

BRIGHT

Things are beginning to look brighter for Big Pharma. Some firms should actually be able to recover from the cliff during 2014, says Sanford Bernstein analyst Dr. Tim Anderson

What is your assessment of 2013 for the pharmaceutical companies in your coverage universe? Is the industry starting to see a “post-cliff” recovery?

I think we are seeing signs of recovery. Predictably, a lot of these patent expirations are washing through the numbers in 2013 such that in 2014, many of those companies I follow will be able to revert to a more steady, consistent level of growth.



What were the big successes in 2013?

Roche’s Genentech unit launched two cancer products, Perjeta and Kadcyla, and both are on track to be big products. Gilenya in MS continues to perform well for Novartis. On the pipeline side, Bristol-Myers Squibb is likely to be first-to-market in the immuno-oncology space, with Roche also set to be a player in that market.

Were there any major failures in 2013?

There haven’t been any R&D blow-ups in 2013, but Merck’s odanacatib (osteoporosis) was one where the delay was a negative.

In terms of growth and profitability, what will the post-cliff period look like for pharma?

While profitability per dollar sold is as high as it has been historically, these new specialty drugs will never reach the revenue potential of the primary care blockbusters of the 1990s into the 2000s. In response, the industry is right-sizing: through cost management and share buybacks, companies can see growth in the high-single digits.

Companies have slashed the SG&A/commercial side—what do you expect for their R&D spend?

Across the names I follow, you will not see major reductions in R&D spending. That fits with the language that all of these companies use, which is that innovation is the path forward. While they have tried to trim the fat in R&D, the key to the future is R&D. This is still a very capital-intensive business.

One analysis shows a pick-up in NMEs approved per \$1B in inflation-adjusted R&D dollars spent. Can we finally herald a return to R&D productivity?

To calculate productivity, you need to look at what those NMEs are doing. The measure of pipeline success is not just regulatory approval, but a drug that sells well. For example, look at Pfizer’s Xeljanz or BMS’s Eliquis. Uptake of both has been slow, which speaks to a difficult access environment in the US and other markets as well.

That said, I would still say that productivity is improving just by virtue of output increasing.

Emerging Markets (EM) have been a mixed bag, with some maturing and others slowing. How will industry’s geographic mix shift over the next 12 months?

While EM accounts for 20% of revenues for big drug companies, we expect that contribution will start to slow down in 2014. At the same time, you will see a return to growth in the US and EU.

What therapeutic categories will see big advances this coming year?

Cancer and HCV are the two areas where there is the most innovation happening that is capable of generating big dollars. The “Holy Grail” continues to be CNS diseases, especially neuro-degeneration, like Parkinson’s or Alzheimer’s disease. However, you won’t see any data in diseases like Alzheimer’s until 2017.

What M&A activity can we expect in the year ahead?

In the large pharma sector, mega-mergers remain out of fashion. However, you will continue to see smaller biotech companies disappear off the radar screen and bolt-on acquisitions and divestitures among the diversified companies.

What is your pick for company of the year, 2013?

For 2013, it would be Bristol-Myers Squibb by a long shot. Everything has gone right for them.

What is your pick for company to watch, 2014?

Eli Lilly is going to be interesting. They are heading into a big cliff period in 2014 and will lose Cymbalta. While it could throw 2014 into disarray, they should emerge from 2014 with a decent growth trajectory. They have great assets in the pipeline for cancer and diabetes. Lilly is controversial among analysts. In my view, that’s a runway for them. If they do things right, there is a long runway for more investors to change their opinion, and that could drive their stock price higher. I would say that Lilly is the most controversial stock I cover, but that controversy is what creates investor opportunity.

FUTURE

A bull market, combined with some phenomenal launches, has buoyed the biotech sector. And the best may be yet to come, according to ISI Group analyst Dr. Mark Schoenebaum

How would you assess 2013 for the biotech companies in your coverage universe? What were the big successes? Any major failures?

We are in an unprecedented bull market for biotech, at least we were for most of 2013. Almost all of my companies did very well on the biotech side. The Tecfidera launch over at Biogen [Idex] was a phenomenal success. There was also the de-risking of the HCV program and the de-risking of the cancer program at Gilead. Celgene raised out-year guidance and had a hit for Abraxane for pancreatic cancer, and a new drug approved in Pomalyst. Vertex had major new data in April in their CF franchise that shot the stock up. All of the major stocks that I cover on the biotech side had good news. Amgen has done a great job with capital allocation, and its stock has done very well mainly on prudent financial management of the company. Also, their pipeline continues to advance.

What will the biotech business look like in 2014?

Well, look, the sector was up over 50% this year, so common sense tells you that 2014 probably is not going to be *that* good.

Any particular headwinds biotech is facing in 2014?

The biggest challenge is that expectations are now very high. And stocks go up if reality exceeds expectations. There is no systematic challenge that I expect to emerge next year that is going to radically change the way people look at the value proposition for the industry. Over the longer term, the biggest concern from a lot of people is the pricing power of biotech and pharmaceutical companies.

Would you proclaim a return to productivity in terms of the biotech names you cover?

I don't separate biotech and pharma; I look at data across both. No single metric is satisfactory, but one I like to keep track of is the number of new drugs approved for each million dollars of R&D money

spent. That number ticked up in 2011 and 2012, but stooped down in 2013. So I am not convinced that R&D productivity has changed.

Which other therapeutic categories are you most excited about?

Well, I think we are all holding out hope that something will hit in Alzheimer's. Merck has the leading program there, something called a BACE inhibitor. If anyone could hit, even with fairly modest efficacy, in Alzheimer's that would be a huge hit. Cystic fibrosis—I think Vertex has a drug coming out in CF that if it works would be a big deal for that community. Suddenly there would be a disease-modifying drug that would work in 30-40% of the CF population.

I think one of the highest-profile debates on Wall Street right now is in the lipid area. We are going to see emergent data on these PCSK9 inhibitors out of pharma and biotech. For the first time in many years, we are going to get real outcomes data on LDL modifiers; that is going to be very high profile. The community needs this.

And then arguably the most exciting area will remain what's going on in immunotherapy for cancer. The leader is Bristol-Myers followed closely by Merck and Roche. Biotech has largely missed the boat on this; this is all pharma.

Is there any hope that Merck could pull ahead of BMS on its PD-1 program?

Probably not ahead, but there is a chance that Merck could close the timeline gap to less than six months, as a monotherapy. Whereas BMS has a lead as a combination therapy with Yervoy in melanoma.

How do investors look at the government shutdown?

It was not an issue that we talked much about. The FDA made some comments that the advisory committee meetings that were scheduled would go on. But, companies already filed and paid their user fees, the agency said it would act. And I think most people did not fear the government shutdown would last very long. So it was not a major issue for the investment community, in biotech and pharma.

What is your pick for company of the year, 2013?

Look at the stock charts. Celgene is up the most, followed by Gilead, followed by Biogen.

What company would you expect to stand out in 2014?

Well, the most exciting launch will probably be—everyone is watching—will be the launch of Gilead's new HCV drugs, and that could happen as early as later this year. It will happen in earnest next year. That is one of the most watched launches of all time, [and] expectations are really high for that. —Noah Pines

