ANDERSON'S 360

For a long-term view of the pharma sector, look no further than Sanford Bernstein über-analyst **Tim Anderson, MD**, who has taken Institutional Investor's top ranking three years running. Noah Pines has Anderson's predictions for the coming year

These past few years, the pharmaceutical industry has faced the challenges of mass patent expiry, decreased R&D productivity and a more demanding regulatory and market-access climate. Are there any important bright spots on the horizon?

TIM ANDERSON: Right now, I see a slow turnaround in R&D productivity. Since the cycle times can be as long as 13 years from test tube to patient, any recovery has to be measured over a period of years. The situation is not going to change remarkably from one year to the next. But it feels like we are so much busier than we used to be. That was why we launched our monthly pipeline report. We were having a tough time keeping up on the data. The fact that we're busier is a soft indicator that we have hit the trough in productivity a few years ago.

As an industry, we have shifted away from crowded markets like hypertension into areas of distinct unmet need. The industry was slow to recognize the need to change its focus, but we have been forced to go into areas of unmet need. You are starting to see quite a few new and novel drugs get approved. And there are more of these novel agents in the pipeline.

Shareholders have gotten so frustrated with the financial performance of companies that they are forcing management teams to rethink how much they are spending on R&D. As a result, a few companies are cutting their R&D budgets. Merck for example just today (Oct. 28) lowered their R&D spend for 2011. With new products starting to pick up and R&D budgets being rationalized, I expect that you will see a return to year-on-year increases in R&D spending go up. The faltering pipeline is what got the industry into trouble. Fixing those pipelines is the solution going forward. That is a very important early trend. [Next year] will be better than 2011, and 2013 will be better than 2012. So these incipient signs are the bright spot. I cannot say that the industry has solved its problems, but I think we have hit a trough.

What do you think about recent events in pharmaceutical strategy? With Abbott spinning off its pharma division to free up the growth of its medical products company and Merck emphasizing consumer and biosimilars, do you envision a profitable future for pharma, and if so how?

TA: I do not expect the industry's growth prospects will return to what they were in the better years of the 1990s. But this is still a highly productive and highly profitable industry. While we may not have the growth of previous years, profit still is high and cash flow is strong. Lack of R&D growth has caused big pharma to diversify, like going into the generics business for example. A decade ago, that would never have been expected. Companies have been forced to develop products of some sort to sell. Abbott splitting up is a unique example and reflects the fact that it became accidentally extremely dependent on a single product. And so they said something like, 'Hey, this is an overhang on our stock. Eventually the Humira party will come to an end.' So they took this bold move of breaking up. Pfizer was considering the same thing. You are seeing companies experiment with different business models. Importantly, though, even the companies with the heaviest patent expiry exposure are certainly not going out of business. Right now, we are in a contraction cycle and we are on the eve of the patent cliff. That will force the industry to contract. But I think at some point, we will achieve a new steady state and start to grow again. Companies are experimenting with the model that best fits their particular circumstances. It is hard to generalize as to which is the best model. Bristol-Myers Squibb, for example, is going in the opposite direction. They spun everything else off to focus on pharmaceuticals.

What's your outlook for the regulatory climate in 2012? Will the changes anticipated from PFUDA V improve the process?

TA: I see the regulatory climate as worse than what it was a decade ago prior to the watershed even of the 2004 withdrawal of [Merck's] Vioxx. Since that time, the agency has been pretty steady state. There are a variety of pushes and pulls, but I don't think you will see any real

change in 2012, positive or negative. It will be pretty stable. You have government funding that could get cut, or user fees that may go up. I don't know what the consequences of that will be. The one area of progress being made is on the biosimilars front. However, it depends on who you ask as to whether that is a good or a bad thing.

What does the climate look like for investment in drug development?

TA: We convened an R&D productivity conference last May and have published the findings from that meeting. We had seven different industry speakers. And when we asked them what will happen with R&D spend, they unanimously said it would likely contract. But when I listen to the companies talk and look at the magnitude of the cuts, the message is 100% consistent that these companies continue to see the great need to invest in R&D. Investors are pushing them to spend less, and there is some academic work saying that just because you spend more, it does not mean that you get more. There will be a net contraction of R&D spend, but the industry will not move away from what they have always done. I still see this as a very R&D-intensive industry that needs some trimming around the margins. If you fast forward 10 years from now, and there has not been a turnaround in productivity, you may start to see some real cuts.

