting worse, but at the end of the day you need to look at novel, new drug approvals. Things like Phase-specific success rates are helpful, but there may be artifact in that. I do see signs of improvement, but you need another year or two to make a firm claim in the direction.

Big Pharma stocks have been up these past few months—Lilly, Pfizer, Merck, etc. What are the drivers of this? What is your outlook for 2013?

TA: The movement in the stocks that you are witnessing does not reflect investors making a fundamental bet on the group. That reflects overall uncertainty in the economy. Pharmaceuticals is a sector that is not as tied to the business cycle, meaning their business doesn't really flex with the state of the economy. This is historically what makes them "defensive" along with certain other sectors, such as utilities. Relative to other non-healthcare sectors, pharmaceuticals look attractive. There is some fundamental improvement, but that is not the major driver of the rise in stock prices. It is more the concerns over the "macro," which historically favors big pharma names.

If I look at some of the names you mentioned, I would say yes, things are looking OK. Pfizer is getting through the Lipitor expiration and they just got Xeljanz (tofacitinib) approved. They are on track to get Eliquis (apixaban) approved, as well. Lilly and Merck also are working their way through patent expiries. With Merck, you should see some new data sets in 2013 and the launch of a new drug—odanacatib—that could be meaningful.

Over the past few years, analysts have been talking about emerging market gains offsetting (to some extent), the patent cliff. Was this reality, or fantasy?

TA: No, I think it's reality. The emerging market growth expectations have moderated, which ties to the business cycle and the economy in certain countries. There are going to be periodic gaps, but on balance, it is the right place for the industry to be. It's a collective region that the industry can't afford not to address. It makes up almost 20% on average of revenues for the industry.

What impact, if any, will this year's elections have on regulatory policy?

TA: I don't think regulatory policy, if you are referring to FDA, really fluctuates very much. I don't see the two linked. I don't think 2013 will be any different now that we know who the president is.

In what therapeutic categories/pathways will we see big advances in 2013?

TA: In oncology you will continue to see new data come out in 2012 and 2013, HCV as well.

What M&A activity can we expect in the year ahead? Do you see venture money being spent on small companies any more?

TA: I think big mergers remain out of fashion. Every management team continues to say that, and the reason is twofold. It ends up making a bigger revenue base that is harder to grow. And it disrupts the most critical business function of R&D. You will continue to see the smaller type of transaction in the $10-20 billion range that the pharma companies define as smaller acquisitions. But I doubt you'll see any large pharma company consolidation.

What are long-term prospects for the pharma industry? Which companies are making the needed changes to adjust to the new environment?

TA: First and foremost, it will come down to pipelines. The industry has been trying to re-focus its efforts, pushing into new disease areas and trying to change the R&D process. Pricing is also a key factor. The US stands out among developed nations in terms of how much it embraces free-market pricing. But in most other markets, the government plays a much stronger and firmer role. My guess is that nothing dramatic will happen in the US. Pharma also needs to continue to successfully penetrate into emerging markets, making sure that certain countries enforce patent protection. Emerging markets will grow as a proportion of revenues.

However, when I look at what China is doing, it makes me nervous that its government will interfere with the natural competitive environment, favoring local companies over multi-nationals. That worries me. ■

Tim's picks

COMPANY OF THE YEAR, 2012

Sanofi

Sanofi has made good progress on various fronts. They have done some good blocking and tackling. They have integrated their acquisitions fairly well, including last year's purchase of Cambridge, MA-based Genzyme.

Roche

Roche has had some major scientific advancement. On the oncology front, they continue to make strong progress, launching three anti-cancer drugs in the last 13 months: Perjeta (pertuzumab) for breast cancer, Erivedge (vismodegib) for basal cell carcinoma and Zelboraf (vemurafenib) for melanoma.

COMPANY TO WATCH, 2013

Eli Lilly

Lilly has made great strides. A year ago, a lot of people had almost written it off, yet now they have one of the fullest Phase III pipelines. They have an oncology drug—ramucirumab—that, on paper at least, could be a better drug than Roche's Avastin. That asset could shift investment community focus away from their Alzheimer's disease drug development. We like LLY's comparatively small revenue base, and if the ramucirumab data show that it works in these broader tumor types, it could be a mega-brand.

Merck

Merck has some really pivotal data coming up. The company could become a very strong pipeline story with both odanacatib (code name MK-0822) for osteoporosis and Tredaptive (code name MK-0524A) for cholesterol. You'll see both data sets over the next six months.