What are the biggest risks, uncertainties or headwinds that drugmakers face in 2012?

TA: The biggest uncertainty is really on the government side: in Europe, for example, the austerity measures that are being discussed, and in the US you have healthcare reform, especially in the Medicare program. What it boils down to is pricing risk. That is probably the major issue. Additionally, you have the potential for corporate tax reform. The current tax laws work to the advantage of US-based companies. If at some point that changes, it would hurt several industry sectors such as pharmaceuticals and high technology. I do not see that as a 2012 threat; the only major 2012 threat is pricing erosion.

As we have observed, the pipeline is slowly improving in terms of both novelty and quantity of late-stage compounds. Do you perceive that this will have a meaningful impact on the productivity drought?

TA: It depends on how you look at it. What I always tell investors is that they have to focus on just two fundamental things: what is coming out of the pipeline and what is going off patent. From a patent perspective, it does not look terribly promising for the industry as we are in the midst of what I've called the patent cliff. At the same time, by the end of next year, the biggest bolus of those expiries is behind us. Then the pipeline contribution becomes more meaningful. You are still going to have a fair amount of challenge in 2012 from a P&L perspective and an income statement perspective, but some of that will wash through by the end of 2012.

With more expensive drugs coming to market, do you expect pricing to be an even bigger target for scrutiny in 2012, or will generics continue to neutralize the need for systemic change?

TA: I do still worry about the industry killing the golden goose by pricing therapies high, such as in oncology. These situations generate very bad headlines and at some point, I fear we may reach a tipping point. You don't necessarily curry good favor by selling such expensive products. At the same time, there is truth that overall drug spend will contract due to this patent cliff we've talked about. Of the top 20 drugs in the world, all lose patent protection by 2017. It is remarkable how the world's biggest drugs are going to disappear. In the case of small molecules (vs. biologics), spending will decrease rapidly—and that will lead to a contraction in overall drug spend. But that point gets lost on politicians; they often find it easy to generate headlines by criticizing drug pricing. In reality you will see drug spending as part of the healthcare dollar contract.

Are you anticipating further merger/acquisition activity in 2012?

TA: Probably not on a large-scale level. What you will see is continued acquisition of smaller companies and maybe other companies trying to ramp up diversified elements like getting into consumer healthcare. These mega-mergers are out of fashion because it is the uniform view that those are disruptive, especially in terms of R&D, which is critical.

What impact are the multi-million/billion-dollar off-label settlements having on companies, notably GlaxoSmithKline's recent $3 billion deal with the feds to resolve multiple investigations into its sales and marketing?

TA: I can tell you that investors write those off as a cost of doing business. I do think it has changed marketing practices over the years. The industry has imposed its own regulations and monitoring. It has cleaned its act up and made marketing practices more restrictive. But I don't think that will be a material contributor to how they run the business or their earnings stream. Even in the face of the $2-3 billion settlements, the stocks don't do anything. Investors view that as a cost of doing business. ■

Anderson's picks

BEST COMPANY, 2011

Bristol-Myers Squibb

The majority view is that Bristol-Myers Squibb is the hands-down winner for 2011. That is why that stock has performed so well despite the fact that they are losing some major products in 2012 (especially antiplatelet drug Plavix and hypertension pill Avapro). BMS has been the only company that has consistently delivered out of its pipeline.

COMPANY TO WATCH, 2012

Pfizer

For 2012, I would keep my eyes on Pfizer. This may seem remarkable since many view Pfizer as a poster child for inefficient R&D. However, in 2012, they may beat BMS in terms of what is coming out. They have JAK inhibitor tofacitinib for rheumatoid arthritis, they have novel anticoagulant apixaban (with BMS), they have kidney cancer drug axitinib—a novel therapy—and they just got lung cancer drug crizotinib approved. So Pfizer is launching some meaningful products, many of which have the potential to cross the billion-dollar threshold.